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Historical Foundations of an Informed Consent of a Patient and Contemporary Challenges in Practice

The idea of protecting the patient's informed consent is not an offspring of the modern era. It was known in the antique period, but it had a different meaning – the concept of informed consent was based on the patient's social status. The long-standing paternalistic attitude disregarded the patient's will and gave the doctor absolute freedom to decide on the issues related to medical intervention for the patient. This approach was based on the belief that the doctor knows what would be better for the patient.

At the beginning of the twentieth century, priority was given to the principle of patient's personal autonomy, which slowly deepened its roots in judicial practice. Modern reality pays attention to the patient's free will, thereby bringing to the forefront the idea of respect for human personal autonomy and dignity. For this purpose, the most important postulates of giving the patient's informed consent (voluntatiness, ability to understand, the patient's authority to make decisions, etc.) were formulated, which cumulatively require protection.

The issue of distribution of the burden of proof is noteworthy. Clinics must work hard to meet their burden of proof, as violations of informed consent are grounds for nonpecuniary damages. If it is accompanied by inhuman or degrading treatment, this is considered a qualifying factor in the European Court of Human Rights and increases the amount of compensation for non-pecuniary damage.

In the field of effective protection of rights, it is important to consider more the approaches of the European court practice of human rights. For this purpose, not only the formal aspect of informed consent should be in focus, but also the protection of its content.

Keywords: *personal autonomy of a patient, paternalism, historical excurse, modern approaches, court practice, burden of proof, compensation*

1. Introduction

When did the idea of a patient's informed consent emerge? What factors contributed to its emergence and how did its form vary in different eras? These are the key issues, which are primarily of interest in a historical context, for which the historical method must be applied. However, these

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issues are also important from a legal perspective, as with their help it can be determined in what form the informed consent originally existed – was it initially formed as a legal concept or later acquired a legal nature? How was informed consent protected in different times and what is the purpose and importance of researching this issue? The topic defines the origins of the idea of the patient's informed consent and will illustrate the features of its development, as well as provide an opportunity to understand the modern vision of it. This is important not only from a theoretical but also from a practical point of view as judicial practice should reflect modern trends and requirements as well.

At the same time, the issue is of interest to the field of medicine. The task is to determine what is the importance of the procedural and substantive parts of the patient's informed consent. While the patient's informed consent is studied by various fields of science, logically, this issue is mainly under the focus of law and medicine.

The abovementioned circumstances are a precondition for clarifying the modern understanding of the patient's informed consent. Accordingly, when the legal content of the informed consent and the mandatory components for granting it are determined, it will be possible to easily evaluate this or that case based on their characteristics. Here, it is interesting to see what approaches Georgia and the European Court of Human Rights have regarding the patient's informed consent. This needs to be studied in depth. This, on its part, is important for the complete and effective protection of the patient's interests.

Therefore, this paper is an attempt to study the historical, philosophical, medical and legal foundations of a patient's informed consent and to determine the relevant implications.

2. The Origins of the Paternalistic Approach

The classical documents in medical historyare the writings of Hippocrates (5th-4th centuries BC) and Thomas Percival's "Medical Ethics" (1803). However, the main concern of these works was to determine how to avoid disclosing information that could harm patients. The ethics of the doctor was also the ethics of non-disclosure of information, in which the right to the patient's consent was practically not considered.[1] In addition, issues of medical ethics and deontology are reflected in the ancient sources. Examples of this are the "Laws of Hammurabi" (ancient Babylonian laws, 18th century BC to BC), Hippocrates' "On Physicians", "Oath" and "Laws" (V-IV century BCE), the Indian "Book of Life" ("Ayurveda" – 5th-4th centuries BCE). The term "ethics" was first used by Aristotle (384-322 BCE).[2]

In ancient Greece, society consisted of free people and slaves. Thus, a doctor could have students from any group. However, after receiving education, they mastered the art of medicine in order to become "doctors". Plato considered masters true physicians, and referred to helpers/assistants

1 *Beauchamp T. L.*, Informed consent: Its History, Meaning and Present Challenges, Cambridge Quarterly of Healthcare Ethics, 20 (04), 515.

2 *Gabunia L., Khetsuriani Sh., Gamkrelidze N., Gumbaridze L., Varazi E.,* Medical Deontology and Prevention of Iatrogenic Diseases, Tbilisi State Medical University, Collection of Scientific Works, N53, 2019, 29 (In Georgian).

as "others". These doctors treated patients differently depending on their social status.[3] Doctors, who were slaves, treated slaves and never explained the details of the treatment to the patients. However, doctors who were free men treated free patients, explained to them the nature of the illness without revealing everything about the condition or its prognosis, and prescribed medication only after obtaining consent. A person trained in public relations or doctors trained in persuasion were sometimes called in to gain this consent. In his book The Statesman, Plato describes that if a doctor forces his patient to do right against accepted norms, it is not considered wrong. Even before Plato, Hippocrates pointed out that the patient must be informed so that he can cooperate with the doctor and give his consent.[4]

Hence, in ancient Greece, a patient's participation in the decisions on medical treatment was considered undesirable. It was generally recognised that a doctor's primary task was to instil the patient's confidence in treatment; Any disclosure of information about possible complications can negatively affect the patient's trust. Later, in the Middle Ages, medical letters encouraged doctors to apply the method of conversation as an opportunity to provide comfort and hope to the patients, thus emphasising that a doctor must have possessed the skills of manipulation and lying. It was widely believed that authority had to be combined with obedience for treatment to be effective. During the Age of Enlightenment, a new belief emerged that patients should be able to listen to the doctor, although deception was still considered necessary to facilitate patient care. In the 1800s, medical professionals were divided on whether to inform patients about unfavourable prognosis . However, most doctors at that time opposed informing them about their health condition.[5]

In fact, the aspects discussed above express the idea of paternalism. The etymology of paternalism is based on the Latin word pater ("father") and patriarchal cultures in which the father was considered the head of the family, an authority figure responsible for the welfare of family members and other subordinates. The term "paternalism" emerged at the end of the 19th century as part of a critique of the inherent value of personal freedom and autonomy. It was associated with excessive protection, which is usually a violation of personal freedom and human autonomy with the intention of creating good or protecting one's interests.[6] Therefore, the paternalistic model was directly related to the patriarchal culture. Its fundamental characteristic was the objectification of the patient. In this sense, the patient was considered an "adult child" who is not able to make a correct, independent and informed decision.[7]

Both paternalism and autonomy aim to benefit the patient, although paternalism is considered the opposite of autonomy. This approach is explained by the fact that the doctor always knows better

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3 *Dalla-Vorgia P., Lascaratos J., Skiadas P., Garanis-Papadatos T.*, Is consent in medicine a concept only of modern times? Journal of Medical Ethics, 2001, 27(1), 59, DOI:10.1136/jme.27.1.59.

4 *Kumar NK.,* Informed consent: Past and present. Perspectives in Clinical Research, 4(1), 2013 Jan, 21-22, DOI: 10.4103/2229-3485.106372.

5 *Murray P. M.*, The History of Informed Consent, The Iowa Orthopedic Journal, Vol. 10, 1990, 104.

6 *Rocio F.-B., Macarena S.-I., Ricardo O., Carmen H., Jose M. R. C., Alfonso C. J.,* Paternalism vs. Autonomy: Are They Alternative Types of Formal Care? Frontiers in psychology, Vol. 10, 2019, 1460-1461.

7 *Klimovich A. I.,* Evolution of doctor-patient communication models in modern medicine, Bulletin of Polotsk State University, Series E, Pedagogical Sciences, Philosophy, №15, 2019, 89. (in Russian).

than the patient what is good for the patient. It was this kind of representation between the patient and the doctor that led to great criticism.[8] It is this notion of the patient-doctor relationship that has drawn much criticism. In paternalism, a doctor makes decisions based on what they consider to be the best interests of the patient, even for patients who are capable of making their own decisions.[9] Under paternalism, the physician was obligated to act in the best medical interests of the patient, whereby the physician considered a "good patient" to be one who submissively accepted the passive role of the infant.[10]

They distinguish between strict and soft, wide and narrow, and active and passive paternalism. As per soft or weak paternalism, the doctor or the state helps the patient to make choices that the patient would have made if he had the willpower and the reason. Under soft paternalism, it is legitimate to interfere with the means agents choose to achieve their own ends if those means do not meet those ends. Strict paternalism prohibits some things and gives the decision-making mandate to others instead. In contrast, milder paternalism is aimed only at weakening the patient's decisions so as not to result in a particular violation of freedom of choice. According to strict paternalism, people can be mistaken or confused about their own goals, and it is legitimate to intervene to prevent uncertainty. This type of paternalism assumes that a person refuses to allow another person to make an autonomous decision when making a choice.[11]

In fact, **the word "paternalism" has acquired a purely negative connotation**, whereas previously it meant paternal care. Before, the patient appreciated this care; now they have decided to determine their own fate, to make free choices based on their own values and beliefs, regardless of the dominating doctor.[12] Therefore, Dworkin rightly remarked that paternalism is a gross interference with the freedom of human action, which is justified by doing good deeds and the interest of protecting the patient's welfare, happiness, needs, interests or values.[13]

From ancient times, the paternalistic attitude of doctors towards patients was replaced by the idea of informed consent from the beginning of the 20th century.[14] The matter is that in the 20th century, decision-making within the framework of the paternalistic "standard of care" framework gradually changed to a more patient-oriented concept: "A person is the master of their own body..." According to this idea, consent must be given voluntarily by an authorised person (the patient), who is well informed about the risks and alternatives to the treatment to be undertaken.[15]

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8 *Komrad M. S.*, A defense of medical paternalism: maximizing patients' autonomy, Journal of Medical Ethics, 9(1), 1983, 38-39.

9 *Sandman L., Munthe C.*, Shared Decision Making, Paternalism and Patient Choice, Health Care Analysis, 18(1), 2009, 61.

10 *Kaba R., Sooriakumaran P.*, The evolution of the doctor-patient relationship, International Journal of Surgery, №5, 2007, 59.

11 *Rodriguez-Osorio C. A.*, *Dominguez-Cherit G.*, Medical decision making: paternalism versus patient-centered (autonomous) care, Current opinion in critical care, Vol. 14, 2008, 709-710.

12 *Krechetova M. V.*, Informed consent for medical intervention, To help the practicing nurse, № 4 (88), 2021, 11. (in Russian).

13 *Dworkin G.*, Paternalism, in: Morality and the law (ed. *Wasserstrom R.*), Belmont California: Wadsworth, 1971, 107, 108; *Dworkin G.*, Paternalism, The monist, 56 (1), 1972, 65.

14 *Kumar NK.*, Informed consent: Past and present, Perspectives in Clinical Research, Vol. 4, Issue 1, 2013, 24.

15 *Murray P. M.*, The History of Informed Consent, The Iowa Orthopaedic Journal, Vol. 10, 1990, 109.

3. Emergence of Informed Consent and Judicial Precedents

Earlier philosophers spoke of "natural rights" that people are given from birth. In modern language, they are called "basic human rights". They are protected in democratic countries and enshrined in international agreements. Socrates, Plato and Aristotle recognised the purpose of ethics and analysed the normative-ethical ideals that influence human life. However, later, at the beginning of the 20th century, philosophers focused on linguistic details or the "logical analysis" of "moral semantics and other matters of metaethics." It has to be mentioned that when doctors, who were under the influence of the political ideology of the authorities, rejected the German government guidelines of 1931 on the modern requirement of informed consent and the independence of ethical expertise, the shoking experiments of the Nazis on humans shook the philosophers. This created the foundation for the widely recognized Nuremberg Code. The principle of informed consent was the most comprehensive among its 10 principles. The Declaration of Helsinki later addressed the importance of review by an ethics committee, which included an informed consent document.[16]

During the Third Reich, Nazi scientists in Germany conducted various and often fatal medical experiments on concentration camp inmates. These experiments were not carried out on voluntary basis. For the most parts, trials were conducted on Jews, Roma and Slavs. After the end of the war, the United States brought the question of the responsibility of twenty Nazi scientists to the International Military Tribunal in Nuremberg, Germany for war crimes and crimes against humanity. Eventually, seven Nazi scientists were sentenced to death, and eight – to various terms of imprisonment. As part of its final decision, the tribunal developed ten principles that later became known as the "Nuremberg Code". It contained the first international rules regarding the conduct of scientific research on humans. According to the code, obtaining voluntary consent from a person is considered an absolute necessity. This means that this person must be able to give consent (capacity); Consent must be freely given and the patient must have sufficient time to think, understand and make an informed decision.[17]

The current concept of informed medical consent differs from the Prussian Directive of 1900 and the Reich Government Directive of 1931. In the post-war regulations, some basic elements can be identified, along with other ethical issues regarding human experimentation. The 1947 Nuremberg Code was widely recognized as the first document on ethical regulations for conducting research on humans through informed consent.[18]

Several decisions on informed consent were made in In American law between 1905-1914.[19] At the beginning of the 20th century, the debate on the concept of informed consent began with four court decisions, which laid the foundation for the principle of patient autonomy. These decisions began in

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16 *Kumar NK.*, Informed consent: Past and present. Perspectives in Clinical Research, 4(1), 2013, 22, doi: 10.4103/2229-3485.106372.

17 *Schuman J.*, Beyond Nuremberg: A Critique of "Informed Consent" in third World Human Subject Research, Journal of Law and Health, Vol. 25, 2012, 124-125.

18 *Vollmann J., Winau, R.*, Informed consent in human experimentation before the Nuremberg code, British Medical Journal, Vol. 313, No. 7070, 1996, 1447.

19 *Dennis B. P.*, The origin and nature of informed consent: Experiences among vulnerable groups, Journal of Professional Nursing, 15(5), 1999, 281.

1905 with the cases of "Mohr v. Williams" and "Pratt v. Davis", then added the cases of "Rolater v. Strain" and "Schloendorff v. Society of New York Hospital." These decisions reinforced the principle of patient autonomy, which in medicine and science was finally established as the foundation for informed consent.[20]

"Mohr v. Williams" is the first major consent case. Mohr consented to surgery on the right ear to remove the diseased parts of the ear. He consented after consulting the family doctor, who was also present at the operation. However, after the anaesthetic was administered to the plaintiff, the surgeon discovered that the patient's right ear was not as diseased as they thought, but the left ear had serious problems. The surgeon thought that the patient should be operated on the left ear and not the right, so he performed the procedure on the left ear. Ms Mohr sued the surgeon after the operation caused further loss of hearing. He claimed that the operation was carried out without his consent, which is why this action was illegal.[21] The court ruled in her favour, emphasizing that consent was not implied, but related to a specific procedure.[22]

In the case of "Pratt v. Davis" in 1905, a court decision in Illinois was appealed by the plaintiff – Parmelia Davis. She sued the surgeon because a hysterectomy (removal of the uterus) wasperformed on the patient without her consent. The doctor had obtained consent for a previous operation however admitted that he had not gotten consent for the second procedure and had not disclosed to the patient that he intended to perform a hysterectomy to treat Mrs. Davis's epileptic seizures. The surgeon testified that he intentionally misled the plaintiff as to the purpose of the operation. He argued that since Ms. Davis was epileptic, she was unable to consent or reasonably assess her own condition. In this case, the court noted that the patient has the right to give consent, which prohibits a doctor or surgeon, no matter how experienced and eminent they may be, from violating the patient's bodily (physical) integrity without the patient's permission.[23]

In 1914, in the United States court practice, in the case of "Schloendorff v. Society of New York Hospital, the court explained that every adult of sound mind has the right to determine for himself what shall be done to their body; a surgeon who performs a operation without the patient's consent is considered an "aggressor", for whichthere are held therefore liable for the harm caused.[24] The term "informed consent" acquired legal force in this case when it was determined that Ms. Schlendorf had given informed consent only for a diagnostic study. The examination was performed under anaesthesia, but the patient was not aware of any tumour that the surgeon had excised without informing her of a possible adverse outcome, and therefore no consent was obtained from the patient.[25]

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20 *Bazzano L. A., Durant J., Brantley P. R.*, A Modern History of Informed Consent and the Role of Key Information, Ochsner Journal, Vol. 21, Number 1, Spring 2021, 81.

21 *Mohr v. Williams – 95 Minn. 261, 104 N.W. at 13, 1905.*

22 *Dennis B. P.*, The origin and nature of informed consent: Experiences among vulnerable groups, Journal of Professional Nursing, 15(5), 1999, 281.

23 *Pratt v Davis, 118 I ll App 161, 1905*; *Bazzano L. A., Durant J., Brantley P. R.*, A Modern History of Informed Consent and the Role of Key Information, Ochsner Journal, Vol. 21, Number 1, Spring 2021, 82.

24 *Schloendorff v*. *Society* of *New York Hospital*, *105* N.E. 92, *N.Y.* 1914.

25 *Kumar N. K.*, Informed consent: Past and present. Perspectives in Clinical Research, Vol. 4, Issue 1, 2013, 22, doi: 10.4103/2229-3485.106372.

Here, the importance of the patient's informed consent and the obligation to express their will was highlighted, which was the basis for the further development of the doctrine. [26]

These were landmark cases that set the legal precedent for protecting patient autonomy, with the plaintiffs being women at a time when women did not have the right to vote in the US, closely linking the right to patient autonomy to a woman's right to consent to medical procedures on her own body. Nevertheless, the principle of informed consent did not become legally mandatory until this term was first publicly reflected in court documents in the 1957 case of " Salgo v. Leland Stanford, Jr. University Board of Trustees."[27]

The point is that in the 1950s and 1960s, the duty to obtain consent in some areas of medicine, such as surgery, became a clear duty to disclose certain forms of information and obtain consent through the courts, both in practice and research. Such a development of events required a new term, and therefore the word "consent" was added before the term "informed" and finally became "informed consent". This term first appeared in the publicly known decision in the case of "Salgo v. Leland Stanford, Jr. University Board of Trustees" (1957). According to the factual circumstances, the plaintiff, Mr Martin Salgo, had aortic atherosclerosis and underwent a trans lumbar procedure to determine its extent. Aortic exploration involved anaesthesia and injection of a material into the aorta to localize the block; X-rays of his gastrointestinal tract were necessary. The doctor stated that his clinical findings were confirmed by further tests, which indicated that removing and replacing a segment of the aorta would help his condition. According to the doctor, such an operation would improve blood circulation in the legs and back, and prolong the patient's life. The doctor did not explain to the patient all the risks of the proposed procedure, however, noted that his circulatory condition was quite serious. The physician reported to the referring physician to perform an aortogram so that appropriate surgery could be performed. Also, it was necessary to examine the gastrointestinal tract. During this procedure, the patient was gived a a contrast agent injection the aorta to detect blockage, and the procedure resulted in permanent paralysis of his lower limbs.[28]

Eventually, Mr Salgo sued the university medical center and its chief surgeon because they had not disclosed the potential risk to him. According to the California Court of Appeals, each physician must have practical knowledge, and fully disclose to the patient the potential risks of the procedure, and the physician shall be held liable, should they not disclose the information that the patient needs for making an informed decision on the medical procedure.[29]

Providing information on the risks and alternatives of treatment is not a new obligation, but only a logical continuation of the already existing duty to inform about the nature and results of treatment. In essence, based on this case, not only new elements were introduced into the law, but also the history

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26 *Cruz P. De*, Comparative Healthcare Law, London, Sydney, 2001, 326.

27 *Bazzano L. A., Durant J., Brantley P. R.*, A Modern History of Informed Consent and the Role of Key Information, Ochsner Journal, Vol. 21, Number 1, Spring 2021, 82.

28 *Salgo v. Leland Stanford*, Jr. University Board of Trustees, District Court of Appeal, First District, October 22, 1957, No. 17045.

29 *Bazzano L. A.*, Durant J., Brantley P. R., A Modern History of Informed Consent and the Role of Key Information, Ochsner Journal, Vol. 21, Number 1, Spring 2021, 82.

of informed consent started. The court focused not only on whether informed consent had been given but also on whether the patient had been adequately informed about the consent.[30]

Later, international guidelines such as the World Medical Association's 1964 "Helsinki Declaration" provided further direction for medical researchers. Nevertheless, the Nuremberg Code remains the most authoritative legal and ethical document governing international research standards.[31]

In 1972, decisions were made in courts of three different US States that reinforced the idea of informed consent and brought to the forefront the importance of its moral requirements. These landmark cases are: Canterbury v. Spence[32], Cobbs v. Grant, and Wilkinson v. Vesey. The Canterbury case focused on the standard of disclosure of information to the patient. The court explained that the patient's right to independent choice determines the scope of the duty to disclose information. This right can be effectively exercised only when the patient has sufficient information to make an informed choice.[33]

These cases established the legal basis and principle of informed consent, as well as the duty of physicians to obtain informed consent for diagnostic and/or therapeutic medical procedures. The concept of informed consent for research on human subjects initially arose as a result of World War II crime investigations.[34]

After the World War II, specifically in 1947, the world adopted the Nuremberg Code, which defined as its first principle that voluntary consent from the patient is necessary to conduct a medical procedure. The purpose of this law was to prohibit experimentation on humans without free and informed consent. Since then, several international documents have reflected the right to give free and informed consent to medical and scientific research experiments. Of particular importance are the Universal Declaration of Bioethics and Human Rights, the 2005 UNESCO Declaration and the 1997 Oviedo Declaration, which intelligibly provide for the right to give informed consent to medical intervention.[35]

Since Beauchamp and Childress published Principles of Biomedical Ethics in 1977, autonomy has been widely recognized as one of the starting points of medical ethics, along with the principles of beneficence, avoidance of harm, and justice.[36] In the medical literature, authors use a "liberal

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30 *Beauchamp, T. L.*, Informed consent: Its History, Meaning and Present Challenges, Cambridge Quarterly of Healthcare Ethics, 20 (04), 516.

31 *Schuman J.*, Beyond Nuremberg: A Critique of "Informed Consent" in third World Human Subject Research, Journal of Law and Health, Vol. 25, 2012, 125.

32 *Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).*

33 *Beauchamp T. L.*, Informed consent: Its History, Meaning and Present Challenges, Cambridge Quarterly of Healthcare Ethics, 20 (04), 516.

34 *Bazzano L. A., Durant J., Brantley P. R.*, A Modern History of Informed Consent and the Role of Key Information, Ochsner Journal, Vol. 21, Number 1, Spring 2021, 82.

35 *Acosta Juana Vaccines I.*, Informed Consent, Effective Remedy and Integral Reparation: An International Human Rights Perspective, Universitas. Bogota (Colombia), No131: 19-64, julio-diciembre de 2015, 25-26.

36 *Murgic L., Hebert C. P., Sovic S., Pavlekovic G.*, Paternalism and autonomy: views of patients and providers in a transitional (post-communist) country, BMC Medical Ethics, 16:65, 2015, 1; *R. Gillon*, Medical ethics: Four principles plus attention to scope, Brit MedJ, Vol. 309, 1994, 184.

individualist concept of autonomy," whereby patients are decision-makers who act consciously, without external or internal controlling influences.[37]

4. Dignity of an Individual and Personal Autonomy of a Patient

Today, a new relationship has emerged between the doctor and the patient, which is based on cooperation. According to this approach, the doctor should understand the patient as unique.[38]

Informed consent is based on the principle of respect for personal autonomy and the idea that the directly authorised person has the right to control his medical care and participation in research. This principle rests on both ethical and legal basis. It is significant that the theory of informed consent was developed (originated) precisely from ethical teachings and was reflected in modern American law. Protecting the patient's interests in this type of decision-making process is clearly consistent with American society's principle of respect for the inviolability of an individual. However, this goal cannot be achieved only through legal initiatives. Moreover, they require a respectful dialogue with the patient about their condition and care, an empathetic treatment that supports the patient's medical decision-making.[39]

The principle of informed consent is based on the notions of liberal individualism expressed by Western philosophers of the eighteenth and nineteenth centuries. The requirement of informed consent is based primarily on the moral principle of personal autonomy.[40] Ideals of personal autonomy stipulate that a person's "personal self-governance" should be free from the control of others or interference from other parties. In this form, this principle is based on two fundamental ideas: **(a) everyone has an individual right to govern themselves and (b) everyone has the opportunity to freely choose their destiny. The requirement of informed consent** is also based on these two theoretical foundations.[41]

Personal autonomy of the patient is one of the leading concepts in bioethics, by which the patient directly has the right to decide independently whether to undergo an operation or not. The patient's personal autonomy is not limited to the recognition of autonomy; It includes more – respect for patient autonomy. According to Kant's deontological ethics, the principle of respect for autonomy arises from the idea that each person is an indisputable superior value, which is why they have the authority to decide their own destiny. If a person is a means of achieving one's own ends, disregarding the will of that person violates their autonomy,[42] human dignity, and ignores their personality.[43]

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37 *Murgic L., Hebert C. P., Sovic S., Pavlekovic G.*, Paternalism and autonomy: views of patients and providers in a transitional (post-communist) country, BMC Medical Ethics, 16:65, 2015, 1-2.

38 *Kaba R., Sooriakumaran P.*, The evolution of the doctor-patient relationship, International Journal of Surgery, №5, 2007, 64-65.

39 *Del Carmen M. G., Joffe S.*, Informed consent for Medical Treatment and Research: A Review, The oncologist, №10 (8), 2005, 640.

40 *Gordon E.*, Multiculturalism in medical decisionmaking: The notion of informed waiver, Fordham Urban Law Journal, Vol. 23, No 4, 1996, 1321, 1326-1327.

41 *Schuman J.*, Beyond Nuremberg: A Critique of "Informed Consent" in third World Human Subject Research, Journal of Law and Health, Vol. 25, 2012, 129-130.

42 See, *Chachibaia, T.,* Bioethical Aspects of Legal Norms of Medical Activity, Tbilisi, 2005, 47-48 (In Georgian).

Dignity implies a moral state on which autonomy is based. Man is granted autonomous rights because he has dignity.[44] Autonomy is considered to be the basis of personality and any common sense. [45] In order not to violate the right to self-determination of a person, it is necessary to considerthe will of a capable (competent) patient. Autonomy is one of the defining components of human honour and dignity. Oart of the broader concept of human dignity is integrated into the right to self-determination, which means recognizing an individual'sl freedom.[46]

Thus, respecting autonomy is a moral obligation to respect the autonomy of others.[47] The patient is an authorised person to determine what to do with their body and health. Medical manipulation without their consent violates the freedom of the patient. Therefore, if this operation is successfully carried out, in Germany, the illegitimacy of the doctor's action is considered to be a disregard of the patient's will, in which the general personal right is violated.[48] **For instance,** a patient was placed in a clinic and treated against their will. The court noted that non-substantial infringement of a person's physical inviolability should also be considered a violation of the right to protection of personal life where the action was taken against their will. In addition, the patient was forcibly administered the drug, which is also considered a violation of privacy.[49]

5. Rules for Issuing Informed Consent and Modern Judicial Practice

5.1. Rules for Issuing Informed Consent

Today, informed consent includes five components:

1. Voluntariness;
2. The ability to make decisions;
3. Disclosure of information about the patient's medical condition;
4. The ability to understand; and
5. Decision-making authority.[50]

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43 *Martini S.*, Die Formulierung der Menschenwürde bei Immanuel Kant in: Vortragsskript eines im WiSe 2005/06 gehaltenen Referats im Rahmen des rechtsphilosophischen Seminars "Die aktuelle Werte-Debatte" bei Prof. *Klaus Adomeit* (Freie Universität Berlin), 2005/06, 5-7.

44 *Schaber P.*, Menschenwürde und Selbstverfügung, Zurich, In: *Byrd Sharon B.; Hruschka J.; C. Joerden Jan*, Themenschwerpunkt: Recht und Ethik im Werk von Jean-Jacques Rousseau, Berlin, 2012, 319.

45 See *Pfordten Dietmar von der*, Zur Würde des Menschen bei Kant, In Fünf Untersuchungen "Menschenwürde, Recht und Staat bei Kant", 1. Auflage, Mentis, Paderborn, 2009, 19.

46 Decision N213-14 of March 12, 2018, of the Civil Cases Chamber of the Tbilisi City Court. *Bichia M.,* Features of Protecting the Patient's Personal Autonomy and of Giving Informed Consent (Georgian and European Approaches), "Law and World", 5(12), 2019, 52-53 (in Georgian).

47 *Gillon R.*, Medical ethics: Four principles plus attention to scope, Brit MedJ, Vol. 309, 1994, 185.

48 *Ehmann H.*, Der Begriff des Allgemeinen Persönlichkeitsrechts als Grundrecht und als absolute-subjektives Recht, in: Festschrift für Apostolos Georgiades, Athen; München, 2005, 128; *Ehman H.,* The Concept of General Right to Personality as a Fundamental Right and an Absolute Right, Georgian Translation, translated by *Bichia M.,* TSU "Journal of Law", N2, 2013, 239. (In Georgian).

49 *Storck v. Germany, 16 June 2005, no. 61603/00*.

50 *Del Carmen M. G.*, *Joffe S.*, Informed Consent for Medical Treatment and Research: A Review, The Oncologist, №10 (8), 2005, 637.

The patient may turn to relatives for advice, whose opinion may influence the patient's choice, however, where the patient perceives this advice as additional information for decision-making, **then their final decision is still considered autonomous**.[51] Hence, voluntariness requires that the patient is free from coercion and pressure in making the decision. Coercion refers to physically inappropriate pressure from individuals or institutions that limit the patient's choices. First, doctors must find out the patient's goals, then present them with appropriate treatment options designed with those goals in mind, and finally give advice.[52]

One of the components of informed consent is the ability to make decisions. This is the patient's ability to make decisions about their healthcare. Accordingly, there is a presumption that a person has the capacity to make a decision until evidence to the contrary is proven.[53] **When the patient cannot understand the nature of the medical intervention and its side effects, there is only one way for him to agree to the medical manipulation.**[54] This entails coercion and violates the principle of voluntary informed consent, which is not allowed.[55]

Also, informed consent includes **disclosure of information to the patient about the medical intervention to be performed and the medical condition**. In this case, the patient is provided with the necessary information to understand the essence of the medical procedure. The information provided relates to the treatment method and purpose, risks, potential benefits and possible alternatives. When disclosing information, simple language should be used, information should be given to the patient in simple language, through simple explanations.[56]

Moreover, **the informed consent document should not contain complex and specific medical terminology.** This is natural as the patient does not have special (medical) knowledge, and in the presence of specific terminology, an ordinary person cannot understand the provided information without further explanations.[57] This may involve the use of medical terminology. For example, the European Court of Human Rights found in one case that the patient did not understand the term "sterilization" which referred to informed consent. Therefore, it was emphasised that the **Latin terminology reflected in the patient's consent document should be understandable to the applicant**.[58] In addition, the patient should have time to understand the expected results, and risks and, having them in mind, decide whether to sign the consent form or not before the operation.[59]

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51 See, *Chachibaia, T.,* Bioethical Aspects of Legal Norms of Medical Activity, Tbilisi, 2005, 47-48 (In Georgian).

52 *Del Carmen M. G., Joffe S.*, *Informed consent for Medical Treatment and Research: A Review*, The Oncologist, №10 (8), 2005, 637.

53 *Ibid.*

54 *V.C. v. Slovakia*, no. 18968/07, November 8, 2011; Ruling N2b/2951-18 of February 28, 2019, of the Civil Cases Chamber of the Tbilisi Court of Appeals.

55 See *Bichia M.,* The Golden Rules of Giving Informed Consent According to the European Court of Human Rights Practice, in the collection of articles: "Protection of Human Rights: International and National Experience", ed. *Korkelia K.,* Tbilisi, 2022, 183-184 (in Georgian).

56 *Del Carmen M. G., Joffe S.,* Informed consent for Medical Treatment and Research: A Review, The Oncologist, 10 (8), 2005, 637.

57 Decision N213-14 of March 12, 2018, of the Civil Cases Chamber of the Tbilisi City Court (In Georgian).

58 *A.S. v. Hungary*, CEDAW/C/36/D/4/2004, August 29, 2006.

59 *E. Hyslop*, European Causation in Tort Law: a Comparative Study with emphasis on Medical Law in the United Kingdom, Germany and Frand and Luxembourg, A thesis submitted for a degree of PhD, Luxembourg, 2015, 169.

Hereby, **the aspect of decision-making by the patient regarding medical intervention should be considered**. Decision-making authority is no less important when giving informed consent. In this case, the most important thing is that it is the patient who has the authority to allow the doctor to carry out the proposed treatment.[60]

5.2. The Most Recent Judicial Practice in Informed Consent

In the law of medicine, the Convention "On Human Rights and Biomedicine" is critical and used in everyday medical practice. According to Article 5 of this Convention, any intervention in the field of health must be carried out after obtaining the voluntary and informed consent of the person. The patient has the right to receive appropriate information in advance about the purpose and nature of the intervention, consequences and risks, as well as, is to freely withdraw consent at any time.[61] According to Article 6 of the same convention, if a minor, as per the law, is incapable of giving consent, the intervention may be carried out with the permission of their representative or an authority or a person or an institution defined by law. When an adult is legally incapable of giving consent due to mental disorder, disease or other similar reason, intervention may be carried out with the permission of their representative or a statutory authority or a person or an institution.

In the practice of the European Court, Glass v. The United Kingdom[62] is noteworthy. Here it was confirmed that a seriously ill child underwent surgery to relieve upper airway obstruction. Post-operative complications (infections) made it necessary for him to be put on a breathing machine. In the first stage, the mother was involved in making treatment decisions. The doctors noted that, despite the best treatment, the patient would not survive, and the patient's family expressed their discontent. The patient's condition indeed improved and the patient was discharged, but a few days later he returned to the clinic with a respiratory tract infection. Considering the serious condition of the child's health, the doctors offered the mother to use diamorphine to alleviate the child's suffering, which the mother refused. The child's condition worsened to such an extent that he was considered to be in the terminal stage of the disease, requiring pain relief. Despite the family's opposition, the doctors and the clinic administration decided to give the patient diamorphine. In a few days, the patient's condition improved.

In the same case, **the medical staff had the burden of proof** that the use of diamorphine without informed consent was due to an emergency. The defendants failed to meet their burden of proof. There was resistance from the family both in the first and second stages of treatment. However, it was clear from the notes of one of the doctors that **the parent's objection could be overcome by applying to the court**. This rule was provided by the law in force in the respondent state. By ignoring these requirements, Article 8 of the European Convention was violated.[63]

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60 *Del Carmen M. G., Joffe S.*, Informed consent for Medical Treatment and Research: A Review, The Oncologist, 10 (8), 2005, 637.

61 *Dove E.S.*, The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era, in Journal of Law, Medicine & Ethics, 2018, 1021-1022.

62 *Glass v. The United Kingdom*, 9 March 2004, no. 61827/00.

63 *Glass v. The United Kingdom*, 9 March 2004, no. 61827/00.

G.M and Other v. The Republic of Moldova[64] is an interesting case. It concerned the termination of pregnancy and the implantation of contraceptives in the bodies of three women with mental disorders. The applicants were beneficiaries of a special medical institution for some time. The doctor of the same institution raped them and made them pregnant. The first applicant had an artificial termination of pregnancy at 17-18 weeks, and the second applicant at 6-7 weeks. Both applicants claimed that they had implanted contraceptives. As for the third complainant, according to her explanation, she became pregnant as a result of the rape, and after she protested, she was placed in another institution and forcibly terminated the pregnancy, and a contraceptive was inserted into her body. However, according to the current legislation of Moldova, forced termination of pregnancy (Art. 151), as well as termination of pregnancy at the 12th week (Art. 159), illegal sterilization by a doctor (Art. 160) is punishable. The applicants argued that the forced medical interventions without their consent were due only to their mental disorder and not for any other reason, such as a risk to the health of the child or the mother. Ultrasound studies presented by the first applicant in the case indicated the presence of a foreign body in the patient's cervical cavity as of April 2014. Thus, an **assumption** was made about the presence of a contraceptive device in the patient's body, however, no investigation was conducted to exclude or confirm this fact. Since an effective investigation was not conducted, in the case of the second and third complainants, **in the absence of prima facie evidence**, the respondent government was taked with rebuting the presumption that contraceptive measures were not used against the beneficiaries. The government could not rebut this presumption. Given these circumstances, the court found the violation of Article 3, instead of Article 8 of the European Convention, as it was established that abortions were performed without consent and the use of contraceptives on patients with mental disorders, who were raped by a doctor in the receiving institution of the same institution .[65]

CASE OF Y.P. v. RUSSIA is noteworthy as well. The patient complained that **the doctors of the maternity hospital sterilised her without her consent,** which was not necessary to save her life. Two years later, when the woman decided to have a child with her husband, she found out that she could get pregnant only through in vitro fertilisation. The national court found against the applicant that there was a medical reason – a ruptured uterus, due to which there was a risk of heavy bleeding. Doctors sterilised the fallopian tubes to prevent further pregnancy. However, the Strasbourg Court did not consider this intervention to be a necessary measure, as it did not serve to save the patient's life. Therefore, a violation of Article 8 of the European Convention was found.[66]

In other disputes, the Strasbourg Court found unauthorised sterilisation without unavoidable medical necessity to be a measure of interference with the patient's right that violated Article 3 of the Convention. This was due to the fact that the applicants belonged to a **vulnerable group** (Gypsies/Roma) and were in the early stages of reproductive life.[67]

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64 *G.M. and Others v. The REPUBLIC OF MOLDOVA*, no. 44394/15, 22/02/2023.

65 *G.M. and Others v. The Republic of Moldova*, no. 44394/15, 22/02/2023.

66 *Y.P. v. RUSSIA***,** no.43399/13, 20/12/2022, §.36

67 *V.C. v. Slovakia*, no. 18968/07, 8 November 2011, §§ 116-19; *N.B. v. Slovakia*, no. 29518/10, 12 June 2012, §§ 79 -80.

Thus, in these types of cases, the clinic bears the burden of proof that it fulfilled its duty to fully inform and explain the medical manipulation. The starting principle of this is that the medical institution providing the service has the authority to develop medical cards, and contracts, as well as a document about the patient's prior, clearly stated, informed consent.

In Georgian judicial practice, shall be noted case[68] where the contract concluded with the patient on the implantation of an artificial crystal provided **for non-surgical intervention, through a seamless laser operation with the insertion of an artificial crystal of the posterior cell.** In the course of the operation, it was found that the patient had a lump on the back capsule of the crystal, in the centre. It was necessary to remove it surgically and, instead of the artificial crystal of the posterior cell, an artificial crystal of the anterior cell was inserted. Two stitches were used on the cornea of the eye. Changes in the patient's eye were detected during the operation, which led to the implantation of an artificial lens not in the back, but in the front cell. The examination conducted on the case considered all actions of the surgeon to be justified.

In addition, the clinic presented the patient's informed consent document, which, in the clinic's opinion, comprehensively described the course of treatment and possible risks. According to the court, **this document did not regulate the disputed medical manipulation.** The court shared the patient's opinion that they signed the consent a few hours before the operation and were not given detailed information. The court considered that the patient signed the document with an unstable psycho-emotional background, that is when they were preparing for the operation and the situation did not correspond to the standard of reasonable judgment of a person in a normal non-stressful state (a medical assistance agreement was concluded, the patient signed the consent and the surgical operation was performed on the same day). In this case, the patient failed to meet the burden of proof in the medical malpractice section. Therefore, the claim for compensation for material damages was unsuccessful, based on Articles 992 and 1007 of the Civil Code of Georgia (hereinafter – CCG), although the **claim for moral damages** was satisfied within the framework of Article 413 of the CCG **due to the violation of the standard of patient awareness**.[69]

It should be remarked here that the illegal placement of a person in a hospital is also a restriction of a person's privacy and freedom as it is **presumed that the patients experience severe spiritual pain and psychological and emotional stress.** For the purpose of involuntary psychiatric assistance, the forced placement of a patient in a psychiatric facility, when there was no medical evidence for this, was assessed by the Court as a violation of Article 5, Paragraph 1, Subsection "e" of the European Convention (Restriction of Immunity and Freedom).[70]

Also, it is evident in Georgian judicial practice that simply the existence of an informed consent document is not satisfactory, it is essential for it to have a sufficiently specific form, which prevents disputes related to the violation of the patient's right to proper information. In one case, it was determined that a patient underwent surgery on the same day he signed a consent form for surgical

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68 Ruling of the Civil Cases Chamber of the Supreme Court of Georgia (Hereinafter – SCGR), July 26, 2019, №ას-645-2019 (in Georgian).

69 SCGR, July 26, 2019, №ას-645-2019 (in Georgian).

70 SCGR, December 22, 2023, №ას-1444-2022 and March 16, 2021, №ას-1129-2020 (In Georgian).

services. After the operation, the patient lost the sensitivity of the lower limbs, and in order to evacuate the bruises, it was necessary to perform another surgery. The patient signed a consent form for reoperation, however, **it did not state that the operation could cause paraplegia of the lower limbs,** which they experienced after the operation. The clinic could not confirm the circumstance **included in the subject of their proof** that the patient was informed about the possible post-operation complications.[71]

As for compensation for moral damages, it is impossible to determine the price of each person's health or life. Hence, the purpose of compensating moral damages is, to some extent, to alleviate the pain and discomfort experienced.[72] In Georgian judicial practice, when determining the amount of non-pecuniary damages, they are guided by the criteria of **reasonableness and fairness**, and also take into account the mental or physical suffering experienced by the victim and the guilt of the person causing the damage, when compensation for damage depends on the culpable action.[73] **The moral damage caused by violation of the body and/or health may not be derived directly from the violation of the law**, but may be a **consequence of it**, such as unsuccessful treatment, long-term helpless condition, the impossibility of active life, change of the rhythm of life and lifestyle, decrease in the joy of life due to the ineffectiveness of treatment, nervous tension that makes a person have an inferiority complex or other negative feelings. However, in this case, it must be proven that the victim's moral **feelings and spiritual suffering are the result of the violation of the body or health.**[74]

In the Strasbourg Court practice, the amount of compensation depends on the degree of violation, for example, in case of violation of Article 3 of the European Convention, the amount of moral damages is higher than in case of violation of Article 8 of the same Convention.

6. Final Provisions

As the research shows, the concept of informed consent has existed even in ancient times, although it differed from its modern understanding. Namely, the essence of informed consent in antiquity was determined by the social status of the patient.

In the beginning, there was clearly established paternalistic approach, which viewed the patient as a passive infant and giving the doctor full authority to decide on the issues of medical intervention on behalf of the patient. This was dictated by the idea that the doctor knew best what would be best for his patient. A paternalistic approach in the field of medical law was in effect for a long time. However, at the beginning of the 20th century, the paternalistic approach was replaced by the principle of

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71 SCGR, June 11, 2021 №ას-253-2021 (in Georgian).

72 See *Gagua, I.,* Burden of Proof in Non-pecuniary Damages, Journal "Justice and Law", N4 (72), 2021, 74 (in Georgian).

73 In case of medical manipulation during the planned operation without informed consent of the patient, 5000 GEL was charged to the clinic in favour of the patient. See SCG, July 26, 2019, №ას-645-2019 (in Georgian).

74 SCGR, September 10, 2015, №ას-979-940-2014; *Bichia, M.,* Some Aspects on Compensating for Non-property Damages, Journal "Justice and Law", No. 3 (51), 2016, 107 (in Georgian).

protecting the patient's personal autonomy. Records of the protection of patient informed consent have emerged in American court decisions, which have become a prerequisite for greater attention to patient personal autonomy.

The personal autonomy of the patient was strengthened in the field of deontology and thus the respect for patient autonomywas emphasised. Soon, its close connection **with the protection of human dignity, on which autonomy is based, became apparent,** and autonomous rights are granted to humans because they have dignity, was soon revealed.[75] **Respect for autonomy in reality implies a moral duty to respect the autonomy of others.**[76] The patient is considered an authorized person to freely determine the fate of their body or health. At this time, the patient's will to medical intervention should be taken into account, otherwise their personal autonomy will be violated.

With the Association Agreement with the European Union, Georgia undertook to develop legal cooperation based on human rights and basic freedoms. From the perspective of approximation with EU Acquis, it is noteworthy **to pay close attention to the relevant decisions of the European Court of Human Rights** (paragraph 2). The decisions of the European Court of Human Rights and the national courts of Georgia confirmed that **the manner and content of the patient informed consent should not only have a formal meaning,** but such consent should be unambiguous, sufficiently specific, well thought out and granted in advance.

The issue is also significant in terms of the distribution of the burden of proof, because in cases of urgent necessity, when obtaining informed consent before medical intervention is excluded, **the clinic bears the burden of proving both the urgency of the medical intervention and reasonableness and foreseeability of consecutive actions.** Upon confirmation of a breach of duty by the medical institution, the patient gains the right to claim compensation for non-propety damage. The European Court of Human Rights uses Articles 8 and/or 3 for non-pecuniary damage compensation. The case provided under Article 3 is considered a serious violation, which increases the amount of compensation for non-property damage. In fact, in the case of violation of informed consent, "**inhuman or degrading treatment" established by Article 3 is considered a qualifying circumstance, due to which the amount of compensation for moral damages** increases.

The national courts of Georgia use Articles 18 and 413 of the Civil Code as the grounds for compensation for moral damages. The judicial practice of Georgia emphasizes that the amount of moral damage must be determined in each specific case, taking into account the individual features of the case itself.

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