

## A COMPARATIVE ANALYSIS OF INFORMED CONSENT LEGISLATION IN UKRAINIAN AND LATVIAN LEGISLATION AND CASE LAW

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**Abstract.** Informed consent is one of the key principles in safeguarding human rights in the sphere of healthcare. It presupposes the expression of the patient's free will relating to his medical examinations, treatment and diagnostic procedures, as well as the physician's duty to inform the patient on the forthcoming medical interventions, including the facts regarding the potential risks of these medical interventions. This principle is one of the elements of contemporary medical law, which has marked the transfer from paternalistic medicine to a modern model of medicine, where the patient is an active participant in the process of medical treatment. In this paper, the authors illustrate the legal aspects of safeguarding the patient's right to informed consent in the legislation and legal practices of Ukraine and the Republic of Latvia. The institute of informed consent, which needs to be safeguarded, as a key element of the legitimacy of a medical intervention (such as surgery, or vaccination), requires a specific form of fulfillment, which is conducted in writing. A medical intervention, excluding cases of emergency, is legitimate only when the consent of the patient is provided; unconsented medical interventions frequently cause lawsuits, where plaintiffs seek to recover damages for performance of a medical intervention without their informed consent. The authors have highlighted these issues while commenting on the recent case law of the Supreme Court of Ukraine and the Supreme Court of the Republic of Latvia.

**Keywords:** informed consent, medical malpractice, medical law, Ukrainian law, Latvian law, patient's autonomy, European Court of Human Rights

### Introduction

Safeguarding patient's rights in the field of healthcare is becoming a frequent legal problem, wherein various violations of patient's rights, as well as ordinary medical malpractice, have caused thousands of lawsuits worldwide over the last decades. In earlier times, the most frequent remedy for medical malpractice was a lawsuit against a hospital, occasionally a medical practitioner, who was allegedly in fault according to the plaintiff's view. This principle has not drastically changed over the decades, but the scope of violations of the patient's rights

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substantially elaborated beyond ordinary medical negligence, such as unconsented medical operations, which were necessary for the patient in the physician's view, who disregarded the necessity to ask the patient's consent, or an unauthorized disclosure of medical information by physicians or hospitals, which also caused lawsuits by the aggrieved parties. Informed consent is a principle of protection of the patient's body integrity and autonomy, where the patient has a right to decide for himself/herself what medical treatment should, or should not be applied to him/her in the course of healing a malady. Historically, informed consent at its earliest, developed in a number of common law jurisdictions, as United States and Canada as well as in XIX and XX century case law of France and Belgium; over the last decades, the European jurisprudence has witnessed a substantial number of legal cases, dealing with the issue of legitimacy of unconsented medical procedures. The principle of informed consent has also been anchored in Art. 5-6 of the Convention of Oviedo (1997), as well as a number of judgments of the European Court of Human Rights, which frequently dealt with medical malpractice cases, which were appealed to the European Court, as a court of last resort. The recent jurisprudence of the courts of Ukraine and Latvia has shown an increased topicality in the issue of safeguarding the patient's right of body integrity, shaped in the institute of informed consent; in the respective cases, the highest judicial instances of both states (the Supreme Court of Ukraine and the Supreme Court of Latvia) have also provided their position for the interpretation and the application of the institute of informed consent. The institute of informed consent has repeatedly become the object of legal research of different legal scholars, such as Rene Demogue (1932), Vincent MacDonald (1933), Michelle del Carril (1966), Gerald Robertson (1984), Christiane Hennau-Hublet (1986), Robert Leflar (1997 and 1997), as well as many others.

The object of the research is the informed consent as a legal institute in Ukraine and the Republic of Latvia. The aim of the research is to analyse the regulation of this institute in Ukraine and the Republic of Latvia, and to conduct its comparison determining its correspondence with the practice of the European Court of Human Rights. In order to fulfill the research, the following tasks are put by the authors:

- 1) to analyse the peculiarities of the regulation of informed consent institute in Ukraine (legislation and case law);
- 2) to display the legislative and jurisprudential regulation of informed consent in Latvian legislation and case law;
- 3) to conduct a comparative analysis of this institute in both states, to display mutual and divergent features;
- 4) to display relevant national case law;
- 5) to research upon the correlation of national legislation with the practice of the European Court of Human Rights.

The methodology of the article is grounded mainly upon the comparative method, which is used for the analysis and comparative of the legal institute of informed consent in Ukraine and the Republic of Latvia. At the same time, a number of other institutes is also used in the work, namely: method of legal case practice is used for illustrating the topic from the side of applying legislation in case law; and the formal-legal method is used to provide a complex characteristics of the legal regulation of the institute of informed consent, and finally, the method of legal hermeneutics, which is used for clarifying the content of the legal norms and the legal gist of the institute of informed consent.

## **1. Development of the institute of informed consent: the past and the present**

The democratic processes of modern society and the objective trends in the development of medical science correspond to the stabilization and strengthening of the principle of the obligation of informed consent in the legal relationship between the patient and the treating person (doctor). It is undeniable, that the factors influencing modern medical science raise the issue of understanding the terms 'information' and 'consent', transforming informed consent into a form of a legal relationship between the treating person and the patient that is more in line with changes in medicine. But it should be noted, that in the history of the world there was a long and winding road to the existence and meaning of the patient's expression of will. In the Continental legal system, the concept of informed consent is primarily known to have been originated in French and Belgian law. One of the earliest examples is the Antiquaille Hospital Case, adjudicated by the Correctional Court of Lyon in 1859, where two doctors were condemned to a fine for conducting a medical experiment to treat a minor patient from ringworm by a syphilitic inoculation, where the court found that such inoculation without the consent of the patient should be regarded as a battery in the sense of criminal law (Correctional Court of Lyon, 1859, p.p. 87-88). In the further doctrine of oldtime French and Belgian medical law, the lack of the consent of the patient was regarded as malpractice (negligence) from the side of the medical practitioner. For instance, in Belgium, the doctrine of

informed consent is well-known by the case of *Dechamps c. Demarche* (1889-1890), where a surgeon conducted an osteotomy on a 3-year-old minor, allegedly without the parent's consent; though not the lack of consent was the fault (it was not properly established), but a lack of diligent post-operative care, which caused a development of a gangrene and a subsequent amputation of the foot (Liege Civil Court, 1889, p. 471-474, Liege Court of Appeals, 1890, p. 281-282). The term 'informed consent' has originated in in French case law in the 1930s, which pronounced 'consentement libre et éclairé' (Court of Cassation (France), 1933; Civil Court of Seine (Paris), 1935, judgment of the court of appeals in the same case: Paris Court of Appeals, 1937), while its American analogue 'informed consent' originated in 1957 in the case of *Salgo v. Leland Stanford Jr. University Board of Trustees*, adjudicated by the California Court of Appeals in favor of plaintiff (California Court of Appeals, 1957, p. 560-579). In England, informed consent is frequently associated with the 1957 judgment of the Queen's Bench Division of the High Court of Justice in the case of *Bolam v. Friern Hospital Management Committee*, where plaintiff litigated with the hospital for suffering damages during an electroconvulsive therapy, the court held that in case the physician's acts are in compliance with established medical practices, and the doctor has shown reasonable skill and care within medical treatment, he could not be held liable for negligence. As to the issue of necessity of informed consent, the Court outlined, that hospital staff usually asked the patient's consent to medical interventions, but then, it was common for the doctors not to warn the patients on the risks of medical interventions, if such risks were small, unless the doctors were asked. (High Court of Justice, Queen's Bench Division, 1957, p.p. 585-594).

The patient, as an autonomous individual, can unambiguously act freely according to his, or her own will, conscience and chosen plan, or intention in the context of his or her medical treatment. However, the content of a patient's consent to treatment may vary: the patient expresses a will in relation to his or her treatment, but this amount may be affected by a number of factors (L. Mazure, 2011). In addition, the most important criteria for the division of the patient's will should be noted, and one of them is the origin of the patient's will. Based on this criterion, expressions of will are divided into: 1) initial, i.e. the patient expresses the will for a specific treatment for the first time (consent to or refusal of treatment); 2) the derivative, i.e. the patient revokes the decision made by changing his will (revocation). (L. Mazure, 2011) One way or another, all these elements were summed up in the concept of the autonomy of the individual's private will. Although there are various theories that explain the concept of personal autonomy and its elements, they all generally acknowledge that there are two basic conditions that characterize personal autonomy: freedom as an independent, non-controlling influence and the ability of a person to act consciously (Beauchamp T.L., Childress J.F., 2001). Predicting the prospects for liberal development, we can see that there is a sign of equality between the autonomy of the will and the individual's right to self-determination, and this approach is reflected in the ruling of the European Court of Human Rights in the case of *Pretty v. The United Kingdom* (App. No. 2346/02), which states that, although none of previous medical law-related cases relating has established that the right to self-determination derives from Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, the European Court of Human Rights considers that the concept of personal autonomy is an essential principle in the context of the interpretation of the aforesaid provision of the European Convention of Human Rights (European Court of Human Rights, *Pretty v. United Kingdom*, 2002, para. 61). The Latvian legal scholars, who conduct research in the sphere of medical law, have also discussed this judgment in the view of patient's right to autonomy (Ašneviča & Slokenberga, 2015, p. 309-310). The right to self-determination includes such rights as, for example, the right to medical treatment and the right to choose the type and option of treatment, and negative rights, in the context of right to refuse (forego) medical treatment (Toebes B., Hartlev M., Hendriks A., Herrmann J. R., 2012, p. 122). While this freedom of choice is important, a patient's decision (according to his or her own beliefs and values, without regard to the patient's irrationality and intelligence) can affect others. For instance, in the USA, the courts usually use the test, amalgamated by the District Court of Appeal in Florida, United States, in the case of *Satz v. Perlmutter* (1978), upon which, a court, dealing with case, where is a dispute relating to refusal of medical treatment, may assess the case upon the following issues:

- 1) The state's interest in preservation of citizen's life;
- 2) The need to protect innocent third parties;
- 3) The state's duty to prevent suicide;
- 4) The maintenance of ethical integrity in medical profession (District Court of Appeal of Florida, United States, 1978, p.p. 162-164).

Informed consent has a “positive” and “negative” side of its interpretation: informed consent presupposes that the patient does not only have a right to determine what medical procedures should be conducted, but has the right to refuse the medical procedure, or at least the method of its performance. The segment of this feature of right to patient’s autonomy in Ukrainian and Latvian healthcare legislation is relatively small, though in both of the states; the healthcare legislation of Ukraine and Latvia provides the patient a possibility to forego medical treatment after signing special documents. In a number of other European States. The patient’s right to forego medical treatment, as provided by Article 5 of the Oviedo Convention, was also considered by the Supreme Court of Poland in its 2005 decision relating to the plaintiff’s right to refuse blood transfusion on basis of her religious beliefs, where the court confirmed this right from the side of the plaintiff, quashing the district court’s judgment to authorize blood transfusion, and remitting the case to the district court (Supreme Court of Poland, 2005). The Conseil d’Etat (France) in its 2001 judgment ruled, that the doctor, who transfused blood to a patient in a critical condition regardless of the patient’s objection on basis of religious beliefs, does not commit a fault in the sense of provision of medical care (Council of State (France), 2001).

The principle of informed consent has also been the subject of the recent case law of the European Court of Human Rights. In *Botoyan v. Armenia* (2022), the Court has again underlined the importance of the right of ones, who face risks to their health condition to obtain information relating to their health, so the said persons would be able to assess the conjectural risks; hence, the Contracting States possess an obligation to provide a sufficient legislative regulatory mechanism in order the medical practitioners could consider the conjectural risks, deriving from prospective medical procedures for the physical integrity of their patients, and informed their patients concerning the consequences of such medical procedures in beforehand so as the latter ones could provide their informed consent (European Court of Human Rights, 2022, para. 98). This statement of the European Court of Human Rights reiterates the statement in the case of *Csoma v. Romania* (2013) and earlier, in *Codarcea v. Romania* (2009), as and affirmed in the most recent judgment of the European Court of Human Rights relating to the patient’s informed consent in the case of *Reyes Jimenez v. Spain* (2022) (European Court of Human Rights, 2009, para. 104-105; European Court of Human Rights, 2013, para. 42, European Court of Human Rights, 2022, para. 30). In *Pretty v. United Kingdom* (2002), the European Court held, that the refusal to accept medical treatment may be thanatoid, though the imposition of medical treatment to an adult, mentally competent person without the consent of the said person would be a violation of the person’s physical integrity, protected under Art. 8 (1) of the European Convention of Human Rights (European Court of Human Rights, 2002, para. 63). The same principle was reiterated by the European Court in the case of *Junkhe v. Turkey* (2008), where the Court held, that any medical intervention, done against the person’s will, or without the free informed consent, has to be regarded as an interference in the person’s private life (European Court of Human Rights, 2008, para. 76).

## **2. The Institute of Informed Consent in Ukrainian Legislation and Case Law**

According to Part 1 of Article 43 of the Law of Ukraine (1992) “Fundamentals of the legislation of Ukraine on health care” (hereinafter – the Fundamentals), informed consent of a patient, who has reached fourteen years of age, is required for the use of methods of diagnostics, prevention of diseases and medical treatment (Law of Ukraine “Fundamentals of the legislation of Ukraine on health care, 1992, Art. 43). If the patient is a minor under the age of fourteen, or a legally incapable person, then the medical interventions may be performed with the consent of their legal representatives. The provisions of Part 3 of Article 284 of the Civil Code of Ukraine (2003) (hereinafter – the Civil Code of Ukraine) stipulate that the provision of medical care to an individual, who has reached fourteen years of age, is carried out with his consent (Civil Code of Ukraine, 2003, Art. 284). According to Part 1 of Article 43 of the Law of Ukraine (1992) “Fundamentals of the legislation of Ukraine on health care” (hereinafter – the Fundamentals), informed consent of a patient, who has reached fourteen years of age, is required for the use of methods of diagnostics, prevention of diseases and medical treatment (Law of Ukraine ‘Fundamentals of the legislation of Ukraine on healthcare’, 1992, Art. 43). If the patient is a minor under the age of fourteen, or a legally incapable person, then the medical interventions may be performed with the consent of their legal representatives. The provisions of Part 3 of Article 284 of the Civil Code of Ukraine (2003) (hereinafter – the Civil Code of Ukraine) stipulate that the provision of medical care to an individual, who has reached fourteen years of age, is carried out with his consent (Civil Code of Ukraine, 2003, Art. 284). The implementation of the general rules on informed consent has many problematic issues related to legal controversies, some of which we will disclose. Consent to medical care must meet such eligibility criteria as: a) awareness; b) voluntariness; c) competence. Part 1 of Art. 39 of the Fundamentals stipulates that the age of the subject to whom medical



information is provided, is the age of adulthood, that is, the age of 18. Therefore, it is not possible to reach an informed agreement between the ages of 14 and 18. It seems that in order to find a proper legal solution, one should refer to the letter of the Ministry of Justice of Ukraine № H-35267-18 (Letter of the Ministry of Justice of Ukraine, 2009), which explains the possibility of using analogy under a set of conditions, including similarities between the circumstances and existing rules upon essential legal grounds. The search for a possible analogy of the law can be provided within the Fundamentals (1992), namely in Art. 44. Thus, the extrapolation of the algorithm of Art. 44 Fundamentals on Art. 43 of the Fundamentals, in order to balance with Art. 39 of the Fundamentals, enables to provide such a normative structure for patients aged 14 to 18: medical care is provided with the consent of the patient, and with the consent of his legal representative, because consent can only be informed, but the patient, who is aged 14 to 18, has no right and the right to medical information. It should be denoted, that Art. 44 of the Fundamentals is devoted, in particular, to the regulation of new methods of prevention of diseases, diagnostics, and treatment in the interests of the patient, including medicines, which are yet to be approved, but only with the written consent of the patient.

According to Art. 6 of the Law of Ukraine ‘On Protection of the Population from Infectious Diseases’ (2000), preventive vaccination for legally-capable adult patients are carried out with their consent after providing objective information concerning the vaccination, the consequences of refusing undergoing vaccination, as well as possible post-vaccination complications. Prophylactic vaccinations are performed with the consent of their objectively informed parents or other legal representatives of patients, who have not reached the age of fifteen, or have been declared legally incapable in accordance with the procedure, established by law. Patients between the ages of fifteen and eighteen, or patients, who were recognized to possess limited legal capacity by a judgment of a court, should be vaccinated with their consent after providing objective information, and with the consent of objectively informed forbearers, or other legal representatives of the said patients (Law of Ukraine ‘On Protection of the Population from Infectious Diseases’ (2000), Art. 6). There is a form of consent for this form of legal relationships – namely, Informed consent and assessment of the person’s health condition, or a minor with one of the forbearers, or another legal representative of a minor for vaccination and tuberculin testing, filling which is one of the stages of medical examination of minors before vaccination in accordance with the Regulations on the organisation and the performance of preventive vaccinations (Order of the Ministry of Health of Ukraine, 2011, No. 595; in the edition of the Order of the Ministry of Health of Ukraine, 2014, No. 551).

In this context, much attention should be drawn to the Recommendations of the Committee of Ministers of the Council of Europe on Child-Friendly Health. The given Recommendations have set out five principles of child-friendly health care, including “participation”, meaning that the minors should have the right to be informed, heard or advised, to express their own opinion independently of their forbearers, as well as the right to have their opinion taken into account. The level of a minor’s participation depends on his or her age, maturity, and the importance of a medical decision that needs to be made. Minors, given their age and maturity, as well as their families, need to be fully informed and involved. Minors should be encouraged to exercise their right to participate actively in making decisions concerning their health and treatment. An interesting international soft law instrument is the Charter on the Rights of Children in Hospitals (Recommendations of the Council of Europe Committee of Ministers, 2011), which provides that minors and their forbearers have the right: a) to information grounded upon their age and level of understanding (Article 4); b) a right to informed participation in making decisions concerning the provision of medical care to them (Article 5). International standards seem to suggest that Ukraine should also ensure the implementation of the child-friendly health care concept by ensuring that minors are informed about their health. There is no doubt, that the age of awareness and the age of consent to health care must be identical. A systematic analysis of international standards and the national legislation suggests that information should be provided to the minor’s legal representative, but given the minor’s age and level of understanding, such information should be provided to a minor patient so that he or she can make an informed decision about his or her health. When highlighting the specifics of exercising the right to consent to medical care for persons aged 14 to 18, it should be borne in mind the need to regulate the rights of persons with limited civil capacity. By analogy with the law, in particular, Part 2 of Art. 44 of the Fundamentals, it follows that along with the consent of such a person with limited legal capacity for medical care, the consent of the legal representative of such a patient must be given. Although at the level of both laws – the Civil Code of Ukraine and the Fundamentals, the form of consent is not specified, but a systematic analysis of the Ukrainian legislation provides the foundation to conclude, that the patient’s consent must be given only in writing, as there is an approved standard form of patient’s consent. The Order of the Ministry of Healthcare of Ukraine of 14 February 2012 No.

110 has approved the form of primary accounting documentation № 003-6/o 'Informed voluntary consent of the patient to diagnostics, treatment, performance of surgery and anesthesia, and the presence, or the engagement of participants in the educational process' (hereinafter – the form No. 003-6/o) (Ministry of Healthcare of Ukraine, Order No. 110, 2012).

Let us highlight a few issues dealing with the issue of using the form № 003-6/o. The analysis of the form №003-6/o and the Instruction on filling in this form, approved by the Order of the Ministry of Health of Ukraine № 110, gives grounds to conclude, that this form is made for adult patients who have the right to receive medical information. Clause 3 of the Instruction stipulates that the attending physician provides the patient with information on the diagnostic and treatment plan, provides in an accessible form information on the probable course of the disease, the consequences of refusing treatment. Therefore, there is no doubt, that this is attributed to a patient who has reached the age of eighteen. Paragraph 11 of the Regulations on the organization of the educational process in health care institutions with the engagement of scientific and teaching staff of higher education institutions, which provide higher education in the field of health care states, that medical care in the educational process is provided, in particular subject to the informed voluntary consent of the patient for the presence of healthcare education students during diagnostics, treatment, surgery and anesthesia, and the engagement of research and teaching staff in the diagnostics, treatment, surgery and anesthesia in the form, approved by the Ministry of Health. Paragraph 11 of the 2020 Regulations on the organization of the educational process in health care institutions with the participation of scientific and pedagogical staff of higher education institutions that provide higher education in the field of health care states that medical care in the educational process is provided, in particular subject to the informed voluntary consent of the patient for the presence of health education students during diagnostics, treatment, surgery and anesthesia and the participation of research and teaching staff in diagnosis, treatment, surgery and anesthesia in the form approved by the Ministry of Health (Decree of the Cabinet of Ministers of Ukraine, 2020, No. 1337). According to the Instruction on filling in the form No. 003-6/o, the patient's consent to the presence of healthcare education students in the diagnostics, treatment, surgery and anesthesia, and the participation of research and teaching staff in the diagnostics, treatment, surgery and anesthesia is filled in by the patient in the healthcare institution, which provides the educational process in the field of healthcare and the students may be present for the necessity of their practical training. It should be denoted, that that the form № 003-/o is used, according to the legislation of Ukraine, in such primary accounting documents as: 1) medical record of an outpatient; 2) medical record of an inpatient; 3) medical record of abortion; 4) history of pregnancy and childbirth. For all other types of forms of primary accounting documentation, which are used in other legal relationships, there are either specially designed forms, or the form of consent is free, as in the field of dentistry when filling out a medical record of a dental patient.

Let us conduct an analysis of the functioning of the institute of 'informed consent' in special legal relations in the field of medical care. COVID-19 has resulted in a spectral complement to the Ukrainian legislation, including the treatment of the coronavirus infection. The Ministry of Health of Ukraine has developed a form of informed consent of the patient (his legal representative) for medical care in accordance with the protocol 'Provision of medical care for the treatment of coronavirus disease (COVID-19)'. This form is used for: 1) treatment of the coronavirus disease under the protocol 'Provision of medical care for the treatment of coronavirus disease (COVID-19)'; 2) use of medicinal products, namely: a) unregistered medicinal products, which are recommended by the official body of the United States of America, the EU Member States, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, the State of Israel for treatment of coronavirus disease (COVID-19) in the country concerned; b) registered medicinal products for indications not specified in the instructions for medical use, provided that there is a proven efficacy in the treatment of coronavirus disease (COVID-19) and/or if such medicinal products are recommended by the official body of the United States, European Union member states, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China, the State of Israel for the treatment of coronavirus disease (COVID-19) in the respective country.

At the same time, the form of informed consent in its content does not cover both cases to which it applies. In particular: 1) the form applies to the segment of treatment according to the 'covid' protocol, because the form states that the patient certifies his consent to the use of the protocol 'Provision of medical care for the treatment of coronavirus disease (COVID-19)'; 2) the use of this form in the use of medicines seems to be concerning, because the given text does not mention the possibility of using, for example, off-label medicines. It is also not mentioned in the Protocol 'Provision of medical care for the treatment of coronavirus disease (COVID-19)' (Order

of the Ministry of Health of Ukraine, 2020, No. 762, in the edition of the Order of the Ministry of Health of Ukraine, 2022, No. 358). Next, let us draw attention to the issue of providing medical care without obtaining informed consent, the general regulation of which is provided in the Civil Code of Ukraine and the Fundamentals. The Civil Code of Ukraine and the Fundamentals allow the provision of medical care to a patient without his consent or his legal representatives in the presence of signs of imminent threat to the patient's life. We emphasize that the exception does not apply to the entire urgent state of man, but only a direct threat to life. Thus, the Ukrainian legislation protects the human right to informed consent for medical care and creates a regulatory platform for active participation in medical relations. There is no direct provision that enshrines the algorithm of providing medical care without the informed consent of the patient in imminent threat to the patient's life. From the literal interpretation of the norm, it follows that the duty of the attending physician will provide necessary medical assistance to the patient. According to Article 43 of the Fundamentals, the patient, who has full legal capacity, has a right to forego medical treatment; in case the refusal of the patient to undergo medical treatment may cause harm to the health of the patient, the physician is obliged to provide explanation of it to the patient; in case of further refusal – to request a formal (written) approval, or certify the refusal in the presence of witnesses. In fact, the institute of refusal of medical treatment has rarely been in the focus of case law. The District Court of Lypova Dolyna, Sumy Oblast in its 2018 decision dealt with the issue of legitimacy of refusal of medical treatment, where a patient (the plaintiff) litigated with defendant hospital because of the defendant's denial to accept his refusal to any medical interventions. The Court upheld the plaintiff's claim, finding, that the patient's right to refuse medical treatment is limited by urgent conditions, by a serious threat to the patient's health and in cases, where the consent of the patient is impossible to obtain due to objective (District Court of Lypova Dolyna, Sumy Oblast, 2018).

The role and significance of informed consent as a legal institute can be illustrated through the prism of Ukrainian jurisprudence. One of the earlier cases on informed consent was heard by the Chernivtsi Court of Appeals (Case No. 10-1/08, Judgment of 03.01.2008). There, a woman lodged a criminal complaint against the doctors of a regional clinical oncological infirmary for severe corporal damage. The criminal case was closed due to lack of the content of crime, and the complainant impugned it in a court, the complaint was dismissed. In her appeal, complainant demanded to quash the judgment of the first-instance court and refer the criminal case for re-opening; the complainant claimed that the operation was conducted without her consent, the treatment was performed incorrectly, and the complainant also claimed that the signature in the informed consent was forged, and no original was augmented to the case (there was only a copy), and that no necessary expertises were conducted; the complainant also claimed that all the writings her medical records in terms of diagnosis and medical examinations were forged. The Chernivtsi Court of Appeals established, that the complainant indeed underwent a surgery due to a severe oncological condition; at the same time, the expertise showed that the diagnosis was correctly determined, and it demanded a surgical operation. The expertises also showed that the writings in the medical records corresponded to her actual health condition, thus, the claim of the complainant in terms of an alleged forgery of medical records was dismissed. The informed consent form provided information that the patient was accustomed with the proposed medical treatment and gave her written consent, which dismissed the arguments in the appeal relating to her claim that she had not given the consent to the said medical intervention. Hence, the appeal was dismissed (Chernivtsi Court of Appeals, 2008).

Cases on informed consent were recently heard by the Supreme Court of Ukraine as well. One of such judgments was handed down by the Higher Specialized Court on Civil and Criminal Cases of Ukraine (such was the name of the cassation court for civil and criminal cases in Ukraine before the reform of the Supreme Court) in 2016. The plaintiff was a woman, whose son was hospitalized to the defendant's clinical traumatology hospital with a preliminary diagnosis of acute pancreatitis. Within the medical examination, the physician informed the son, that there was a perforation in the duodenum requiring an immediate surgical intervention. Being in severe pain, the man signed the consent to the performance of the operation, but after the operation, the after-operational diagnosis was changed, which determined the condition as acute edematous pancreatitis, which, under the Order of Ministry of Healthcare of Ukraine No. 279 (2010) presupposed conservative treatment. Plaintiff claimed that by such acts, the physician did not provide correct information to the patient relating to his state of health; the son had already been operated because of acute pancreatitis several months before the operation, wherein the post-operative period lasted with complications, and had he received correct information relating to his state of health, he would have foregone the operative information. Plaintiff also stressed that the consent to a surgery, signed under the condition of severe pains should not be considered as valid. According to the facts of the cases, provided in the judgment,

the plaintiff's son died several days after the operation was performed; the plaintiff additionally demanded repayment damages for funeral expenses and the installation of a monument. The court of first instance found in favor of defendant, finding that there was no infringements of plaintiff's rights and there was no causal link between the defendants' acts and the demise of plaintiff's son. The court of appeals affirmed the judgment of the lower court. The Higher Specialized Court on Civil and Criminal Cases of Ukraine held to dismiss the appeal in cassation. The Court found, that according to the case facts, the plaintiff's son was brought to the defendant's hospital in urgent order, where he was hospitalized for medical examination and was preliminarily diagnosed with the condition as mentioned above; the roentgen of the abdomen found free gas in the abdomen cavity, and the physicians diagnosed the patient with a pre-operative diagnosis of a perforated ulcer of the duodenum, which required an urgent surgical intervention, to which the consent of the patient was given. The Court also established, that as of the facts of the case, the patient was provided with explicit information on his health condition from the side of the physician, that the condition required a surgical operation including absolute indications for this operation, and in the course of the talk by the patient and the doctor, they both came to a conclusion in terms of the types of surgical procedures. According to the established facts of the case, during the revision of the bowel, no perforation was found indeed; but instead, suppurative processes on the pancreas were found, after which medication treatment was prescribed. The Court also denoted, that according to the Order No. 279 of the Ministry of Health of Ukraine (April 2, 2010), the existence of free gas in the abdomen was an absolute indication for an urgent surgery. So, the Court found, that the plaintiff did not prove the fault of the defendants, and dismissed the appeal in cassation (Higher Specialized Court of Civil and Criminal Cases of Ukraine, 2016).

One of the most recent cases on informed consent was heard before the Supreme Court of Ukraine (in the panel of judges of the First Judicial Chamber of the Civil Court of Cassation in the composition of the Supreme Court of Ukraine) in 2021. The facts of this case were the following. The plaintiff was the mother of the daughter, who was vaccinated from poliomyelitis on February 23, 2016. After vaccination, plaintiff's daughter became ill, and was diagnosed with acute flaccid paralysis, which is a side effect of the poliomyelitis vaccine, and was recorded as an adverse event, which had happened after the vaccination. An official inspection, which was conducted on March 25, 2016 by the commission, which was established in accordance with the Order of the Department of Health of the Rivne Regional State Administration of March 16, 2016 No. 33, as well as the medical records, a multitude of vaccination procedure violations by the defendants were found. Plaintiff demanded to compensate pecuniary damages deriving from her daughter's medical treatment, as well as the moral damages, which was caused by the defendants' acts, because of which her daughter's health condition deteriorated, as well as procedural costs. The court of first instance, the District Court of Sarny, Rivne oblast dismissed the plaintiff's claim, holding that the plaintiff did not prove defendants' fault, the illegality of defendants' acts, and the causal link between the acts of the defendants with the damages suffered. The Rivne Court of Appeals did not uphold the plaintiff's claim, finding that the court of first instance correctly dismissed the plaintiff's claim, as there was no direct and undisputed evidence of the causal link between the vaccination and the damage to the plaintiff's daughter's health; the evidence basis was contradictory, which does not give legal grounds to establish the said fact. The plaintiff lodged an appeal in cassation, and claimed, that the courts of first and second instances erred in dismissing her lawsuit, and did not consider that her daughter's health was damaged because of the violations of the vaccination procedure, namely: 1) the said vaccination was carried out without a room for vaccination; 2) there was no medical examination of her daughter by the physician; 3) the thermometry was not conducted; 4) there was no permission of the doctor for vaccination; 5) there was no individual vaccination plan for the minor (the plaintiff's daughter), who had a breach of the vaccination graphic and the vaccination calendar; 6) there was no informed consent from the side of the forbearers, which was not lodged to them. The Civil Court of Cassation in the composition of the Supreme Court of Ukraine has established, that by dismissing the claim of the plaintiff, the lower courts did not properly establish the circumstances of the case, and did not conduct a proper legal assessment of the evidence provided by the litigating parties, and did not check whether the vaccination of the plaintiff's daughter was performed in accordance with the law. The Civil Court of Cassation in the composition of the Supreme Court of Ukraine held, that the conclusions of courts, in particular, concerning the assessment of evidence relating to the causal link, contained assumptions, which is forbidden under Part 6 of Article 81 of the Code of Civil Procedure of Ukraine.

According to the law, the procedure of vaccination shall include a number of components:



- The medical staff are obliged to provide information concerning the procedure to the patient, or his, or her forbearers;
- The medical staff are obliged to conduct a medical examination of the person undergoing prophylactic vaccination;
- The medical staff, who are conducting vaccination, are obliged to ascertain the presence, or the absence of contraindications;
- The medical staff must abstain from prophylactic vaccination in case there are such contraindications;
- The medical staff, who conduct vaccination to patients under age fifteen, are obliged to receive the consent of the forbearers.

According to the established case facts, that priorly to vaccination, the paramedic did not conduct a thermometry of the plaintiff's daughter, and no data relating to the medical examination was entered into the plaintiff's daughter's medical record. The Civil Court of Cassation in the composition of the Supreme Court of Ukraine also held, that the lower courts did not consider that the paramedic, who had performed the vaccination to the plaintiff's daughter, was also obliged to provide the minor's forbearers with objective information concerning the vaccination, and obtain their consent to it. According to the certificate of official inspection (dated March 25, 2016), the members of the commission found that the form of informed consent and assessment of the health of a person, or a minor by one of the forbearers, or other legal representative of the minor for vaccination or tuberculin testing (Form No. 063-2/o), is submitted not in accordance with the form, which is approved by the Order of the Ministry of Health of Ukraine of December 31, 2009 No. 1086. So, the informed consent of the forbearers was not obtained. The Civil Court of Cassation in the composition of the Supreme Court of Ukraine held, that the informed consent form was not contained in the materials of the case, and the plaintiff denied signing a consent form at all. The Civil Court of Cassation in the composition of the Supreme Court of Ukraine held, that the courts of lower instances did not consider the circumstances referred above, and, referring to lack of proof of the causal link between the procedure of vaccination of plaintiff's daughter, and the deterioration of her health condition, as plaintiff did not exercise her right to forensic examination during the court proceedings, in violation of procedural law, the arguments of the plaintiff, who was relying on the fact of the negative reaction of her daughter to the vaccination, was not considered by the courts of lower instances; the courts of lower instances did not give an assessment of the evidence, upon which the plaintiff substantiated the causal link between the vaccination, and the damages, that were suffered. The Supreme Court of Ukraine ruled to annul the contested decisions, and remanded the case for reconsideration to the court of first instance ( Civil Court of Cassation in the composition of the Supreme Court of Ukraine, 2021).

To sum up, cases involving the issue of informed consent are mostly quite recent in Ukrainian case law. The two judgments of the Civil Court of Cassation in the composition of the Supreme Court of Ukraine illustrate, that such cases are medical malpractice claims for damages, which involved some malpractice from the side of the medical practitioners. Both afore-mentioned cases involved the issues of providing specific medical information (in the first case, it was proved, that plaintiff's son was provided necessary information relating to the forthcoming surgery, and in the second, no informed consent to vaccination from the minor's forbearers was obtained). Henceforward, the issue of the patient's informational rights was involved in both cases, which were observed above. The explanation of the institute of informed consent by the Higher Specialized Court on Civil and Criminal Cases of Ukraine in the 2016 judgment, and the Civil Court of Cassation in the composition of the Supreme Court of Ukraine, has notoriously enriched the Ukrainian case law relating to the protection of patient's rights, medical malpractice and issues of vaccination.

### **3. The Institute of Informed Consent in Latvian Legislation and Case Law**

In Latvian law, the patient's right to choose for himself, or herself of what medical treatment is better, or rather what medical treatment is more available, from treatment and diagnostic options offered by the medical practitioner, has considerably increased from the view of legislation and case law. Currently, informed consent is a concept that plays an important role in the relationship between a doctor and a patient, as it forms an essential part of medical ethics and human rights (Center for Disease Prevention and Control of the Republic of Latvia, 2019). There is no doubt today that patients' rights are based on the principle of human dignity, which in turn is closely linked to other fundamental human rights, including integrity and autonomy. Integrity refers to physical and mental integrity of the patient's body, unless the patient has given his or her consent or there have been

legitimate grounds for doing so. In the legal framework, the protection of this principle is usually ensured at the same time as the protection of human autonomy and self-determination. Informed consent of a patient within the meaning of the European Court of Human Rights, may be disclosed in the context of the right to self-determination and autonomy, which underlies the principle of informed consent (Birģelis, 2014, *Jurista vards*, Nr. 16). The authors A. Lytvynenko and T. Jurkeviča claimed in their recent article, that the institute of informed consent amounts a considerable quotient of a contract for healthcare services (Lytvynenko, Jurkeviča, 2022, p. 33-42). In Latvian contemporary jurisprudence in relation to medical malpractice, informed consent is understood as a process, within which the medical practitioner provides the patient with explicit information relating to the patient's treatment in a conceivable form to the patient, in result of which the patient provides informed consent (Administrative District Court (Rezekne), 2022). The Recommendations for Healthcare Institutions on Informed Consent, Version 1.2, March 2019 (in Latvian: Ieteikumi ārstniecības iestādēm par informētu piekrišanu. Versija 1.2. 2019. gada marts) presuppose, that informed consent encompasses each medical procedure; and the principle of the patient's free will means that the patient provides informed consent without any impact from the side of medical staff, relatives or friends. Informed consent is presupposed to be relevant at the time of treatment, and had any circumstances, as risks, or alterations in the treatment plan changed, in such case the informed consent must be repeated (Center for Disease Prevention and Control of the Republic of Latvia, 2019). The Recommendations provide that informed consent should be reached in writing (mostly to various surgical operations and medical manipulations, that may constitute a certain risk for the patient's health, or are conducted under general, or local anesthesia, or when the treatment is conducted as a part of a clinical trial), in some cases – verbally, or non-verbally, for instance, to minor medical examinations or laboratory tests (Center for Disease Prevention and Control of the Republic of Latvia, 2019).

The concept of informed consent presupposes an absolute prerequisite of the patient's consent to treatment. The Oviedo Convention stipulates that any activity relating to health may be carried out only with the voluntary and informed consent of the person concerned (Oviedo Convention, 1997). The Law on Patients' Rights stipulates that treatment is permissible if the patient has given informed consent (Law of the Republic of Latvia "On the Rights of Patients", Art. 6 (1)); and that the patient's right to information about his or her state of health is also proclaimed, ie the patient has the right to ask questions and receive answers before giving informed consent (Law of the Republic of Latvia "On the Rights of Patients", Art. 6 (1)). By asking a medical practitioner questions the patient exercises his or her right to information, as the explanation of the definition of informed consent provided in the Law of the Republic of Latvia "On the Rights of the Patients" states that the patient consents to treatment based on timely information on the purpose, risk, consequences and methods of treatment (Law of the Republic of Latvia "On the Rights of Patients", Art. 1 (2)). The said information should be provided in a form that is comprehensible to the patient, explaining the medical terms and taking into account the patient's age, maturity and experience (Law of the Republic of Latvia "On the Rights of Patients", Art. 4 (5)). The explanation of the term "informed consent", as of Art. 1 (2) of the Law on The Rights of Patients should be understood, as a consent, which the patient gives 1) in writing; 2) orally; 3) by actions which clearly establish, that the patient opts to submit to a certain medical procedure; the informed consent should be provided freely, after the explanations, provided by the medical personnel, which includes the following: 1) the purpose of treatment; 2) the risks of treatment; 3) the consequences of treatment; 4) the methods of treatment. Technically, informed consent is not mandatory to be given in writing, but only if request by the patient himself, or the attending physician (in legislation: Art. 6 (2) of the Law on the Rights of Patients, in jurisprudence, see: Judgment of the Vidzemes Regional Court, 2018).

This legal framework is in line with the case law of the European Court of Human Rights. According to the judgment of the European Court of Human Rights of 15 January 2013 in the case of *Csoma v. Romania*, in cases where there is a risk to the patient's health, it is especially important to inform the patient so that the patient can assess the situation and make appropriate decisions (European Court of Human Rights, *Csoma v. Romania*, 2013, para. 42). However, it should be noted, that the structure of informed consent is still unclear: its rationale, its structure and consequences. Several theorists and practitioners define informed consent as a fundamental private human right, but this perception points to the fault of medical practitioners, rather than to fundamental human rights. Others emphasize that patient autonomy is part of a fundamental right, but is not seen as a new fundamental right (Hondius, 2010, p. 173). In Latvian law, any medical procedures without the informed consent of the patient are prohibited, unless the cases, when: 1) the denial in conducting the necessary medical procedure endangers the patient's health, and there is no possibility to obtain the patient's consent, or the consent of the patient's representative (Art. 7 (8) of the Law on the Rights of Patient); 2) within surgical or otherwise intrusive medical

procedure the treating physician has a right to provide non-planned treatment without the consent of the patient in case the patient necessitates urgent medical help, or a non-performed medical procedure would cause more damage to the health of the patient (Art. 7 (9) (Law on the Rights of Patients, Art. 7 (8)-(9)). The jurisprudence shows, that the latter provision could be proved only in case the circumstances of urgency, or the fact that the non-performance of the medical procedure could cause aggravated damage to the health, are enclosed to the respective medical records (Administrative District Court (Rezekne), 2022).

The institute of refusal of medical treatment also received its reflection in the law of Latvia, namely the aforementioned Law on the Rights of Patients, Art. 6 (4)-(7). Upon Art. 6 (4) of the Law on the Rights of Patients, the patient has a right to forego medical treatment in various different occasions, which include: 1) before the start of medical treatment; 2) from a certain method, which is used in the medical treatment; 3) refuse treatment during the conduction of it. In case the patient opts for refusing medical treatment, the mechanism for certifying such decision is very similar to the one in the legislation of Ukraine: the refusal (relating to the decision to refuse, or terminate treatment, or forego a certain method) should be provided in writing, indicating that the patient had received all necessary information (Art. 6 (5)); the physician, at the same time, owes a duty to encourage the patient to visit a different doctor; if the patient denied the refusal in a written form, then two adult, and fully legally-capable witnesses need to certify the patient's refusal in writing (Art. 6 (6)). According to Art. 6 (7) of the Law on the Rights of Patients, the patients have to inform the healthcare institutions in case they have authorised another person to consent/refuse (in overall, or to a method) to the proposed medical treatment (Law on the Rights of Patient, 2009, Art. 6 (4)-(7)). An outstanding historical case relating to the patient's refusal of treatment after a working casualty will be reviewed by the authors below.

The Senate's judgment No. SKC-216/2013 is of utmost concordance of the explanation of the institute of informed consent in the Republic of Latvia. In this case, in December 2010, the plaintiff lodged a lawsuit to recover damages against a psychoneurological hospital. He claimed, that since March 2009, he stayed at the State Center of Social Help (in Latvian: Valsts sociālās aprūpes centrā), but when he left the Center upon his own will in June 2009, he was forcibly returned and hereinafter placed in an isolator; and since he was able to open the door of the isolator, he was apprehended again, and was forcibly brought to the psychoneurological hospital. Plaintiff was hospitalised against his will, being in a recumbent position and confined in handcuffs; then, plaintiff stayed in a closed ward for a week, when a physician visited him, though not telling the terms he had to stay there, nor discussing any aspects of treatment. Plaintiff later claimed in his talks with the doctors, that his health was deteriorating, as he thought, because of wrong application of medicines; plaintiff also had no knowledge of what medicines he consumed. When plaintiff was released from the hospital in August 2009, no physician council assembled in order to assess his health condition or decide on necessity of forced treatment; that day, a member of medical staff, giving no explanations, asked plaintiff to sign the documents which would affirm his consent to treatment. Plaintiff later complained to the Healthcare Inspection, which conducted an examination, finding a violation of Art. 67 of the Medical Treatment Law, as forced hospitalisation is not provided by a council of doctors, and the council of doctors had to gather three days after plaintiff was brought to the hospital at latest; moreover, the physician on duty did not receive the plaintiff's written consent to hospitalization, as provided in Art. 68 of the Medical Treatment Law; there was also proof that plaintiff was forcibly apprehended and maintained, and was given medicines to control his behavior. Hence, the examination displayed that the defendant's acts violated the law, and the plaintiff had sustained considerably moral damage and humiliation. Plaintiff sued the defendant hospital on basis of Art. 92 and 94 of the Constitution, the Art. 1632 and 2352 of the Civil Code, as well as the provisions of the Medical Treatment Law, namely Art. 20, 21, 65, 67 and 68. The court of first instance (District Court of Valka) partially upheld the plaintiff's claim, however the Vidzemes Regional Court, hearing the appeal from the side of both plaintiff and defendant, dismissed the claim. Foremost, Court held, that the norms of the Patient's Rights Law, where the concept of informed consent considerably enlarged, could not be applied, as it was not yet in force at the time when the disputable legal relationships took place. Next, the plaintiff did not prove the existence of a legal foundation to claim damages because of the defendant's acts, upon which plaintiff was deprived of freedom (being confined at the psychoneurological hospital). The conditions under which the plaintiff was maintained were not disputed; the Healthcare Inspection had established, that in June 2009, the psychiatrist physician had justifiably decided that plaintiff's state of health required hospitalisation, as at that time, the plaintiff behaved aggressively, and his health condition displayed such impairments, which could seriously deteriorate the plaintiff's health. So, the psychiatrist acted in compliance with Art. 68 (1) (2) of the Medical Treatment Law, which presupposed provision of psychiatric medical assistance without the consent of the patient. It was not

disputed that the physician on duty did not obtain the plaintiff's informed consent, but since more than four months passed since the violation occurred, the Healthcare Inspectorate held to refuse to open the case upon and administrative misdemeanor committed by the physician. It was also not disputed that plaintiff signed the consent to hospitalisation in his medical record, though there was a dispute relating to the date of such signature (whether it was when plaintiff was admitted to the hospital – in June 2009, or when plaintiff was released – in August 2009). According to the testimony of one witness, plaintiff signed the consent form soon after hospitalisation (the same day he was hospitalised, when his condition was stabilized); plaintiff also did not manage to prove that he signed the consent form before he was released from the hospital, fearing he would remain confined in the hospital unless he had signed the said consent form. According to the afore-mentioned facts, the court came to a conclusion that the plaintiff had signed the consent form in June 2009 the day he was hospitalised, and there was no deprivation of freedom from the side of defendant in the sense of Art. 2352 of the Civil Code. The appellate court also did not find any negligence from the side of the defendant, and the mere fact that plaintiff's consent was obtained after plaintiff had calmed down, did not toll to negligence; plaintiff did not prove that he was not provided information regarding his treatment; the medical record featured the therapy, which was prescribed to the plaintiff, and his complaints were also briefly written; the physicians, who acted as witnesses in the proceedings, also confirmed they provided information to the plaintiff. Plaintiff decided to lodge an appeal in cassation, which was reviewed by the Supreme Court of the Republic of Latvia (Senate's Department of Civil Cases), and the Court decided to annul the judgment of the Vidzemes Regional Court, remanding the case to the appellate court for a new review. The Court came to the following conclusions. Firstly, the Court held, that people, who are suffering from psychiatric ailments, possess a considerable amount of rights, provided in international-legal instruments, and any deprivation of liberty must be conducted only with strict compliance with the law; at the same time, the people, who were deprived of freedom, have a right to sue, and the court has to determine the legitimacy of the confinement, and order to release the person, who was confined, has such decision been illegitimate; the victims of illegitimate confinement should have a right to compensation. The Supreme Court denoted, that the norms of the Medical Treatment Law, the hospitalisation to a psychiatric hospital could be voluntary; without the consent of the patient; after a court judgment in a criminal case as a forced medical measure. No doubt was cast relating to the confinement of plaintiff – as a matter of fact; thus, the question at stake was to determine of whether such confinement was conducted in accordance with the law. The Court discussed the provisions of Art. 67-68 of the Medical Treatment Law, as well as the Regulation of the Cabinet of Ministers of the Republic of Latvia No. 1046 (December 19, 2006, in the edition acting from August 2, 2008 to August 31, 2009), according to point 112.3, the emergency brigade should provide urgent medical assistance to a victim (or a sick person) on the place of a incident, while transporting the patient to a healthcare institution, in case an acute illness, or an exacerbation of a chronic illness, which threatens the life of the patient – acute mental disorders, which are characterized by the patient's aggressive behavior, or suicide attempts. Hence, the Supreme Court designated, that the psychiatric medical assistance should be provided in association with the principle of voluntariness, and such medical assistance conducted without the consent of the patient should be provided in exceptional cases, when the mental disorder 1) threatens the patient's life; 2) when the patient, due to this mental disorder, behaves aggressively, or there are suicide attempts. Then, the Court explained, that the psychiatric medical assistance without the consent of the patient must also be conducted in strict provision with the law: namely, a doctor council has to examine the patient in 72 hours – to treat the patient without the patient's consent, or to terminate the psychiatric medical assistance. In the former case, the healthcare institution is obliged to inform the district court on this fact, and the judge, after having assessed the facts of the case, may decide, whether to order the maintenance of the sick person in the psychiatric hospital, or to release the sick person from the hospital. The decision of the council of doctors must be assessed by the court, as the possibilities of confined persons to protect their legal interests are considered to be quite restricted. The Senate had outlined, that there is no exceptions to the legal procedure, described above, and established, that the order, provided by Art. 68 of the Medical Treatment Law, was not fulfilled, as it was determined by the Healthcare Inspection. Hence, the Supreme Court (Senate) held that the appellate court erred in interpreting the provisions of Art. 68 of the Medical Treatment Law, erring in establishing that the plaintiff was hospitalised voluntarily. Analyzing the legal nature of the patient's informed consent, the following most important legal aspects are noted, the Supreme Court denoted, that the patient's consent is the constituent, which makes the treatment legitimate, unless it concerns involuntary medical treatment, and the patient's consent is conditional on basis of the patient's ability to express his, or her will, that the patient is sufficiently informed (the patient is informed concerning the treatment, its risks, alternatives etc.), and the voluntariness of the patient (informed consent is free and is not given under any coercion from the side of any third persons). Hence, the Senate held, that in case a medical procedure is performed to the patient without the patient's consent with no



objective reason, then it should be regarded, as a violation of the law, upon which civil liability is imposed under Art. 1635 of the Civil Law and Art. 92 of the Constitution of the Republic of Latvia. Hence, the Supreme Court held to annul the judgment of the appellate court (Supreme Court of the Republic of Latvia, 2013).

The principles, outlined by the Senate of Latvia in the judgment No. SKC-216/2013 are the core contemporary aspects of informed consent. This approach could be also found in modern literature on medical law and ethics (Montgomery, J. 1997, p. 227; Kennedy, I., A. Grubb, 1998, p. 110-112, Pattinson, S.D., 2006, p.p. 100-101; Justickis, V., 2010). The principle of informed consent, which provides for fulfilling an obligation of providing the patient sufficient information on his further medical treatment, firmly corresponds. This statement of provision on necessary information fully corresponds to what Latvian medical practitioners and medical institutions offer to their patients (Center for Disease Prevention and Control of the Republic of Latvia, 2019), and, of course, is enshrined in the Law on the Rights of Patients (2009), namely: the patient has the right to receive information from the treating physician about his, or her health condition, including diagnostics, medical treatment, examination and rehabilitation plan, prognosis and consequences, including functional limitations, caused by the disease, prevention options, as well as the patient's right to receive information on the results of treatment, unforeseen outcome and reasons (Law of the Republic of Latvia "On the Rights of Patients", Art. 4 (3)).

The structure, significance and place of informed consent in legal relations in the field of medical treatment in the legal sphere of Latvia can be judged by analyzing the rulings of the Supreme Court of the Republic of Latvia, the Senate. The facts and the judgment of the Department of Administrative Cases of the Senate of the Republic of Latvia of March 24, 2020 in the Case No. A420172018, SKA-790/2020 are provided as follows.

In October 2015, the plaintiff, a woman, applied to a hospital, complaining on abdominal pain and an abnormal weight gain. The surgeon, to whom she applied, advised a gastric reduction surgery, and referred plaintiff to a number of pre-operative examinations. The operation was conducted in mid-January 2016, and unfortunately the plaintiff suffered from bleeding in the isolated part of the stomach as well as several other post-operative complications; the plaintiff stayed in the hospital until early February 2016. Next, the plaintiff went to the gynecologist, complaining of lower abdomen pains, and the examination showed an ectopic pregnancy in the left fallopian tube, and the said organ was removed shortly thereafter. Later, the plaintiff was also diagnosed of having spleen problems, and in April 2016, plaintiff underwent an laparoscopic abscess drainage so as to prevent abscess. Plaintiff considered that the surgeon did not provide professional treatment and caused damages to plaintiff, complained to the National Health Service, claiming compensation from the Medical Risk Fund with a demand to recover damages for deterioration of health, as well as moral damages. Plaintiff received compensation in accordance with the decision of National Health Service dated July 13, 2017, however, plaintiff was refused compensation in terms of the medical expenses, which plaintiff sustained concerning the prophylactics of the abscess. However, plaintiff did not consent to such compensation, and applied to the Ministry of Health with a complaint, demanding a substantially larger compensation than it was actually received by her, and demanded the reimbursement of medical expenses of the abscess prophylactics procedures, as well as moral damages in terms of violation of Art. 16 of the Law on the Rights of Patients because of a non-compliance with the terms of reviewing the complaint (as of Art. 16 (6) of the Law on the Rights of Patients). However, the decision of the Ministry of Health dated January 18, 2018 rejected her complaint, and so the plaintiff decided to lodge an administrative lawsuit in order to obtain compensation for the damages sustained, however plaintiff lost the lawsuit on the first and second instance. The Administrative Regional Court, joining the findings of the Administrative District Court found, that, the physician did not determine of whether the patient had an endocrinological disease, which could be the reason for obesity, no conclusions from the endocrinologist, the gynecologist and the family physician were obtained, the reasons for obesity were not examined in complex, nor were any alternative methods of treatment observed). According to the facts that were established hereinabove, the court found that decision of the National Health Service had correctly determined the violations occurring during the provision of medical care, since: 1) the surgeon did not thoroughly conduct the health condition of the patient; 2) the contraindications to the operation were not established; 3) the alternative methods of treatment were not assessed. One more violation of medical care was also established in terms of post-operative control in the first day after the operation – at the first day after the operation, it was prescribed to control the patient's pulse, pressure, temperature and the blood analysis, which was not conducted (except temperature control). At the same time, the other post-operative complications, as it was held further, were not a consequence of medical errors, or negligence. It was also established, that the damages due to the afore-mentioned medical treatment violations

were not very severe, for instance, they did not cause disability to the patient, or negatively affect the patient's quality of life, or survival. So, the plaintiff's appeal was rejected, and the plaintiff lodged an appeal in cassation. The Supreme Court of Latvia, having reviewed the case, decided to annul the judgment of the Administrative Regional Court, and to remand the case to the Administrative Regional Court for a new judgment.

The part of the judgment relating to informed consent can be divided into three parts:

1. First of all, the Senate emphasizes that medical treatment is always associated with a certain risk. Damage to a patient's health can also occur if the doctor has done everything in good conscience and no faulty action has been identified. Reasonably chosen treatment can also cause unavoidable consequences, as well as side effects and complications independent of the physician's acts (Para. 8 and 9 of the Judgment);
2. With regard to the consequences of the treatment (the consequences of the operation, including the possible consequences in the case of professional surgery) and the non-professional conduct of the doctor, account must also be taken of whether the treatment was given with the patient's informed consent. Namely, when assessing whether such treatment (surgery) would have been performed at all, the patient's ability to give informed consent must also be assessed. Pursuant to Art. 1 (2), Clause 2 of the Law the Republic of Latvia "On the Rights of Patients", informed consent is the patient's consent to medical treatment, which he or she gives orally, in writing or by such actions, that explicitly confirm consent, and gives it freely on the basis of timely information on the purpose of treatment, the risks, consequences and methods to be used ("Informed consent is the consent of a patient to medical treatment which he or she gives in oral or written form, or by such activities which explicitly certify the consent, moreover, it is given freely on the basis of the information provided by a medical practitioner in a timely manner regarding objectives, risks, consequences and methods used for medical treatment"). Pursuant to Art. 6 (1) of the Law of the Republic of Latvia "On the Rights of Patients", treatment is permitted if the patient has given informed consent. The patient has the right to ask questions and receive answers before giving informed consent. ("Medical treatment shall be permitted if the patient has given informed consent thereto. The patient has the right to ask questions and receive answers prior to giving informed consent.") In its turn, in accordance with Art. 4 (3) of the Law of the Republic of Latvia "On the Rights of Patients", a patient has the right to receive information from the attending physician about his or her health condition, including the diagnosis of the disease, treatment, examination and rehabilitation plan, prognosis and consequences, as well as functional limitations and prevention options. ("A patient has the right to receive information regarding his or her state of health from the attending physician, including regarding the diagnosis, the plan for medical treatment, examination and rehabilitation of the disease, the prognosis and consequences, the functional restrictions caused by the disease and opportunities for prophylaxis"). Thus, a doctor who decides on a particular method of treatment, as the competent medical practitioner, must be responsible for providing the patient with informed consent and not base his treatment uncritically on the patient's unwillingness to receive information relating to specific medical treatment. (Paragraph 12 of the Judgment). This leads to the conclusion that the decision on the choice of treatment is nevertheless made by the doctor as the most competent person and is responsible for this decision, while the doctor is also responsible for the extent to which information about this treatment is provided to the patient, i.e. the doctor is responsible to providing the patient with information that ensures that informed consent is obtained. In general, then, it can be concluded that informed consent is ancillary to, and not essential to, the choice of treatment. The Senate points out, that even if a patient wishes to receive specific treatment, and comes to the doctor with a wish to perform surgery, it does not release the doctor from the obligation to examine the indications and contraindications, if necessary – to consider psychological factors and obtain informed patient consent.
3. If the court concludes that, in the particular circumstances, given the medical indications and contraindications and the patient's informed consent to the treatment, the operation would not have been performed, it could be a ground for non-professional treatment of the consequences in the case of an operation performed, however, would not have occurred if the operation had not been performed at all (Paragraphs 12 and 13 of the Judgment). This reference to liability of a medical practitioner for the damages, caused by the treatment of a patient on the basis of the patient's informed consent also demonstrates that informed consent is only an element in the choice of treatment, not an only or leading one. (Supreme Court of Latvia (Senate), 2020).

The recent Latvian case law relating to cases on informed consent, or the physician's duty to inform the patient relating to the risks of certain medical procedures have also increased in their amount. A number of such cases have been heard both in the Supreme Court of the Republic of Latvia (Senate), as well as by other lower courts. Such cases were claims for damages originating from various medical malpractice. In the recent case of the Supreme Court of the Republic of Latvia (Senate), SKA-790/2020, the Senate has provided a substantial explanation on the institute of informed consent, which augmented the Senate's position in the civil case SKC-216/2013, which related to an unconsented hospitalization of a patient to a psychiatric hospital. These two cases of the Senate have created valuable legal precedents in the field of medical law and especially, the institute of informed consent.

#### **4. Corollary and a Comparative Analysis**

Having reached to the corollary chapter of the paper, the authors conducted a comparative analysis of the institute of informed consent in Ukraine and the Republic of Latvia. In both states, the liability for conducting an unconsented medical operation tolls to civil liability (i.e. a civil lawsuit for recovering damages). In both Ukraine and the Republic of Latvia, in medical malpractice cases, the courts carefully assess the validity of informed consent given by the patient in terms of its actual compliance with the principles, laid down by the legislation. For instance, in the case of the Higher Specialized Court of Ukraine on Civil and Criminal Cases (2016), the plaintiff had argued that her son's consent to surgery could not be considered as valid, as it was provided during the time when the man was in a deplorable health condition; and in the case of the Supreme Court of Latvia No. SKC-216/2013, the dispute lasted around the issue of plaintiff's provision of informed consent to psychiatric medical treatment. The legislative provisions of informed consent in Ukraine are contained in the Fundamentals (1992), the Civil Code (2003), as well as a number of other legal acts, whereas the main legislative framework for the institute of informed consent in the Republic of Latvia is the Law on the Rights of Patients (2009), and before it was enacted, the consent to medical treatment was enshrined in the provisions of the Medical Treatment Law (1997).. Apparently, informed consent is viewed not only in the sense of patient's consent to medical treatment, but as the physician's duty to inform the patient on possible risks of the future medical treatment, explain its peculiarities, discuss the alternatives in treatment, if any, and so on. In such view, both of the plaintiffs in the case of Higher Specialized Court of Ukraine on Civil and Criminal Cases (2016) and the Supreme Court of the Republic of Latvia (2020) alleged a lack of information provided to the patient (in the former case – the plaintiff's son, in the latter case – the plaintiff herself), and in both cases, the courts had to examine whether the physicians had complied with their duty to inform the patients; in the first case, it was established, that the patient was provided with all necessary information regarding the future surgery and agreed to undergo it, whereas in the second case it was established, that the surgeon did not obtain the conclusions of plaintiff's health conditions from other physicians, and the contraindications to the operation, or the other methods of treatment were not assessed. Both situations actually display how complex may be the institute of informed consent in the sense of the patient's information rights. In terms of foregoing medical treatment, the legislative provisions of Ukrainian and Latvian laws are very similar. In Ukraine, the institute of refusal of treatment had received an extensive coverage in a 2018 judgment of the Lypova Dolyna District Court of Sumy Oblast. The Latvian legislation is very detailed in terms of refusing medical treatment, though the jurisprudence upon this subject is very rare: one old case has been discussed by the authors in this paper. To sum up, the legislation of Ukraine and the Republic of Latvia provide strict requirements for the fulfillment of this principle, and a multitude of legal issues, such as the provision of medical information for patients under eighteen years of age, as well as information relating to vaccination, the discussion of the overall theory of informed consent in modern medical law and its application by the European Court of Human Rights were reviewed by the authors. The authors observe, that the legislation of Ukraine and the Republic of Latvia corresponds to the high standards of contemporary medical law, and the principle of informed consent remains the key principle between the patient and physician both in Ukraine and the Republic of Latvia.

#### **Conclusions**

The concept of patient's rights is becoming more and more topical nowadays. Far more lawsuits regarding violations of patient's rights, which are of relatively recent origin could be beheld worldwide, and claims regarding unauthorized medical procedures are also becoming more frequent. The institute of informed consent is called to

protect the patient's body integrity, as well as his, or her right to choose the appropriate medical treatment, which is necessary upon his, or her view, as well as to withstand the undesired treatment. Lawsuits regarding unconsented medical procedures, as well as the breaches of physician's obligation to inform the patient relating to forthcoming treatment have recently become more frequent both in Ukraine and the Republic of Latvia. In both states, the acting legislation provides a framework for the appropriate functioning of the institute of informed consent. The Ukrainian legislation in terms of informed consent is built upon the Fundamentals (1992), as well as a number of legislative provisions in other laws and bylaws, whereas the Latvian legislation in terms of informed consent is founded upon the Law on the Rights of Patients (2009) and the Medical Treatment Law (1997). The recent case law of both states has shown a number of claims for damages for unconsented medical procedures, which were heard by the cassational courts of Ukraine and the Republic of Latvia: these cases were commented upon in detail. The increase in the amount of case law in both Ukraine and the Republic of Latvia also tends to show the topic of protecting patient's rights is becoming more concordant in Ukraine and the Republic of Latvia.

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