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Patient Autonomy in Ukrainian Law

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The article discusses the legal institution of patient autonomy in Ukrainian law from the side of a historical and comparative perspective. Being of twofold nature, patient autonomy encompasses both the patient's right to undergo treatment, surgery and other medical interventions explicitly with a free and informed consent, as well as the patient's right to forego medical treatment (informed refusal) without being obliged to state a justified reason for it. Albeit Ukrainian legislation is clear in relation to the provision of consent for treatment – both normatively and documentarily, the institute of informed refusal needs certain upgrade, especially in the view of the existing case law. The author also discusses a handful of relevant judgments of the European Court of Human Rights on the subjects, as well as the historical vaults of informed consent and informed refusal, being case law from different states of the world, encompassing the European Union, England, the United States of America, Canada, and Japan. The author hallmarks the necessity of the patients not only to know their respective rights, but also to be able to protect them, which is expressed in the enrichment of the legal culture of the patients. Apart from the above-mentioned statements, the author makes a statement that medical malpractice lawsuits in Ukrainian courts have become far more frequent than they used to be a decade ago.
Keywords: informed consent, informed refusal, Ukrainian law, patients' rights, medical malpractice litigation.

Paciento autonomija Ukrainos teisėje

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Straipsnyje aptariamas paciento autonomijos institutas Ukrainos teisėje istoriniu ir lyginamuoju požiūriu. Būdama dvejopo pobūdžio, paciento autonomija apima tiek paciento teisę gauti gydymą, be to, kad jam būtų atlikta operacija ir kitos medicininės intervencijos aiškiai davus laisvą ir informuotą sutikimą, tiek jo teisę atsisakyti medicininio gydymo (informuotas atsisakymas) neprivalant nurodyti pagrįstos priežasties. Nors Ukrainos teisės aktai yra aiškūs dėl paciento duoto sutikimo dėl gydymo – tiek normatyviniu, tiek dokumentiniu požiūriu, informuoto atsisakymo institutą reikėtų atnaujinti, ypač atsižvelgiant į esamą teismų praktiką. Autorė taip pat aptaria keletą aktualių Europos Žmogaus Teisių Teismo sprendimų šiomis temomis, istorines informuoto sutikimo ir informuoto atsisakymo ištakas, kurios yra įvairių pasaulio valstybių, įskaitant Europos Sąjungą, Angliją, Jungtines Amerikos Valstijas, Kanadą ir Japoniją, praktika. Autorė pabrėžia pacientų būtinybę ne tik žinoti savo atitinkamas teises, bet ir mokėti jas ginti, o tai padeda gerinti pacientų teisinį išmanymą. Be paminėtų teiginių, autorė teigia, kad medicininių klaidų ieškiniai Ukrainos teismuose tapo daug dažnesni nei prieš dešimtmetį.
Pagrindiniai žodžiai: informuotas sutikimas, informuotas atsisakymas, Ukrainos teisė, pacientų teisės, medicininės aplaidumo bylinėjimasis.

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Introduction

Over the past decade, the number of court cases in Ukraine, in which disputes about an improper provision of medical care were being considered, has increased several times, if not even dozens of times. The injured party no longer has the habit of keeping quiet about the alleged breach of rights, and does not write complaints to various instances, demanding a disciplinary inspection, but immediately goes to court with a claim against the healthcare institution for a compensation of damages. Thus, even the practice of the Supreme Court, which in Ukraine performs the function of the cassation instance in all civil, criminal and administrative cases, already has more than a dozen cases regarding an improper provision of medical care and violation of patients' rights over the past 5 years. Meanwhile, the number of similar cases of lower court instances is calculated in the dozens. Then, the question arises – where does such an immense number of court cases come from? It lies in the fact that doctors do not comply with the legislation, or patients become too picky, or *vice versa*, is it that the legislation does not regulate all aspects of medical legal relations? Obviously, the first, second, and third options are all correct. In Ukraine, there is no separate lawdefining patients' rights, which were actively adopted in the European Union countries after (and in some cases before) the adoption and ratification of the *Oviedo Convention*[1]; to some extent, the Law of Ukraine "*Fundamentals of the Legislation of Ukraine on Health Care*" (1992) mostly covers the provisions that are usually included in European laws on patients' rights, but not to the full extent. What is more, there is no such institution as a patient's rights ombudsman (a vivid example of the implementation of which is Poland), where such an institution has been operating since 2009, and the patients' rights ombudsman, among other things, can represent the injured party in court. As Ukraine seeks to join the European Union, it will need to harmonize its legislation with that of the EU Member States, which, among other things, have special laws on the protection of patients' rights, which provide for guarantees of rights included in the *Oviedo Convention*, sometimes with an even broader interpretation. The practice of the European Court of Human Rights in the field of medical law is gradually being implemented in court cases considered in Ukraine, in particular, by the Supreme Court, but the Oviedo Convention has, unfortunately, not yet been ratified by Ukraine.

The author also would like to foreground that, as of 2023, the Supreme Court has issued a fairly significant number of rulings regarding violations of certain patient rights. Below is a decision of this court, which raised the issue of violations of certain patients' rights with the objective to show the relevance of this problem in the judicial practice of Ukraine:

1) Patient's right to compensation for damages due to negligence of medical professionals committed during the treatment of the patient, the conduct of medical procedures, the provision of medical services, etc. (based on Articles 1166, 1167, 1195 of the Civil Code of Ukraine): Resolution of the Supreme Court of November 15, 2018 in the case No. 761/24076/15-ц[2]; Resolution of February 27, 2019 in the case No. 755/2545/15-ц[3]; Resolution of November 25, 2019 in the case No. 264/7310/15[4]; Resolution of November 27, 2019 in the case

[1] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, European Treaty Series – No. 164.

[2] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 15 lystopada 2018 roku u spravi № 761/24076/15-ts, provadzhennia № 61-26051sv18.

[3] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 27 liutoho 2019 roku u spravi № 755/2545/15-ts, provadzhennia № 61-47866sv18.

[4] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 25 lystopada 2019 roku u spravi № 264/7310/15-ts, provadzhennia № 61-32917sv18.

No. 661/2894/16-ц[5]; Resolution of November 4, 2020 in the case No. 686/6022/18[6]; Resolution of January 19, 2022 in the case No. 308/4164/15-ts[7]; Resolution of February 9, 2022 in the case No. 161/7881/20[8], Resolution of October 26, 2022 in the case No. 572/2718/19[9], Resolution of November 30, 2022 in the case No. 344/3764/21[10], Resolution of December 23, 2022 in the case No. 459/3913/21 (*Supreme Court (Ukraine)*, judgments of 2019, 2020, 2022)[11];

2) Patient's informed consent to medical interventions: Resolution of the Highest Specialized Court of Ukraine in Civil and Criminal Cases of December 21, 2016, in the case No. 645/323/15-ц[12], Resolution of the Supreme Court of March 14, 2018 in the case No. 537/4429/15-ц (*Highest Specialized Court of Ukraine*, judgment of 2016; *Supreme Court* (Ukraine), judgment of 2018)[13];
3) Informed consent in cases of vaccination of minors (infants and adolescents) without parental consent: Resolution of the Supreme Court of December 5, 2018 in the case No. 128/2994/15-ts[14]; Resolution of July 21, 2021 in the case No. 572/3616/19[15];
4) Violation of the confidentiality of medical information: Resolution of December 4, 2019 in the case No. 760/8719/17[16]; Resolution of November 11, 2020 in the case No. 442/4791/17[17]; Resolution of June 29, 2022 in the case No. 205/9115/19[18];
5) Patients' rights in the field of assisted reproductive technologies: Resolution of August 3, 2022 in the case No. 344/1962/19[19];
6) Criminal liability of medical professionals for actions that led to serious consequences for the patient's health (Part 1 and Part 2 of Article 140 of the Criminal Code): Resolution of

[5] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 27 lystopada 2019 roku u spravi № 661/2894/16-ts, provadzhennia № 61-18365sv18.

[6] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 04 lystopada 2020 roku u spravi № 686/6022/18, provadzhennia № 61-22818sv19.

[7] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 19 sichnia 2022 roku u spravi № 308/4164/15-ts, provadzhennia № 61-850sv21.

[8] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 09 liutoho 2022 roku u spravi № 161/7881/20, provadzhennia № 61-11435sv21.

[9] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 26 zhovtnia 2022 roku u spravi № 572/2718/19, provadzhennia № 61-10218sv21.

[10] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Tretoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 30 lystopada 2022 roku u spravi № 344/3764/21, provadzhennia № 61-2466sv22.

[11] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 23 hrudnia 2022 roku u spravi № 459/3913/21, provadzhennia № 61-10157sv22.

[12] Vyshchyi Spetsializovanyi Sud Ukrainy z rozghliadu Tsyvilnykh i Kryminalnykh Sprav, Ukhvala vid 21.12.2016, Sprava No. 645/323/15-ц

[13] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho tsyvilnoho sudu vid 14 bereznia 2018 roku u spravi № 537/4429/15-ц, provadzhennia № 61-4449sv18.

[14] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 05 hrudnia 2018 roku u spravi № 188/2994/15-ts, provadzhennia № 64-44011sv18.

[15] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 21 lypnia 2021 roku u spravi № 572/3616/19, provadzhennia № 61-13844sv20.

[16] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Tretoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 04 hrudnia 2019 roku u spravi № 760/8719/17, provadzhennia № 61-9359sv19.

[17] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 11 lystopada 2020 roku u spravi № 442/4791/17, provadzhennia № 61-37882sv18.

[18] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 29 chervnia 2022 roku u spravi № 205/9115/19, provadzhennia № 61-10283sv21.

[19] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 03 serpnia 2022 roku u spravi № 344/1962/19, provadzhennia № 61-3085sv22.

April 20, 2021 in the case No. 712/12532/14-к[20]; Resolution of June 21, 2022 in the case No. 744/315/16-к)[21]; Resolution of June 30, 2022 in the case No. 460/703/17[22];

7) The patient's right to receive medical and hygienic products: Resolution of February 10, 2021 in the case No. 235/6366/18[23].

Novelty of the study and research methods. Many studies on the topic of medical law are theoretical in nature and show the actual presence of certain rights in the patient, while focusing specifically on the description of rights, but not on their protection. Patient rights are often violated in certain healthcare institutions, and this is unlikely to surprise anyone in the modern world. However, it is more correct, in the author's opinion, to talk about the practical protection of patients' rights, in particular, judicial – when the injured party applies to the healthcare institution with a claim for compensation for damages. Of course, there are also extrajudicial ways to resolve such disputes, for example, by writing complaints to higher authorities, or attempts to resolve the dispute through mediation – but how effective are they? If, in the first case, the party that committed certain actions that led to damages (losses) can, as a rule, only bear disciplinary responsibility, then, in the second case, mediation is an exclusively voluntary way of resolving disputes, to which one of the parties to the process may not agree, or not fulfill the conditions that the parties to the dispute came to during its resolution through mediation, and not bear any responsibility for this – in this case, the injured party will already have to go to court to protect their rights. Then, in such a case, the fact becomes obvious that judicial protection in our reality is, undoubtedly, the most effective way of resolving disputes. In addition, all decisions of higher courts create a legal precedent in similar cases, and this rule now also works in the legal system of Ukraine. In particular, the practice of the Supreme Court in medical cases is quite extensive, and it includes more than a dozen cases of medical negligence and violations of patients' rights over the past five years, which indicates the significance of such cases in the domestic arena. Therefore, the author of the article chooses to carry it out in a rather innovative way – through the analysis of the relevant judicial practice, both modern and historical, which allows us to see how the protection of patients' rights was being carried out at different times. The author also believes that the judicial method of protecting patients' rights is not only the most effective of all existing ones, but that it also creates legal precedents that are necessary for study by both lawyers practicing and conducting research in the field of medical, civil law and public health, and medical professionals who also need to know their rights and obligations. It should be remembered that neither the legal nor the medical sphere of legal relations can exist separately from other legal relations that currently exist in society, and therefore the relevance of medical law to medical activity is too high to claim that it should not be taken into account. For example, in Canada, in the 1980s, sociological research was conducted among doctors on the topic of their knowledge of the court case *Reibl v. Hughes*[24], where the Supreme Court of Canada developed approaches to the concept of informed consent in Canadian law[25]. That is why the author of the article decides to conduct her research, largely basing the factual material on judicial

[20] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Pershoi sudovoi palaty Kasatsiinoho Kryminalnoho Sudu vid 21 kvitnya 2021 roku u spravi № 712/12532/14-k, provadzhennia № 51-6099km20.

[21] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv sudovoi palaty Kasatsiinoho Kryminalnoho Sudu vid 21 chervnia 2022 roku u spravi № 744/315/16-k, provadzhennia № 51-5915km21.

[22] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho Kryminalnoho Sudu vid 30 chervnia 2022 roku u spravi № 460/703/17, provadzhennia № 51-km22.

[23] Postanova Verkhovnoho Sudu (Ukraina) v skladi kolehii suddiv Druhoi sudovoi palaty Kasatsiinoho Tsyvilnoho Sudu vid 10 liutoho 2021 roku u spravi № 235/6366/18, provadzhennia № 61-13388sv19.

[24] *Reibl v. Hughes* (Supreme Court of Canada) [1980] 2 S.C.R. 880, 07.10.1980.

[25] ROBERTSON, G. B. (1984) Informed Consent in Canada: An Empirical Study, 22 Osgoode Hall L. J. 139.

practice and adhering to the approach that judicial protection of patients' rights is the most effective and efficient option in the modern world.

The **subject** of the research is the legal relations in the field of healthcare, or, more precisely, in the field of medical care. It is there that conflict-involving situations arise, which then turn into claims by patients against healthcare institutions due to the negligence of medical professionals or due to violations of other rights.

The **object** of the study is the protection of patients' rights in certain areas. The list of patients' rights is broad enough to cover it in its entirety – indeed, dissertations or even monographs are sometimes devoted to the protection of patients' rights only in certain areas. Accordingly, the object of the research is the legal institution of the patient's autonomy in its twofold nature – informed consent and informed refusal.

The **research methodology** includes the following methods:

1) *Comparative method*: based on the study of the protection of patient rights in different states of the world, as well as on the analysis of legislation and legal positions of courts in making decisions in various medical malpractice or healthcare-related cases;
2) *Method of analysis and synthesis*: the author conducts a systematic analysis of legal institutions, applicable norms of legislation and legal positions of courts, which is later systematized in approaches to the protection of patients' rights in one way or another in the countries of the world.
3) *Historical method*: the author pays significant attention to the formation of patients' rights from a historical point of view in different countries of the world, where legal precedents were created that reflected the position of the courts regarding the protection of a particular right of patients. In particular, the author proves the origin of the institution of informed consent from the French law, and also notes the peculiarity of the origin of the patient's right to protection of medical confidentiality in different countries of the world, including among relatively old cases. The author also uses many examples of the application of the institute of informed consent of the patient among historical judicial practice.
4) *Hermeneutic method*: the author uses this method, which consists in interpreting the norms of laws and court cases to a large extent in order to show the essence of the practical application of the norms of national legislation and international law, as well as to assess the legal position of courts that based their decisions on certain norms of law, court precedents, torts, etc., in order to provide a legal basis for protecting a particular right of the patient, especially under the conditions that the relevant legislation has not yet been adopted at the time of consideration of the case.

1. Informed Consent of the Patient

Informed consent of a patient is a documented and voluntarily signed document by the patient, certifying the consent to undergo medical treatment, surgical interventions, manipulations, sometimes diagnostic procedures and certain clinical medical trials, within the framework of one healthcare institution, or to conduct a single specific medical procedure or manipulation. The primary purpose of informed consent of a patient is to protect their right to autonomy. In essence, such consent confirms the patient's awareness and his/her voluntary consent to record this decision. For quite a long time, the legislation of Ukraine did not establish requirements for the registration and documentation of "*informed consent of the patient*", and there was also no unified approach to the methods of legally fixing informed consent. However, the

situation changed in February 2012, when the Ministry of Health of Ukraine issued Order No. 110, which approved the form of primary accounting documentation No. 003 and for conducting "*Informed voluntary consent of the patient to diagnosis, treatment and surgery and anesthesia*". In the direct wording of the Order of the Ministry of Health of Ukraine No. 2837 dated 09 December 2020, the prescription "…and for the presence or participation of participants in the educational process" was added to the name of the documentation form[26]. Indeed, the adoption of a standard written consent of the patient is an advantage, as it ensures proper recording of the fact of the medical procedure itself. It is also important that, in the event of a conflict situation, the 'consent' helps to clearly establish what information was provided to the patient, and what decision was made by him. However, the specified document also has shortcomings in the sense that not complete and detailed information about the disease, the examination and treatment plan, the nature, purpose and duration of the medical and diagnostic process is provided to the patient; nor is the patient fully informed about the possible adverse consequences of the medical intervention under consideration that are possible during its implementation. Therefore, there are contradictions between what was indicated by the patient in the informed consent they completed, that the patient received information about the features of diagnosis and treatment, and that the patient would not receive any instructions on such features. Therefore, such a document, in the form that it exists today, fails to protect not only patients, but also doctors, because in the event of a disputed legal relationship, the document is unable to ensure the properly established content and volume of information provided by the doctor. Obviously, this form of primary accounting documentation requires changes and additions, including information on the use of diagnostic and treatment methods, while taking into account the specifics of such methods of conducting medical and diagnostic procedures. Accordingly, the legal consolidation of informed consent requires further regulatory and legal improvement, while taking into account the specifics of medical intervention in the human body. It should also be noted that there are several types of informed consent for medical manipulations or interventions, and each of them is also consolidated by a distinct separate order of the Ministry of Health of Ukraine. Thus, there is informed consent for a pregnant woman to perform an operation for the artificial termination of an unwanted pregnancy (abortion). This form is approved by the Order of the Ministry of Health of Ukraine dated May 24, 2013, No. 423[27]. This consent includes a number of specific complications that may arise during the procedure and some other relevant information: the diagnosis and grounds for the operation or the procedure for artificial termination of unwanted pregnancy (abortion), the term of which is from 12 to 22 weeks. Another type of informed consent is the consent to participate in clinical trials of medicinal products, approved by the Order of the Ministry of Health of Ukraine dated 23 September 2009, No. 690[28]. The next step is to approve the form of informed consent at the official level of maintaining primary accounting documentation in healthcare institutions.

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[26] (1) Nakaz Ministerstva Okhorony Zdorovia Ukrainy vid 14 liutoho 2012 roku № 110 «Pro zatverdzhennia form pervynnoi oblikovoi dokumentatsii ta instruktsii shchodo yikh zapovnennia, shcho vykorystovuiutsia v zakladakh okhorony zdorovia nezalezhno vid formy vlasnosti i pidporiadkuvannia».

(2) Nakaz Ministerstva Okhorony Zdorovia Ukrainy vid 9 hrudnia 2020 roku № 2387 «Pro vnesennia zmin do formy pervynnoi oblikovoi dokumentatsii № 003-6/o ta Instruktsii shchodo yii zapovnennia».

[27] Instruktsiia shchodo zapovnennia formy pervynnoi oblikovoi dokumentatsii № 002-1/o «Napravlennia na hospitalizatsiiu vahitnoi zhinky dlia provedennia operatsii (protsedury) shtuchnoho pereryvannia nebazhanoi vahitnosti, strok yakoi stanovyt vid 12 do 22 tyzhniv». Zatverdzheno Nakazom Ministerstva okhorony zdorovia Ukrainy 24.05.2013 № 423.

[28] Nakaz Ministerstva Okhorony Zdorovia Ukrainy vid 23.09.2009 № 690 «Pro zatverdzhennia Poriadku provedennia klinichnykh vyprobuvan likarskykh zasobiv ta ekspertyzy materialiv klinichnykh vyprobuvan i Typovoho polozhennia pro komisii z pytan etyky».

Informed consent of the patient is the right of the patient not to be subjected to medical intervention without the consent given to them, most often in writing. Informed consent also applies to the conduct of tests, medical experiments and diagnostic procedures. In the modern European Union law, informed consent is provided for in Article 5 of the 1997 Oviedo Convention[29], as well as in numerous regulatory acts of a recommendatory nature. The legal essence of informed consent of the patient is relatively heterogeneous from the point of view of different legal systems; moreover, today, there is no unified theory in which state this concept arose due to a fairly significant number of judicial precedents, which number a hundred or more years. The authors T. Jurkeviča (Urkevich) and A. Lytvynenko note that the concept of informed patient consent marks a gradual departure from paternalistic medicine, which assumed that the doctor would, in practice, decide instead of the patient what treatment would be necessary, and what medical and diagnostic procedures, in this case, would be appropriate for it[30]. As a rule, the classification of the division into paternalistic and modern (Western) medicine is characteristic of Western countries; whereas, in the Far Eastern countries, such as Japan, until relatively recently, the healthcare system was characterized by highly traditional, paternalistic principles, which implied significant patient trust in the doctor, which often led to doctors hiding diagnoses (and often oncological ones) from patients, without being held responsible for this until recent decades, although, at the same time, in recent decades, the number of claims for negligence of medical professionals has increased many times, as evidenced by the studies of N. Higuchi[31], R. Leflar[32], and A. Lytvynenko[33]. Paternalism existing in the traditional Japanese medicine primarily played a psychological role, since, by not informing the patient of a certain diagnosis, the doctor did not wish the patient any *harm*, but rather worried about how negatively such a diagnosis could affect the patient's condition[34]. Nevertheless, the Supreme Court of Japan, in a 1995-dated judgment, where the relatives of a patient who died of cancer sued a doctor for failing to inform her of the true diagnosis, which led the patient to decide to discontinue treatment for a certain period of time (at which time, the cancer had progressed to a terminal stage), concluded that the responsibility of a medical professional should be assessed based on the available treatment methods and customs of medical ethics that were in effect at the time of the legal relationship (which, however, became controversial only later), and, in the 1980s, doctors often did not inform patients of their true diagnoses (especially those related to cancer), and decided that, in this case, the doctor would not be liable[35]. From the subsequent judicial practice of this state, a number of cases, recently described by A. Lytvynenko (2021), it may be firmly concluded that the paternalistic approach to informing patients subsequently alternated significantly towards a more modern one[36].

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[29] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, European Treaty Series – No. 164.

[30] URKEVICH, T. I. and LYTVYNENKO, A. A. (2022). The Doctrine of Patient's Informed Consent in the Legislation and Jurisprudence of Czech Republic, Austria and the Latvian Republic. *Medicne Pravo, 1*(29), 49–94, see pp. 54–58.

[31] HIGUCHI, N. (1992). The Patient's Right to Know of a Cancer Diagnosis: A Comparison of Japanese Paternalism and American Self-Determination, 31 Washburn L. J. 455, at pp. 465–467.

[32] LEFLAR, R. B. (1997). Informed Consent and Patient's Rights in Japan, 33. *Hous. L. Rev. 1*, p. 24.

[33] LYTVYNENKO, A. A. (2021). Protecting Patient's Rights in a Post-Traditional Legal System: Comparing Latvian and Japanese Medical Jurisprudence. *Medicne Pravo, 2*(28), 18–46, at pp. 24–25.

[34] HIGUCHI, N. (1992) The Patient's Right to Know of a Cancer Diagnosis: A Comparison of Japanese Paternalism and American Self-Determination, 31 Washburn L. J. 455, pp. 465–467.

[35] *Supreme Court of Japan*, Judgment of 25 April 1995, 1991 (O) 168, Minshu Vol. 49 (4), 1163, Section II-IV.

[36] LYTVYNENKO, A.A. (2021). Protecting Patient's Rights in a Post-Traditional Legal System: Comparing Latvian and Japanese Medical Jurisprudence. *Medicne Pravo, 2*(28), 18–46, see pp. 29–32.

It is quite difficult to determine in which country of the world the concept of informed consent of the patient originated. Although a number of authors are inclined to believe that the original title 'informed consent' comes from the United States common law (in particular, the most famous judicial precedents are: *Mohr v. Williams*[37], *Schloendorff v. Society of New York Hospital*[38], *Salgo v. Leland Stanford University Hospital*[39], *Canterbury v. Spence*[40], the authors Jurkeviča (Urkevich) and Lytvynenko believe that the French court practice on this issue occurred much earlier, in particular, the term '*consentement libre et éclaire*' began to be used in medical malpractice litigation two decades earlier[41] (since a 1933-dated case, adjudicated by the French Court of Cassation)[42], whereas the English term '*informed consent*' has been used in judicial practice since 1957, starting with the case of *Bolam v. Friern Hospital Management Committee*[43]. The author A. Lytvynenko, in his article on the "*Antiquaille Hospital Case*"[44], which took place in the 1850s and the judgment in the matter of which was made by the Lyon Criminal Court on December 15, 1859, describes a trial taking place in 1859, where the defendants were two doctors who conducted a medical experiment on the treatment of ringworm on a 10-year-old minor patient by performing a syphilitic inoculation. Based on the described trial, the court considered the actions of the doctors as a *medical experiment* with an exclusively scientific purpose, since the doctors published a scientific article about this case and the treatment method, and moreover, without concealing the fact that the experimental treatment method was applied *without* an urgent medical purpose, and, of course, was carried out without the consent of the parents of the minor patient; from the point of view of the legal qualification of the offense, the court noted that even a needle injection without the consent of the patient would be considered a violation of bodily integrity, and, in fact, would be causing bodily harm to the patient – both doctors were fined under Articles 311 and 319 of the Criminal Code of 1810[45]. Based on the facts of the "*Antiquaille Hospital Case*", a booklet about this case was compiled in 1860[46].

Unfortunately, until 2021, this notable case remained extremely little known, although the judgment in this case, as the author believes, actually laid the foundations of medical ethics in matters of the patient's informed consent, which later appeared in many court precedents and legislative acts, in particular, the laws of the EU states on patients' rights. Therefore, it can be stated that everything new is well-forgotten old. A similar position regarding the fact that an operation without the patient's consent is the cause of bodily harm was taken by the German Supreme Court (*Reichsgericht*) in a judgment of May 31, 1894, which still remains one of the key precedents on the topic of informed patient consent in German law. In this case, the doctor tried to save the foot of a young patient suffering from tuberculosis

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[37] *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (Minn. 1905), 23.06.1905, p. 12, etc.

[38] *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125 (N.Y. 1914); 105 N.E. 92, 14.04.1914, p. 125, etc.

[39] *Salgo v. Leland Stanford Etc. Bd. Trustees*, 317 P. 2d 170 (Cal. Ct. App. 1957), 154 Cal. App. 2d 560, Docket No. 17045, 22.10.1957, p. 170, etc.

[40] *Canterbury v. Spence*, 464 F. 2d 772 (D.C. Cir. 1972), No. 22099, 19.05.1972, p. 772, etc.

[41] URKEVICH, T. I. & LYTVYNENKO, A. A. (2022). The Doctrine of Patient's Informed Consent in the Legislation and Jurisprudence of Czech Republic, Austria and the Latvian Republic. *Medicne Pravo,1*(29), 49–94, p. 63.

[42] *Cour de Cassation* (France), 31 octobre 1933, Recueil Sirey, 1934 I., 11.

[43] *Bolam v. Friern Hospital Management Committee*, [1957] 1 W.L.R. 582 [1956 B. No. 507], 20.02, 21.02, 22.02, 25.02, 26.02.1957.

[44] LYTVYNENKO, A. A. (2021). The Rise of the French Doctrine of Informed Consent: Criminal Responsibility for an Unauthorised Medical Experiment – The Case of the Antiquaille Hospital and Subsequent Notable Judgments, *Athens Journal of Law 7*(4), 603–616.

[45] *Trib. correctionnel de Lyon* (1859). Dall. Per. 1859, III., p. 87–88.

[46] BOUCARD, C.-V. (1860). Inoculation d'accidents secondaires syphilitiques: [affaire de l'Hospice de l'Antiquaille]. Lyon.

of the tarsal bone. The operation, despite all his efforts, was unsuccessful. In addition, the girl's father was generally against the operation and preferred to take his daughter home, but when he informed the medical professionals of this decision, the doctor only replied that everything was ready for the operation and that it was too late to change anything in the treatment. The unsuccessful operation later led to the fact that the foot had to be amputated, which resulted in the opening of a private prosecution against the doctor. The Supreme Court, having assessed the circumstances of the case, recognized the need to obtain the patient's consent to medical intervention, explaining that in any other case, such medical intervention would be qualified as an offense under Art. 223 of the German Criminal Code of 1871 – causing bodily harm[47]. Many decades later, the German Federal Supreme Court, in a 1954 judgment that raised the issue of informed consent in the context of the doctor's obligation to inform the patient of the negative or dangerous consequences of a certain operation, stated that the scope of such an obligation is not defined, but it apparently depends on how dangerous the side effects of a certain medical intervention may be for the patient's health[48]. In the Netherlands, the doctrine of informed consent arose, as well as in many other countries around the world, from the case law of the mid-20th century: in a judgment of 2 March 1936, the High Council of the Netherlands (equivalent to the cassation court in the Dutch judicial system) explained that if a dentist performs an operation without the consent and proper expression of the patient's will, this should be regarded as an excess of the doctor's authority to perform a certain medical intervention, thus being punishable under Art. 254 of the Criminal Code[49] (*Hooge Raad (Nederlands)*, judgment of 1936, NJA 1936, 353). In England, the institution of informed consent arose relatively late, also, largely due to the lack of judicial precedent created in the system of higher courts of the United Kingdom, and a precise explanation of the legal nature of an operation without the consent of the patient can be found in the case of *Chatterton v. Gerson* of 1981, where the court, from the point of view of tort law, qualifies such actions as the commission of bodily harm by a doctor (the tort of 'battery' in English law), but does not classify them as negligence (in the sense of the tort 'negligence' in the common law system)[50]. For example, one of the cases related to the issue of informed consent, *Bolam v. Friern Hospital Management Committee* in 1957 concerned the failure of the physician to properly inform the plaintiff of the dangers of electroconvulsive therapy, as a result of which, he suffered several injuries and filed a lawsuit against the hospital, but the court decided that the possible negligence of the doctor (and, consequently, the hospital's liability) should be assessed from the point of view of the doctor's observance of adequate conditions of care for the patient, as well as on the basis of those standards of patient treatment that were in force at the time of the emergence of the disputed legal relationship[51].

From the point of view of modern medical law, this case is also relevant to informed consent, since it raised the issue of the doctor's obligation to inform the patient about the risks and dangers of certain medical interventions or diagnostic or therapeutic procedures, although the claim itself was considered by the court from the point of view of possible negligence in the doctor's actions. In Australia, the institution of informed consent was formed in the late 1980s – early 1990s, largely due to two

[47] *Reichsgericht* (*Deutschland*), III Strafsenat, Urteil vom 31.05.1894, Rep. 1406/94, ERG Strafsachen Bd. 25., Sache Nr. 127, S. 375–389.

[48] *Bundesgerichtshof* (Deutschland), Urteil vom 10.07.1954 – VI ZR 45/54.

[49] *Hooge Raad (Strafkamer)* (Nederlands), 2 Maart 1936, Weekblad van het Regt/Nederlandse Jurisprudentie 1936, Nr. 352, pp. 2–3.

[50] *Chatterton v. Gerson et al*., [1981] 1 Q.B. 432 [1976 C. No. 1138], 21.01, 22.01, 23.01, 24.01, 25.01, 31.01.1980, see pp. 432–445.

[51] *Bolam v. Friern Hospital Management Committee*, [1957] 1 W.L.R. 582 [1956 B. No. 507], 20.02, 21.02, 22.02, 25.02, 26.02.1957, see pp. 582–594.

precedents – *Ellis v. Wallsend District Hospital* (1989)[52], and *Rogers v. Whitaker*[53], the legal doctrine of which was built on the basis of the judicial practice of the states of the Anglo-American legal system – the USA, England, Scotland, Canada, Australia, and New Zealand. The Canadian jurisprudence on patient consent to medical intervention developed throughout the 20th century, and, by the 1970s, it had already developed the concept of 'informed consent', which is largely known from the cases of *Hopp v. Lepp*[54] and *Reibl v. Hughes*[55] (both adjudicated by the Supreme Court of Canada in 1980). It should be added that, due to the fact that a number of Canadian provinces use a civil code modeled after the French one, legal precedents have been formed both according to the Anglo-American legal system and according to the Continental (civil law) one. The former includes such cases as *Marshall v. Curry*[56], *Kenny v. Lockwood* (1931–1933)[57], *Parmley v. Parmley*[58], while the latter includes *Parnell v. Springle*[59], *Caron v. Gagnon*[60], and *Dufresne v. X.*[61]. There are undoubtedly different other judicial decisions to mention, some of which have been described in A. Lytvynenko's article on Canadian case law relating to informed consent in the 20th century[62]. From the perspective of the common law doctrine in the context of patient consent, the Canadian judgment of *Marshall v. Curry* is outstandingly significant: the dispute arose when a surgeon removed the plaintiff's testicle during an operation to remove an inguinal hernia: the plaintiff's health deteriorated, which, due to an accident with a fall in his youth while working as a sailor, already involved quite serious issues – the plaintiff suffered from the consequences of spinal injuries, his intestine was practically non-functional, and the plaintiff used a catheter for urination. During the hernia operation, the surgeon assessed the danger of the situation with the testicle, deciding to remove it without the plaintiff's consent, and, over time, the plaintiff's condition somewhat improved. Nevertheless, the plaintiff decided to sue the surgeon as he did not consent to the operation. The court, however, recognized that the surgeon acted in a situation that he justifiably considered sufficiently dangerous to the plaintiff's health for the doctor to make the decision to remove the testicle on his own. The court indicated that an operation without the patient's consent should be considered as causing bodily harm (assault), but there are situations where a doctor has the right to perform an operation without the patient's consent in cases of urgent necessity to save the patient's life and health[63].

It is quite difficult to assess how the doctrine of informed consent developed in Ukraine before 1991, given that, historically, a number of Ukrainian lands that are now part of Ukraine were part of other states in the previous centuries (Austrian/Austro-Hungarian Empire, Russian Empire, Second Rzeczpospolita, Romania). For example, the Criminal Code of 1852 of Habsburg Austria, which was in force in Galicia until the collapse of Austria-Hungary in 1918, and which was subsequently in force until 1929 during the Second Rzeczpospolita, contained a number of provisions regarding the criminal

[52] *Ellis v. Wallsend District Hospital* (1989) 17 N.S.W.L.R. 553, 31.05, 01.06, 19.10.1989.

[53] *Rogers v. Whitaker*, [1992] H.C.A. 58, 175 C.L.R. 479 (1992), 28.04, 19.11.1992.

[54] *Hopp v. Lepp* (Supreme Court of Canada), [1980] 2 S.C.R. 192, 20.05.1980.

[55] *Reibl v. Hughes* (Supreme Court of Canada), [1980] 2 S.C.R. 880, 07.10.1980.

[56] *Marshall v. Curry*, [1933] 3 D.L.R. 260, 15.05.1933.

[57] *Kenny v. Lockwood*, [1932] O.R. 141, [1932] 1 D.L.R. 507, 01.12.1931.

[58] *Parmley v. Parmley*, [1945] S.C.R. 635, 20.06.1945.

[59] *Parnell v. Springle*, 5 Rev. du Jur. 74 (1899), 20.01.1899.

[60] *Caron c. Gagnon*, Cour Supérieure du Québec, 68 S.C. 155, 1930 CarswellQue 184., 1930.

[61] *Dufresne c. X.*, Cour Supérieure du Québec, [1961] C.S. 119, 1960 CarswellQue 129, 1960.

[62] LYTVYNENKO, A. (2021) Unauthorized medical intervention and informed consent in the common law of Canada prior to the Supreme Court's decision of Reibl v. Hughes (1899–1980). *Chasopis Kijivskoho Universytetu Prava. 2020/4*, 260–282.

[63] *Marshall v. Curry*, [1933] 3 D.L.R. 260, 15.05.1933.

liability of medical professionals – notably, Articles 356, 357 and 358. In one case, a doctor convicted of negligence under Article 356 would have to pass a re-qualification exam in order to continue practicing medicine[64]. At the same time, the injured party could choose another way to protect his or her rights and file a civil claim under Articles 1299, 1300, 1315 of the Civil Code of Habsburg Austria. From the relatively few known precedents of the Supreme Court of Royal Austria (judgment of 4 January 1906 in the case No. 18553 ex 1905[65], judgment of 7 September 1915 in the case no. Rv I 448/15[66]), it appears that civil liability of a doctor for performing an operation without the patient's consent, or for failing to explain the essence of the operation (in particular, the case Rv I 448/15 is meant here) was interpreted by the courts as professional negligence of the doctor in the performance of his or her official duties. However, in the same case Rv I 448/15, the Supreme Court of the Royal Austria noted that the doctor is not under an obligation to inform the patient about all theoretically possible negative consequences of the operation, although, but in general, the obligation to inform concerning the most frequent ones on the part of the doctor still remained[67]. These judicial precedents could, hypothetically, be applied in West Ukrainian People's Republic, since the law of the times of Royal Austria continued to apply there, so the courts could well rely on the conclusions of the Supreme Court of the Royal Austria. The concept of patient consent to medical interventions existed in the Russian Empire, which, until 1917, included part of the lands of Central and Eastern Ukraine. This concept also emerged due to a legal precedent, namely the case of *Dr. Modlinskiy*, the judgment on which was made in cassation by the Governing Senate on December 19, 1902 (Criminal Cassation Department of the Governing Senate). In this case, Dr. P. Modlinskiy performed a laparotomy on a 17-year-old peasant girl, having felt a tumor in the patient's abdomen during a medical examination, when the girl and her family arrived at the doctor's private clinic in order to remove a minor neoplasm on her face. The operation was performed without the consent of the patient or her parents, and due to a high mortality rate of laparotomy at that time, the outcome of the operation was difficult to predict; shortly after its performance, the patient developed peritonitis, which caused her demise. According to the examination conducted by the lower courts, the cause of death was found to be the operation itself, although the outflow of fluid from the tumor into the patient's abdominal cavity was also questionable. The Senate noted that if a patient comes to a doctor, he or she does not come under the doctor's 'order', and this does not mean that the doctor can perform any medical intervention without the patient's consent, including one that could, in theory, lead to the loss of an organ or the functionality of an organ, or pose a significant risk to life. The very right to engage in medical activity does not give doctors such a right. It was established that Modlinskiy did not commit any *negligence* directly during the operation, but Modlinskiy's guilt was precisely that his performance of the operation without the consent of the patient or her parents led to her demise, even despite the obvious absence of malice or self-interest in his actions, and the doctor himself was sentenced to a week of arrest and spiritual repentance[68]. In theory, courts in the Ukrainian People's Republic, where laws and regulations adopted in the Russian Empire continued to apply

[64] *Strafgesetz* (Österreich), 01.09.1852, R.G.Bl. Nr. 117.

[65] *K.K. Oberster Gerichtshof*, Entsch. vom 4. Januara 1906, Ziffer 18553 ex 1905, Glaser/Unger (begründet), Pfaff, Schey & Krupský (fortgeseβt), Bd. 45, Nr. 4449, S. 820–822, Zentralblatt für juridische Praxis, Bd. 26, S. 816–817, Entsch. Nr. 276.

[66] *K.K. Oberster Gerichtshof*, Entsch. vom 7. September 1915, Rv I 448/15, Glaser/Unger (begründet), Schey/Štěpán (fortgeseβt). Bd. 52, Nr. 7557, S. 844–848.

[67] *Ibid*.

[68] *Pravitelstvuyuschij Senat* (Ugolovnyj Kassatsionnyj Departament) (Russian Empire), Po delu doktora meditsyny Petra Modlinskago, 19.12.1902, № 33. Reshenija Ugolovnago Kassatsionnago Departamenta Pravitelstvuyuschago Senata za 1902 g. S.-Peterburg: Senatskaja Tipografija, pp. 84–91.

(until they were replaced by newly-adopted domestic legislation)[69], could use the above-mentioned judgment as a precedent. Moreover, the legislation of the Ukrainian People's Republic (1917–1918, 1918–1920) and the Ukrainian State (1918) was active in the field of healthcare[70], and thus it is quite obvious that had the history of the Ukrainian People's Republic/Ukrainian State lasted longer, we could see a lot of judicial precedents in healthcare-related cases, in particular, adjudicated on basis of newly-adopted national regulations.

It should be noted that a number of interesting historical judicial precedents were formed precisely by courts located in the territories that are currently part of Ukraine. Such cases are quite unique artifacts, since the history of medical law in Ukraine until recent years was practically not reflected in the works of authors in the context of the existence of a certain practice of courts in Ukrainian lands of past centuries. In this context, we can note the work of A. Lytvynenko on the practice of courts in the town of Lviv during the Second Rzeczpospolita in 1919–1939 in cases relating to negligence of medical professionals[71]. A rather interesting precedent was created in courts in Western Ukraine at the beginning of the 20th century. Thus, in the courts of Chernivtsi (first instance: judgment of December 19, 1903, case no. Cg. I, 231/3) and Lviv (appellate instance: judgment of February 22, 1904, case no. Bc. III, 32/4), a civil case was heard, where a woman desired to perform hair removal by using X-rays after a doctor assured her that the procedure was safe, as a result of which, the patient suffered burns; the courts of first and second instance ruled in favor of the defendant. However, the Supreme Court of the Royal Austria (case No. 5721, judgment of April 20, 1904) decided that since such procedures had not yet become established medical practice, in such a case, the doctor had no right to provide a guarantee to the plaintiff that the procedure was safe, and overturned both judgments of the lower courts[72]. Another precedent regarding informed consent was created in Lviv in the early 1930s: a patient sued the health insurance company because of a cystoscopic examination without proper information and consent, which caused him to suffer from a number of serious kidney diseases. History has preserved the case numbers and dates of the court decisions: District Court of Lviv, February 1, 1933, case no. I Cg 566/30 and Court of Appeal of Lviv, June 16, 1933, case no. I.C.A. 336/33[73]. The case was considered in cassation proceedings in the Supreme Court of the Second Polish Republic (Warsaw), which decided to quash the decision and refer the case to the court of first instance (judgment of May 8, 1934 in case C II Rw. 3048/34)[74]. Regarding the patient's consent, the Supreme Court in Warsaw notes that the patient's consent to a medical examination is mandatory and provided for by law, namely in Article 21 of the Decree of the President of the Republic of Poland "*On the Practice of Medicine*" of September 25, 1932[75], and disagreed with the opinion of the lower courts regarding the non-obligatory

[69] Law of Ukrainian Tsentralna Rada "On exclusive right of the Tsentralna Rada to promulgate the legislative acts of the U.P.R." (Ukr.: «Zakon pro vyključne pravo Central'noji Rady vydavaty zakonodavči akty UNR»). *Ukrajins'ka Central'na Rada. Dokumenty i materialy. U dvoch tomach*. Tom I (4 bereznja – 9 hrudnja 1917 r.). Kyjiv: Naukova dumka, 1996, № 224, pp. 477–478.

[70] ZHVANKO, L. (2016). Hetmanat Pavla Skoropadskoho (kviten – hruden 1918 r.), osnovy derzhavnoi polityky u sferi okhorony zdorovia ta sotsialnoho zakhystu naselennia, Chastyna II (17.06.2016).

[71] LYTVYNENKO, A. A. (2022) Praktyka Okruzhnoho ta Apeliatsiinykh sudiv Lvova u spravakh shchodo nedbalosti medychnykh pratsivnykiv protiahom 1919-1939 rokiv. *Medicne pravo, 2*(30), 49–63.

[72] K.K. Oberster Gerichts- und Cassationshof, Entscheidung vom 20 April 1904, Nr. 5721, EOG Ziv. S. Bd. 41 (Neue Folge, Bd. 7), Nr. 2672, S. 250–251.

[73] Briefly reported in: *Glos Prawa*, Nr. 7-8, 06.1934, str. 518.

[74] Wyrok Sądu Najwyszsego (Izba Cywilna) (II Rzeczpospolita), 8 maja 1934 r., C II Rw. 3048/33, Orzecznictwo Sądów Polskich, T. 13, Poz. 316, str. 315–317.

[75] Rozporządzenie Prezydenta Rzeczypospolitej z dnia 25 września 1932 r. o wykonywaniu praktyki lekarskiej. Dz.U. 1932. Nr 81. Poz. 712. Dziennik Ustaw. Nr. 81 (1932). Poziom Nr. 712. S. 1517–1520.

nature of informing the patient about the risks of performing certain medical or diagnostic procedures (the courts came to this conclusion based on expert testimony)[76]. Thus, the Lviv courts established a significant precedent regarding the patient's informed consent in the early 1930s.

The institution of informed consent of the patient is also reflected in the practice of the ECHR through the prism of relatively recent cases. Thus, in the case of *Pretty v. United Kingdom* (2003), which, however, was not about informed consent, but rather about active euthanasia (which, however, the court did not consider legal, as did the courts in the United Kingdom, and which is still not considered legal, and the consideration of cases on the lawfulness of the termination of life-sustaining treatment, the court refers to the competence and discretion of the national courts, which follows from the case of *Lambert v. France*[77], it was stated that medical intervention without the patient's consent would constitute a very serious violation of his or her bodily integrity[78]. In the 2013-dated judgment of the European Court of Human Rights, *Csoma v. Romania*, the Court considered a dispute concerning the negligence of medical professionals, and noted that the signatory states to the European Convention on Human Rights must ensure that there is legislation that would adequately protect the rights of the patient in cases of negligence of medical professionals, including, and would enshrine the principle of informed consent to medical interventions[79]. One of the recent cases where the European Court of Human Rights expressed its opinion on aspects of the patient's consent to medical interventions is the case of *Reyes Jimenez v. Spain*, which raises the issue of the proper registration of the informed consent of the parents of a minor, and the actual legality of carrying out medical interventions on a minor without a properly registered (that is, in writing) informed consent for a surgical operation. The circumstances of this case were as follows. The applicant, who was a minor at the time of the medical intervention (and an adult at the time of the Court's judgment on the merits of the case), was taken to a hospital in Murcia at the age of six with a number of motor disorders, headaches and vomiting. During the examination of the minor patient, a tumor was discovered in the cerebellum, and the patient was soon admitted to the intensive care unit of the same hospital, where two operations were performed in January–February 2009, and the third was performed on the same day as the second. However, the patient's condition did not improve, and rather the opposite happened: later, the minor patient became completely immobilized due to complete paralysis, which also affected the inability to swallow, chew, talk and perform any motor activity. The parents of the minor patient saw medical negligence in such a difficult situation, filing an administrative complaint with the Department of Health and Social Policy of the city of Murcia, demanding compensation in the record amount of 2.35 million Euros. It should be added that while in the case of the first and third operations, the consent to its performance was signed by the parents of the minor patient, the second operation was performed only with their verbal consent (later, it was with the second operation that potential medical negligence was associated). The Department of Health and Social Policy of the city of Murcia initially did not respond to the complaint until the parents of the minor patient filed a lawsuit in court (after filing the lawsuit, the answer came – quite expectedly, a negative one). In their lawsuit, the parents of the minor patient stated that the sharp deterioration in their minor son's health occurred after the second operation, about the features and risks of which they were not provided hardly any information at all, and consent to its conduct was not issued in writing.

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[76] Wyrok Sądu Najwyszsego (Izba Cywilna) (II Rzeczpospolita), 8 maja 1934 r., C II Rw. 3048/33, Orzecznictwo Sądów Polskich, T. 13, Poz. 316, str. 315–317.

[77] *Lambert v France*, European Court of Human Rights, Judgment of 5 June 2015, App. No. 46043/14, [2015] ECHR 545.

[78] *Pretty v. United Kingdom*, European Court of Human Rights, Judgment of 29 April 2002, App. No. 2346/02, [2002] ECHR 427.

[79] *Csoma v. Romania*, European Court of Human Rights, Judgment of 15 January 2013, App. No. 8759/05.

In a judgment of 20 March 2015, the High Court of Murcia dismissed the claim of the parents of the minor patient, while relying largely on the response of the Department of Health and Social Policy of Murcia, as well as on the testimony of the doctor who actually performed the operation, who, in turn, claimed to have informed the parents of the minor patient of the features and risks of the second operation orally, while emphasizing that they were similar to the first operation (where the consent of the parents of the minor patient was concluded in writing). The court considered the conclusions of the medical inspection, which found no signs of negligence in the actions of the doctors, as well as the hospital documentation (maintained by the operating doctor), which indicated that this was a second operation ('re-operation'), and that the possible risks of the operation should be considered the same as those that existed during the first operation. Other medical reports heard in the case also gave a rather positive assessment of the doctors' performance. The court also found that there had been no delay in the diagnosis on the part of the doctors, and in the context of the lack of written consent for the second operation (for which, as previously noted, the written consent of the minor patient's parents had been obtained). The court therefore ruled that there had been no negligence on the part of the doctors, and therefore the claim of the minor patient's parents was dismissed. This judgment was appealed by the minor patient's parents to the Spanish Supreme Court, where the claimants argued that the law had been incorrectly applied in the context of the consent to medical intervention that had not been in writing, as required by Articles 8, 9(2) and 10(2) of the Law of Spain on Patients' Rights (No. 41/2002). The Supreme Court, in its judgment of May 9, 2017, rejected the plaintiffs' appeal, by reasoning that the first-instance court had already thoroughly investigated the circumstances of the case, having analyzed numerous pieces of evidence regarding the facts regarding the medical interventions and the second operation (the plaintiffs placed the main emphasis on it), the Supreme Court took into account the operating doctor's notes in the medical documentation, and the fact of constant communication between the parents of the minor patient and the operating doctor, and the court of first instance was given a proper assessment of the fact of obtaining consent (although this consent was not provided in writing). The Supreme Court also added that the second operation was a result of the first one, since the removal of neoplasms of this type (it was an astrocytoma) in most cases requires a second operation. Consequently, the plaintiffs filed an *amparo appeal* (petition for judicial protection) with the Spanish Constitutional Court, which, however, decided to reject it because, in the Court's opinion, the appeal did not raise issues of constitutional law. As a result, the plaintiffs filed an appeal with the European Court of Human Rights.

The position of the applicant (represented by the father) was largely the same as the position in the cassation appeal to the Supreme Court of Spain: in fact, it concerned the clinical episode – the second operation, and the consent of the minor patient's parents to the first operation, according to the plaintiff, did not mean that the minor patient's parents were aware of the second operation, and that it was right when the patients (in this context – their authorized/legal representatives, since the patient himself was a minor at the time of the medical intervention) received proper information not only about the specifics of the medical intervention, but also about its possible risks and consequences. Considering that, each time, the minor patient's health condition was different before each medical intervention, the risks before the second operation, according to the plaintiff, were greater (seemingly, than before the first operation – *the Author*). Then, in this case, the parents of the minor patient did not receive accurate information in writing and did not have a real opportunity to make a considered decision regarding the medical intervention. In particular, the applicant's father recalls that the medical record contained inscriptions "Pay attention!", which precisely indicated that the information of the parents of the minor patient by the operating doctor was actually insufficient. From the point of view of the representatives of the respondent state (Spain), since the claim was based not on Art. 6, but on Art. 8 of the European Convention on Human Rights, the

Court, accordingly, should not have verified the circumstances of the case established by the Spanish courts, and also based its position on the fact that the Spanish courts, when considering the case, established that the second operation was only a repeated operation, since the tumor was not completely removed during the first operation, and accordingly, the second operation contained the same risks and benefits as the first one. The dispute did not concern the validity of the informed consent of the minor patient's parents to the first operation, and the specifics of the second operation were explained orally to the minor patient's parents; the representatives of the respondent State (Spain) explained that the only alternative to this operation was the absence of treatment (it is not difficult to understand that the absence of the appropriate medical intervention could further worsen the applicant's health condition – *the Author*). As for the third operation performed on the minor patient, its necessity arose due to a number of postoperative complications, and the plaintiff's parents gave their consent to its performance – this clinical episode was also not contested by the plaintiff's representatives. Another argument of the representatives of the respondent State was that the *Oviedo Convention* did not contain a requirement for informed consent to be concluded in writing. The European Court of Human Rights noted that the main point of the claim was not that the representatives of the claimant accused the hospital of some negligence during the operation (instead, it was about the lack of adequate informed consent for the second operation, which also included, in the opinion of the applicant's parents, the lack of a proper explanation of the nature of the second operation and its possible risks), as is actually required by the provisions of the *Oviedo Convention*. Spanish national law, moreover, provided that in case the future medical intervention could pose certain risk to the patient's health, then informed consent must be concluded in writing. Correspondingly, according to the applicant's representatives, they were unable to assess all the risks and dangers of the upcoming medical intervention because they were not properly informed about the second operation that was to be performed on their son. According to the European Court, the Spanish courts relied in their decisions on the factual similarity of the first and second operations and did not provide an explanation of the motives of the judgment on the very issues on which the applicant's (plaintiff's in domestic courts) parents' position was based, including why, in fact, the consent to the second operation did not satisfy the requirements of Article 10(2) of the Law of Spain on Patients' Rights. The court assessed that, apparently, the purpose of the first and second operations was indeed the same – the removal of a tumor from the cerebellum, but the operations were performed at different times. From the point of view of the Spanish courts, verbal consent was sufficient in the case of the second operation, and these operations cannot be qualified as two different medical interventions, which, according to Spanish law, would require signing of an informed consent form. What is more, the inscription "Pay attention!" on the medical record indicated that it could barely be claimed that the applicant's parents were adequately informed about the second operation performed on their son and had consented to the operation in the manner required by the rules on obtaining informed consent. As regards the argument of the representatives of the respondent State (Spain) that the *Oviedo Convention* does not require the conclusion of informed consent in writing, the Court notes that although the Convention does not indeed require this, it is necessary to be guided by the rules established in national law – in fact, Spanish law has established such a rule. The Court notes that the judgments of the Spanish courts have not provided a distinct response of whether, in accordance with the law, the applicant's parents had indeed given informed consent in accordance with the applicable rules. In view of the afore-mentioned considerations, the European Court of Human Rights held that there had been a violation of Article 8 of the European Convention on Human Rights in the present case. Accordingly, the judgment was made in favor of the applicant[80].

[80] *Reyes Jimenez c. Espagne*, Cour Européenne des Droites de l'Homme, Troisième Section, 8 mars 2022, Requête nº 57020/18.

2. Informed Refusal

The patient's informed consent also has its downside, which is expressed in the patient's right to refuse medical interventions. This patient's right is enshrined in Part 3, Article 43 of the Law of Ukraine "*Fundamentals of the Legislation of Ukraine on Health Care*" (adopted after the restoration of Independence in 1992)[81]; however, at present time, a documented form certifying the patient's refusal of medical interventions has not been officially created (i.e., by an order of the Ministry/Minister of Health), and, in practice, it is written in an arbitrary form, which, of course, cannot but raise questions among lawyers and medical professionals regarding the legal significance and validity of such a document. By the way, historical case law shows that the concept of refusal of further treatment existed earlier: in the judgment of the District Court of Lviv of February 27, 1939 (case No. I.C.J. 1596/37), it is mentioned that the father of a minor plaintiff, believing that the fracture of the humerus, which occurred during his son's stay in the health care facility, occurred due to the fault of the medical professionals, wrote a refusal of his minor son's further stay in the hospital under his own responsibility, which was referred to as a 'reverse' in the court judgment[82]. Accordingly, it can now be stated that the precedential practice and hospital documentation of the 1930s knew such a kind of records. Nowadays, in modern Ukraine, the issue of refusal of medical interventions is also reflected in a judicial precedent – the judgment of the Lypovodolynsk District Court of Sumy Region dating back to 2018, in case No. 581/625/18. Let us discuss the circumstances of this case, the court's judgment and the court's reasoning. The plaintiff filed a lawsuit against the Lypovodolynsk Central District Hospital (the defendant), demanding to accept his refusal of any medical interventions, and claimed that a month before the lawsuit, in August 2018, the defendant refused his request. The plaintiff claimed that the defendant imposed his services on him, and also called himself a single person (that is, having no family), and therefore, in his opinion, the employees of the Central District Hospital could have performed certain medical interventions without his knowledge in the event of his loss of consciousness. It is also known that his request to the defendant was drawn up as a citizen's request. The defendant's representative in court denied the claim and explained the situation that arose in the dispute, by stating that the plaintiff in July 2018 applied to the hospital, claiming a complete refusal of any medical interventions, and that the procedure for refusing medical interventions was explained to him verbally (at the same time, no documents were issued to the plaintiff in writing, and this fact was not disputed), and also confirmed that the plaintiff was not provided with any medical assistance at that time, no medical documentation was kept regarding the plaintiff, and there was no connection between the central district hospital and the plaintiff, except for his receipt of medicines under state-funded programs. Having considered the circumstances of the case, the court established that the legislation does not contain a unified approach to the registration of the patient's refusal of medical interventions (nor was there any specific established form of medical documentation for this, either), and Art. 43 of the Fundamentals only indicated that the refusal of medical intervention should be formalized in one way or another. Taking into account the domestic legislation and international law, as well as the practice of the European Court of Human Rights, the court concluded that a person may refuse medical interventions with his/her informed consent in all cases, except for those cases when the failure to provide medical care would directly threaten the life and health of this person, and also when consent cannot be obtained for objective reasons. The court

[81] Zakon Ukrajiny vid 19 lystopada 1992 roku "Osnovy zakonodavstva Ukrajiny pro ochoronu zdorov'ja" (Vidomosti Verchovnoji Rady Ukrajiny (VVR), 1993, № 4, st. 19).

[82] Wyrok Sądu Okręgowego we Lwowie, Wydzial I Cywilny, 27. Lutego 1939 r., Sygn. akt. I.C.J.1596/37 (Tsentralnyi Derzhavnyi Istorychnyi Arkhiv Ukrainy, m. Lviv, F. 151, op. 4, spr. 405).

also adds that a person has the right to exercise the right to refuse medical interventions both in the current situation and in the future. Thus, the court ruled in favor of the plaintiff[83]. The form of refusal of medical interventions does not appear in the domestic medical documentation to this day. It remains to be hoped that such a form will be created sooner or later. It is quite apparent, that a medical professional cannot be held responsible for the consequences of a patient refusing treatment or medical interventions for some specific reasons (as is expressly stated in Part 4 of Article 34 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care"); however, the legal significance of a document regarding the refusal of medical intervention is the most important issue that will save medical professionals from trouble. Such documents exist in many countries of the world, and their regulatory content is quite heterogeneous due to differences in legislation and judicial practice in matters of admissibility of termination of life-sustaining treatment, which will inevitably lead to the demise of the patient – in a number of states of the world, such issues are resolved in court.

The author would like to outline an important concept of patient autonomy and refusal of medical treatment, expressed in a legal document, referred to as a 'patient's will', frequently named as a 'living will' in Western legal literature, being tentatively associated with a testament. In a recent work on the '*patient's will*' by A. Lytvynenko, the author cites the legal characteristics of this document, as well as the issues of its legal significance, and also the possibility of impugning the validity of the document in court, etc.[84]. The '*patient's will*' is, in fact, a legally significant document which establishes what medical assistance the patient would prefer to receive, and what he or she would not prefer in the event of complete incapacity (e.g., comatose state, lethargic sleep, vegetative coma, etc.). A. Lytvynenko's work mentions that the first '*patient's wills*' began to appear in the Netherlands and the USA in the 1970s, but they were not immediately reflected in the legislation, and the judicial practice of the Netherlands knew the mentioning of similar documents dating back to the early 1980s, although the legal significance of such documents was questionable[85]. In Ukraine, there is no analogue of a '*patient's will*', although situations where such a document may be useful do indeed exist in everyday life. Thus, the above-mentioned petition of the plaintiff from the case of the Lipovodolynsk District Court of Sumy Region of 2018 somewhat resembles a '*patient's will*', in particular, regarding the fact that the patient preferred not to be provided with any kind of medical assistance in cases where he is unconscious. However, the court clearly drew the line to which the patient's right to refuse medical interventions extends. In the event that a doctor does not provide a patient with medical assistance even under such a life position, he or she may thus fall under criminal liability under Art. 139 of the Criminal Code of Ukraine, and it is obvious that the court will not take the patient's previous wishes not to receive medical assistance into consideration (at least following the example of the plaintiff in the above-mentioned case – under any circumstances), unless the acting legislation is changed in this direction. Then the question is rather in the implementation of such a '*patient's will*' – even if such a '*patient's will*' is legalized according to the Western model, then, in this way, or a number of legislative acts on medical care issues will have to be amended, and, what is more, it cannot be excluded that the patient's right to terminate life-sustaining treatment with the appropriate permission of the court will have to be implemented – the fact is that '*patient's wills*' in a number of Western states (USA, Great Britain, Austria, Germany, Italy, etc.) were actually developed with the expectation that one day both

[83] *Rishennia Lypovodolynskoho raionnoho sudu Sumskoi oblasti* (Ukraine), 14.11.2018, № 77840579, sprava № 581/625/18.

[84] LYTVYNENKO, A. A. (2021). Pravova kharakterystyka «zapovitu patsiienta»: doktryna i sudova praktyka. *Medicne pravo*, 1(27), 52–68.

[85] *Rechtbank Rotterdam*, 01.12.1981, Nederlandse Jurisprudentie 1982, Nr. 63.

doctors and lawyers will encounter the position of a patient who would prefer not to continue living under certain circumstances. Nevertheless, significant difficulties in the implementation of a '*patient's will*' were shown in the case of the Supreme Court of Austria in 2012[86]. Indeed, what, in this case, should be the mechanism for implementing a '*patient's will*' if the patient, for example, refuses a blood transfusion or other procedures aimed at preserving his/her life? In this case, to adapt the mechanism of the '*patient's will*' in the legislation of Ukraine, it is necessary to decide whether such a document will have a sufficiently limited functionality – that is, it will not concern any issues of the termination of life, which would lead to criminal liability of doctors (in this case, it should be recognized that the '*patient's will*', which provides that the patient refuses medical interventions, the refusal of which would lead to death, is legally null and void), or to implement it in full, and, in this case, the changes will also affect Article 139 of the Criminal Code of Ukraine. By the way, history knows such cases. Thus, the Supreme Federal Court of Germany, in its judgment of July 3, 1984 in the case No. 3 StR 96/84, acquitted a doctor who decided not to save the life of an elderly woman who had attempted suicide by taking a significant dose of morphine and sleeping pills, although the doctor was physically able to provide her with medical assistance (and shortly before her demise, the patient sent the doctor a declaration that looked like a prototype of a '*patient's will*'), but he nevertheless decided to respect her 'expression of will', and the Court considered that, in the case at stake, the doctor's actions should be considered permissible[87]. Undoubtedly, such cases contain an extremely difficult legal dilemma, the solution of which lies in the adoption of the appropriate legislation. On the one hand, the patient's autonomy is a significant value, which belongs to the fundamental human rights, whereas, on the other hand, doctors should not suffer from the manifestations of the patient's autonomy.

Refusal of medical interventions may often have nothing to do with aspects of termination of life-sustaining treatment (in states where the legislation and/or judicial practice have granted this permission), but concern certain medical procedures. The most common, from the point of view of judicial practice of the states of the world, is the refusal of blood transfusion, which quite often occurs due to the religious beliefs of representatives of religious organizations (most often, religious sects), the adherents of which interpret the provisions of the Holy Scripture in such a way that adherents were inhibited to receive blood transfusions in any situations, even under the conditions of obvious danger to health, which could cause demise. It is highly noteworthy that, in fact, in the Bible, there is nothing, from which a ban on blood transfusions could be derived, and such a procedure simply did not exist at the time of writing the Holy Scripture, and therefore it is obvious that such interpretations are apparently only the vision of the representatives of religious sects. Nevertheless, they are also citizens who have constitutional rights, and the constitutions of the states of the world always recognize the right to freedom of religion, the right to health care, to bodily integrity, the right to private and family life, etc. Therefore, it is apparent that the representatives of religious sects cannot be discriminated against in any aspect of life due to their religious beliefs, and the rule of informed consent also applies to them, which is why it cannot be said that religious beliefs do not exert any influence on decision-making regarding medical interventions – as they definitely do. In 1967, the organization of Jehovah's Witnesses in the state of Washington, USA, instituted a class action on behalf of all adherents of this sect against the hospitals and government agencies operating in Washington D. C., demanding that, in the event of hospitalization of the adherents due to illness, injury or accident, blood transfusion procedures not be

[86] *Oberster Gerichtshof* (*Österreich*), 2012.08.10. 9 Ob 68 / 11g.
[87] *Bundesgerichtshof*, Urteil vom 3 Juli 1984 – 3 StR 96/84, BGHSt. 32, 267.

performed on adherents of this religious sect because of their religious beliefs[88]. They lost the lawsuit, but later lawsuits pursuing to ban blood transfusions for adherents of various religious sects became widespread, and, in some cases, the litigating adherents managed to win the cases. Moreover, it cannot be said that the adherents were completely ignorant to the fact that doctors who did not perform blood transfusions would be held liable – some of them signed petitions that would release the representatives of health care institutions from liability in the event of their demise[89]. We will cite several cases from different countries of the world so that the reader could have an idea of how such legal proceedings take place, what the positions of the parties are, etc.

1) *John Kennedy Memorial Hospital v. Heston* (1971), United States of America. The plaintiff in this case was the hospital, since, under the US law, if a patient does not consent to an emergency operation or procedure, the hospital can apply to the court by filing a petition for an order to perform it (quite often in court cases one can find such a reference as an '*emergency writ*', that is, '*immediate order*'). The defendant, being an adherent of the religious sect of Jehovah's Witnesses, was hospitalized after a car accident; due to a ruptured spleen, she needed an immediate operation, which necessarily included a blood transfusion, but she refused the procedure, and her mother signed a form releasing the hospital from liability. The hospital applied to the court with a petition for the appointment of a guardian who would consent to the blood transfusion (this is also a fairly typical legal construction in the event that the patient himself and/or his/her relatives also refuse medical intervention aimed at saving the patient's life and/or health). The court session was held at night, a guardian was appointed, who, accordingly, gave permission for this blood transfusion, and the defendant ultimately survived. Although the case was a '*moot case*', where the subject of the dispute was already exhausted, the court decided to consider the case and give a judgment, since the case raised a rather complex issue. The court emphasizes that the right to religion is not absolute, and there is no constitutional right that would provide that a certain person, based on his/her belief, no matter how bizarre it may be, can choose death. The state may limit a person's right to religion in a number of cases, which has been confirmed by the practice of a number of American courts, including the Supreme Court of the United States. While it would not be possible to say about any suicidal tendencies of the defendant – she did not intend to decease at all, but the teachings of the sect forbade her to agree to a blood transfusion; the court firmly concluded that the hospital operates to provide medical assistance to patients, and the essence of the work of any medical professional is to save the life and health of the patient. Given that all medical professionals act according to the standard of providing medical care, the answer to the question is that preserving human life is in the interest of the state. Accordingly, if a patient suddenly refuses medical procedures or medical interventions, as a result of which death may occur, then medical professionals must act in accordance with the standards of their profession, which, as is known, is to save the life and health of a patient. Therefore, the court found that the representatives of the plaintiff hospital were absolutely right in their actions[90].

2) *Malette v. Shulman*, Canada. In 1979, the plaintiff was involved in a traffic accident and suffered multiple injuries. After she was admitted to a hospital in Kirkland, Ontario, Canada, the doctor concluded that the patient required intravenous glucose with lactated Ringer's solution. However, due to the persistent bleeding, a decision was soon made to give her a blood transfusion. However, the nurses found a card in the plaintiff's personal belongings stating that she was an inherent Jehovah's Witness

[88] *Jehovah's Witnesses of the State of Washington D.C. v. King County Hospital et al.*,278 F. Supp. 488 (1967), Civ. No. 6595, 08.06.1967.

[89] *John F. Kennedy Memorial Hospital v. Heston*, 59 N.J. 576; 279 A.2d 670 (1971), 13.07.1971.

[90] *Ibid*.

and did not accept blood transfusions (although the plaintiff was not opposed to alternative methods of treatment). The plaintiff's family, along with the local church elder, arrived at the hospital shortly afterwards and expressed their displeasure at the defendant's intention to give her a blood transfusion, and the plaintiff's daughter signed a form releasing the hospital from liability. The dispute between the defendant doctor and the plaintiff's family left all parties to their own devices – neither the doctor was able to convince the believers, nor were they able to convince the doctor that blood transfusions should not be performed: the defendant proceeded from the position of medical necessity in performing blood transfusions, and also believed that such cards could have been signed by the plaintiff under pressure from the family (i.e., not expressing her true position). As a result, the defendant doctor decided to ignore this document (which, by the way, the court later recognized as legally significant), and, given the position of the surgeon, who also approved the blood transfusion, the procedure was performed, and the plaintiff survived, recovering quite quickly. Nevertheless, she decided to file a lawsuit against the hospital and its employees involved in her treatment and the blood transfusion procedure. The Ontario Court of Appeal ruled in favor of the plaintiff, although the court of first instance did not satisfy her claim. The doctor's liability, in the court's view, was that he had violated the plaintiff's right to bodily integrity, and that there was no question of any negligence on the part of the doctor; although the concept of informed consent in Canada was still in its final form, it did not include the concept of refusal of medical intervention at that time, although, in view of the patient's right to preserve his or her bodily integrity, it can be stated that it also existed, at least to some extent. The court points out that the plaintiff's card, which stated that she would not prefer to receive any blood transfusions, was a perfectly appropriate means of informing the doctors that this procedure would limit their choice of treatment. Any medical intervention without the patient's consent should be considered as causing bodily harm, falling under the common law tort of 'battery' (in particular, this was what the court had argued in the earlier case of *Marshall v. Curry* in 1933); the court also emphasized that the mere fact of the absence of negligence in the actions of a medical professional does not mean that a surgical operation performed without the patient's consent is lawful; patient self-determination encompasses, *inter alia*, the patient's right to refuse medical interventions, regardless of what the doctors may think of the patient's position. As for the plaintiff's card, the court noted that it was the only way for the doctors to be informed of the patient's position regarding her unwillingness to undergo a blood transfusion procedure in the event that she was unconscious. The content of the document (and the court considered the plaintiff's card to be legally significant) clearly indicated her understanding of the consequences of refusing this procedure, and there was nothing to indicate that the plaintiff would prefer to die or that the card was made under pressure from certain third parties. Therefore, the court considered that the card, which contained information about the unwillingness to undergo a blood transfusion, properly expressed the plaintiff's will. The court ruled in favor of the plaintiff[91].

3) Judgment of the Supreme Court of Japan of 2000. The patient, who was a relative of the plaintiffs, suffered from cancer (hepatic angioma) and, on the basis of religious beliefs (being an adherent of Jehovah's Witnesses since her youth), refused a blood transfusion while she was in the hospital. The patient was transferred to a hospital that often dealt with patients who could refuse certain medical procedures on the basis of religious beliefs (the events took place in 1992 – a date in Japanese judicial practice often has significant significance in medical cases, since the court assesses the case, including from the point of view of medical practice and the development of medical science at the time of the emergence of the disputed legal relationship). The patient's representative informed the doctor, who

[91] *Malette v. Shulman* (Ont. C.A.), 72 O.R. (2d) 417; [1990] O.J. No. 450, 30.03.1990.

was known to frequently work with members of this religious sect as patients, that the patient was suspected of having liver cancer and requested that blood transfusions not be administered during the operation, unless metastases were already present, to which the doctor agreed. The patient's family members also wrote letters to the hospital (it should be noted that, in Japan, letters written by relatives or patients themselves to health care institutions expressing their wishes are common practice, and these letters can be considered in court if necessary in the event of lawsuits), stating that the patient would not want a blood transfusion, and that they would not blame the hospital if the blood transfusion had any negative consequences. During the operation, the doctors concluded that the blood transfusion was necessary to save the patient's life, and she survived. The patient died 5 years after the operation, but no causal link between the performance of the operation and the patient's demise was established, and the patient's relatives did not actually allege this in their lawsuit against the hospital (instead, they sued for an unconsented blood transfusion procedure). The Supreme Court of Japan found that if, in the case of the patient, her will was clearly expressed, then, in such a case, the doctors had to respect it, and if, at a certain stage of treatment, the doctors considered a blood transfusion necessary, they had to leave it to the patient's choice. It was also found that, a month before the operation, the doctors had concluded that a blood transfusion would be absolutely necessary, but decided not to inform the patient about it. Thus, the Supreme Court came to an inference that the patient was thus deprived of a choice as to whether or not to agree to the operation, and ruled in favor of the plaintiffs[92].

Inferences

Summarizing the above, it can be concluded that:

1. Informed consent of the patient is a legal institution that protects both doctors and patients. On the one hand, it is the protection of a medical professional in terms of responsibility for carrying out medical or diagnostic procedures and operations without the patient's consent, on the other hand, it is a guarantee that the patient was properly informed about the features of the medical intervention and provided a properly executed consent to them.
2. Undoubtedly, the formalization of the informed consent process cannot include absolutely all cases and exceptional circumstances that may occur during the conduct of a particular medical intervention, therefore, lawsuits arise where, as it turns out, informed consent was obtained, but there were circumstances that allow us to say that this consent was given improperly, or did not involve the procedure that was performed, or during the medical intervention to which consent was given, manipulations were performed that were not provided for by this informed consent.
3. It follows that 'informed consent' is a concept that should be qualified in a narrow sense and cannot cover any default procedures; in other words, it would be wrong to assume that if a patient enters a hospital or a clinic, he or she automatically agrees to anything that the attending physician and other health professionals propose to him or her. Thus, the principle, which was laid down in the case of *Mohr v. Williams* in the United States as early as 1905[93], should be understood as meaning that informed consent applies only to those actions to which the patient specifically consents, and the only exception to this rule (neither historical nor modern case law has ever denied this) is urgent cases where the patient's consent cannot be obtained, or where the patient's life and health are at risk, and therefore the doctor may perform medical interventions to save the patient's life and health without his or her consent.

[92] *Supreme Court of Japan*, Judgment of 29 February 2000, 1998 (O) 1081, Minshu Vol. 49(2), 582.
[93] *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (Minn. 1905), 23.06.1905, p. 12-etc.

4. Historically, informed consent of the patient was formed as a protection of the patient's bodily integrity, and often in the very literal sense of the word. For example, the Supreme Court of Germany (*Reichsgericht*) in the year 1894 case indicated that an operation performed without the patient's consent should be considered a criminal offense under Art. 223 of the German Criminal Code of 1871, which punishes the commission of bodily harm (and technically, medical intervention, especially surgical, is deemed as such)[94], and, in England, in the year 1981 case *Chatterton v. Gerson*, it expressed a similar position, according to which, unauthorized medical intervention should be considered as the commission of bodily harm (in British tort law – '*battery*')[95]; a similar position was expressed by courts in Canada, in particular, in the 1933-dated case of *Marshall v. Curry*[96]. Thus, it can be stated that the institution of informed consent protects the patient's identity, as well as his/her bodily integrity from unauthorized medical interventions, the permission for which is given by the patient himself.
5. It should be noted that the patient's consent to medical intervention includes not only the patient's consent itself, but also the fact that the patient must provide it consciously – that is, with proper explanations from the doctor. The courts began to pay attention to this somewhat later than to the presence of consent as such. Thus, the concept of "*consentement libre et éclaire*" first appeared in the practice of the French Court of Cassation in a 1933-dated judgment; in Canada, the doctor's obligation to inform about the features of future medical and diagnostic procedures was discussed by the courts in the cases of *Kenny v. Lockwood*[97] and *Parmley v. Parmley*[98], although the concept itself crystallized only in the 1970s and early 1980s. In the notorious English case of *Bolam v. Friern Hospital Management Committee*, the issue was much more about explaining the patient the specifics of electroconvulsive therapy than about obtaining consent to it, which was not in question[99]; a similar case concerning the application of electroconvulsive therapy, both from the point of view of obtaining consent and from the point of view of the patient's safety, was considered by the Court of Appeal of Brussels in Belgium in 1962[100]. Health professionals should also remember that informed consent is only valid if it meets all the criteria set out in the law for it; the recent ECtHR's judgment in the case of *Reyes Gimenez v. Spain* highlights this perfectly: although the consent of the parents of a minor patient was given, it did not meet the standards of Spanish law for the conclusion of informed consent[101].
6. From the afore-given, we can conclude that informed consent must have a number of inherent features and characteristics in order to be legitimate, namely:
   – be provided for specific medical, diagnostic and treatment procedures;
   – be concluded in writing, since it is written consent that is a legally significant document, the validity of which will not require, in the event of a lawsuit, excessive efforts on the part of the medical professional to prove it;

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94 *Reichsgericht* (*Deutschland*), III Strafsenat, Urteil vom 31.05.1894, Rep. 1406/94, ERG Strafsachen Bd. 25., Sache Nr. 127, S. 375–389.

95 *Chatterton v. Gerson et al*., [1981] 1 Q.B. 432 [1976 C. No. 1138], 21.01, 22.01, 23.01, 24.01, 25.01, 31.01.1980, see pp. 432–445.

96 *Marshall v. Curry*, [1933] 3 D.L.R. 260, 15.05.1933.

97 *Kenny v. Lockwood*, [1932] O.R. 141, [1932] 1 D.L.R. 507, 01.12.1931.

98 *Parmley v. Parmley*, [1945] S.C.R. 635, 20.06.1945.

99 *Bolam v. Friern Hospital Management Committee*, [1957] 1 W.L.R. 582 [1956 B. No. 507], 20.02, 21.02, 22.02, 25.02, 26.02.1957.

100 *Cour d'Appel de Bruxelles* (Belge), 11 janvier 1962, *Pasicrisie* 1963 II, 23–25.

101 *Reyes Jimenez c. Espagne*, Cour Européenne des Droites de l'Homme, Troisième Section, 8 mars 2022, Requête nº 57020/18.

- must include informing the patient about all the features, risks and adverse effects of medical intervention;
- must be signed by the person without any pressure from medical professionals and other persons (for example, relatives);
- must be concluded in accordance with the norms of the law that determine the form, age from which a person signs informed consent independently, certification of the fact of civil capacity, etc.;
- if a person, for one reason or another, cannot provide an informed consent on their own, this must be done by an authorized representative of the person (mother, father – if the person is a minor or underage, guardian, custodian, including one of the parents, if the person's civil capacity is limited, or the person is incapacitated);

7. As for the limits of the patient's right to refuse medical intervention, this position strongly depends on the legislation and judicial practice of each state in the world where this legislation is in force, and where such cases are considered. Thus, such states as the USA, the UK, France, Germany, the Netherlands, Italy, Australia, Canada and a number of others allow that the termination of life-sustaining treatment, in particular, by the previously expressed will of the patient, is permissible and does not contradict the legislation and judicial practice.
8. A number of other states, for example, Poland, Ukraine, Romania, the Czech Republic, Türkiye and others, do not recognize this approach. Often, the impetus for solving this problem is important judicial precedents considered by higher courts, which, subsequently, either lead to changes in legislation or create a judicial precedent, the essence of which will later become a guiding principle for other courts when considering similar cases – it often happens that the legislation does not regulate the issue that will be considered by the court. A vivid example of this point is the *Englaro* case in Italy in 2007 and 2008, the judgment on which was rendered by the Court of Cassation of Italy – for the first time in this country, the court allowed the termination of life-support treatment for a person who had been in a permanent vegetative state for almost 15 years at the time of the 2008 decision of the Court of Cassation[102].

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