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INFORMED CONSENT IN MEDICAL LAW IN THE ROMANIAN LEGAL SYSTEM. A COMPARATIVE LAW PERSPECTIVE

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Abstract

This paper aims to analyse the principle of consent in the medical act from a comparative law perspective. While the introduction gives a brief presentation of the definition of consent from the perspective of legal doctrine, the content of the paper analyses some legislative landmarks in the Romanian legal system, as well as in the French and Spanish legal systems. Consent is one of the basic principles of modern medical bioethics and an essential element of the validity of the medical contract, ensuring respect for human dignity and protection of the patient's bodily integrity. While Romanian law is based more on the idea of information, Spanish law analyses consent from the point of view of a personalist right, including it in the short list of personal rights enshrined in Law 1/1982 on the protection of honour, image and privacy. French law, on the other hand, has a long history of case law regulating consent in medical acts, with the Teysier and Mercier cases being worth mentioning.

Keywords: consent, medical contract, informed, human dignity.

1. Introduction

Since the Nuremberg Code, informed consent has been one of the pillars of contemporary medical ethics. Indeed, following the trials of the Nazi doctors condemned for having carried out atrocious medical experiments in the concentration camps during the Second World War, the international community established various norms, most of which are still in force today, allowing medical research to be supervised with integrity, starting with the free and informed consent of each patient. Participants in medical research must now have given their consent without any constraints and with full knowledge of the facts, thanks to an appropriate explanation.

As a general definition, consent is one of the essential conditions that must be met at the conclusion of any civil legal act, together with capacity, object and cause, the legislator establishing a series of conditions that must be met for it to be valid, conditions that may vary in civil and medical law.

According to the LaRousse dictionary, consent is: "action of agreeing to an action, to a project; acquiescence, approval, assent: He acted with my consent.". The definition of consent provided by the LaRousse dictionary is also associated with the definitions of informed, express and tacit consent:

- "*Informed consent* is the agreement of a patient, of legal age and fully lucid, to receive medical or surgical treatment after having been clearly informed by a physician of the risks involved and the possible consequences. (Information prior to informed consent is now a legal requirement).
- *Express consent*, that which is written or expressed verbally.
- *Tacit consent*, that which is assumed by the law in the case where the contrary will is not expressed."

The Civil Law Dictionary defines it as "the essential component of the legal will which gives expression to the subject's decision to conclude a legal act and thus to be legally bound".

Moreover, the doctrine defines consent as "the agreement of two or more persons on one and the same point (...) the result of two or more wills coming together" or "the decision to conclude a civil legal act, manifested externally" (Matefi, 2018).

Also, when analyzing the concept of consent in general and its validity, we should take into consideration the legal regulations imposed by the GDPR (General Data Protection Regulation) which requires consent to be freely given, to be specific, informed and unambiguous, but also the right of a data subject to withdraw consent at any time.[i]

2. Consent to the medical act in the Romanian legal system

The right to physical and mental integrity is a fundamental right of the person, intimately linked to the right to life in that the right to life also includes the right to physical integrity of the person, and any injury to the physical integrity of a person implicitly affects the right to life of that person. In Romanian law, the guarantee of the right to integrity proclaimed by the Constitution and the Civil Code (Articles 61(2), 62, 63(1) and (2)) is also made effective by the criminalisation in the Criminal Code of acts against physical and mental integrity or health (Fărcaș & Fărcaș, 2012).

Seen from the perspective of a right of personality, the right to physical integrity is recognised and protected by both civil and criminal law instruments. From a civil law point of view, the issue of physical integrity arises in the context of the possibility of disposing of one's own body - the right to dispose of oneself - which we find today regulated in Article 60 of the new Civil Code, which states that "a natural person has the right to dispose of himself, provided that he or she does not violate the rights and freedoms of others, public order or good morals", as well as in article 26 paragraph 2 of the Romanian Constitution. The right to self-determination is in permanent correlation with medical law, i.e. any medical intervention on the human body which necessarily requires the patient's consent.

The right to health protection is guaranteed by Article 34 (1) and (2) of the Romanian Constitution, ensuring the citizen's health through the preservation and development of his physical and mental qualities, which are provided through health care and the health insurance system, regulated by special laws.

Patient consent is also governed by the legal provisions laid down in Law 95/2006 on healthcare reform published in the Official Gazette no.652 of 28 august 2015 and Law 46/2003 on patients' rights published in the Official Gazette no.51 of 29 january 2003. The special legislation regulating the concept of consent in the medical field appears as a transposition of the concept from common law to an environment where this concept meets fundamental human rights, but especially human dignity and privacy protected by medical ethics (Fărcaș & Fărcaș, 2012).[ii]

For the informed consent of the patient to undergo a medical act to be considered valid, it must be given in writing. The mandatory written form of informed consent is a *sine qua non* without which the medical act cannot be carried out.

In the process of obtaining the patient's written consent, the doctor has a duty to provide the patient with the essential information about the medical act for which consent is sought in a way that is reasonable to the patient's capacity to understand, so that the patient can receive all the information about the benefits and risks of the medical act.

In order to give informed consent, the patient must be fully competent, that is, 18 years of age or older. Minor patients need parental consent, but the law provides for two exceptions, as provided for in rhe article 661 of Law 95/2006:

"*a) emergency situations, when the parents or legal representative cannot be contacted and the minor has the necessary discernment to understand the medical situation in which he/she finds him/herself;*

b) medical situations related to the diagnosis and/or treatment of sexual and reproductive problems, at the express request of the minor over 16 years of age."

However, there are also situations where consent cannot be obtained, for various reasons. The main point to remember on this issue is that the doctor or medical staff who does not have the patient's informed consent is held professionally liable for his or her actions, the exceptions being limited to emergency situations or when the patient's life or health is in danger. In this case, a medical decision taken without the patient's consent must be proportionate to the seriousness of the danger and considered accordingly.

Chapter three of the Law 95/2006 *on the reform in the romanian health sector* provides in its art.660-662 that, in order to be submitted to a medical intervention with potential risk for the patient, the patient shall be asked for written consent after having previously been given all medical information at a scientifically reasonable level for the patient's understanding. The information must contain: the diagnosis, the nature and purpose of the treatment, the risks and consequences of the proposed treatment, the viable treatment alternatives, their risks and consequences, the prognosis of the disease without treatment.

Expression of consent implies full legal capacity to act on the part of the patient, but there are a number of exceptions to this rule:

- *emergency situations, when the parents or legal representative cannot be contacted and the minor has the necessary discernment to understand the medical situation in which he/she finds him/herself;*
- *medical situations related to the diagnosis and/or treatment of sexual and reproductive problems, at the express request of the minor over 16 years of age.*

The medical representative performing the procedure is directly responsible for obtaining the patient's written consent, except in the case of an emergency situation where the patient is unable to give consent and the legal representative or next of kin cannot be contacted concerning the emergency situation. In the latter case, the medical representative may request the authorisation to perform the medical act from the guardianship authority.

However, there are also situations where none of these circonstances can cover patient consent and therefore the medical act will be carried out without the patient's consent in emergency situations where the time delay before consent is given would irreversibly endanger the health and life of the patient.

In the process of obtaining the patient's consent to a medical act, another aspect as important as the patient's bodily integrity is the patient's privacy. In this respect, the law provides for a right to confidentiality of medical information that the patient provides when entering into the medical contract and to the protection of his/her privacy.[iii]

3. A comparative law perspective

3.1. French legal system. The consentement principle

If Romanian law is mainly concerned with the aspect of information, the elements that informed consent must contain have been marked by French jurisprudence in the Teyssier case[iv] where the French Court of Cassation established for the first time in the history of French law that *"(...) there are rights of the patient whose ethical basis lies in respect for the human person" (...) and ordered that:*

- (...) a doctor is bound, except in cases of force majeure to obtain the patient's consent before performing an operation and that by violating this obligation (...) he seriously infringes the patient's rights (...);

- (...) a surgeon must inform the patient of the exact nature of the operation to be performed, the possible consequences and the therapeutic alternatives (...);

- (...) the absence of consent (...) was the cause (...)" (n.b. - of the damage).

The Teyssier decision was, however, preceded by other French court decisions stipulating the need for patient consent (Costea, 2018).

Medical law derogates from ordinary law, interests and questions by its particularities. However, the Mercier decision of 1936 seems to have denied this by forcing an ordinary "medical contract" between the doctor and his patient. But the medical relationship, far beyond a contractual logic, seems to be unable to blend into the civil law elements of contract law. As such, consent, keystone of this medical matter, does not meet the standards of contract law yet imposed by the Court of Cassation.

If we start from a fairly classic presumption, which has moreover been current for more than 60 years since the Mercier decision of 1936, consent in medical law would be of a contractual nature. If there is a medical contract, then consent must have the classic characteristics required by the law of obligations. In this sense, it would be sufficient for the patient to give certain, free and informed consent for the medical relationship to radiate from a perfect and non vitiated contract (Porcher, 2019).

French doctrine has developed two views on the subject of the right to respect for the human body. In a broader sense, it concerns the prerogatives conferred by law on respect for the human body. But the object of the right to respect for the human body refers more precisely to the prerogatives protected by this right, and here the discussion involves the human body in its wholeness and materiality, on the one hand, and the products and elements of the human body, on the other.

Article 16-1 of the French Civil Code, after stating that "everyone has the right to respect for his body", underlines the importance of this principle by stating in paragraph 2: "the human body is inviolable". Following the model imposed by Article 9 of the same Code, the emphasis is placed on the defensive prerogative attached to the right to respect for the human body, backed up by the provisions of article 16-2 of the Civil Code, namely the power to oppose violations of the body. This power also implies a second prerogative: the freedom to dispose of one's body, within the limits imposed by public order and the rights of third parties. Everyone is the owner of his or her own body and can decide what he or she accepts or does not accept with regard to it, which is why acts without consent are punishable (Saint Pau et al., 2013).

Consent to an injury to the human body must necessarily be given prior to the action. Consent must also be freely and clearly expressed, which is why French law expressly requires it in medical matters (art.L.1111-4, para.3 french public health code), biomedical experiments (art.L.1122-1 french public health code), any modification of the characteristics of blood before the removal (art.L.1221-6, para.2 french public health code), removal of organs from a living person (art.L1231-1, para.3 french public health code), removal of tissues or cells and collection of products of the human body from a living person (art.L1241-1, para.2 french public health code), assisted medical procreation (art.L.2141-10 french public health code), examination of genetic characters (art.16-10, para.2 french civil code) and end of life (Zenati-Castaing & Revet, 2006).

Article 16-3 paragraph 2 of the French Civil Code states that "the consent of the party concerned must be obtained in advance, unless his condition makes necessary a therapeutic intervention to which he is unable to consent."

The French Public Health Code states in article L1111-2, paragraph 1 that "everyone has the right to be informed about their state of health. This information concerns the various investigations, treatments or preventive actions proposed, their usefulness, their possible urgency, their consequences, the frequent or serious risks normally foreseeable that they

involve, as well as other possible solutions and foreseeable consequences in the event of a refusal. He or she shall also be informed of the possibility of receiving, when their state of health permits, in particular when it concerns palliative care within the meaning of Article L. 1110-10, outpatient or home care. Account shall be taken of the person's wish to receive one of these forms of care. When new risks are identified after investigations, treatments or preventive actions have been carried out, the person concerned must be informed, unless it is impossible to find them."

In this regard, case law has definitively decided that the burden and, therefore, the risk of non-performance of the obligation falls on the patient, who is obliged to prove that he was not informed of the risks of the medical intervention. However, the case law then changed, with the French Court of Cassation deciding in 1997 that "the doctor is under an obligation to inform his patient of the risks and it is also for him to prove that he has fulfilled this obligation", a rule which applies to all professionals who are under an obligation to provide information (Terré & Fenouillet, 2012).

Medical contracts are recognised as valid when they result from a direct medical procedure on the human body, due to the fact that it is based on a legitimate interest justifying it and the consent of the patient. Thus, French law makes the medical act subject to the integrity of the human body subject to two conditions: it must meet a medical need for the person or, exceptionally, in the therapeutic interest of another person, and it must contain the prior consent of the person concerned. In any event, consent must be clearly expressed, particularly as it makes the doctor liable for all the consequences of the operation if he does not inform the patient of the risks involved beforehand, so that the patient can give his informed consent. On the other hand, if the patient is informed by the practitioner of the risks of the medical intervention and refrains from refusing what is recommended, then he or she cannot blame the doctor (Cornu, 2007).

3.2. Spanish legal system

Both Spanish doctrine and autonomous legislation[v] and case law have identified informed consent as an autonomous (free, voluntary and conscious) authorisation of the patient to perform a medical procedure.

Consent to a medical act can also be defined here from the perspective of personality rights, as in the Romanian and French systems. Therefore, the Spanish doctrine defines informed consent as a personalist right of the patient to decide autonomously (freely, voluntarily and consciously) on the occasion of any health action. This decision must be taken by the patient after interacting with the health professional in a process of continuous dialogue in which the latter has explained all the necessary information to the patient, sometimes requiring written proof of information and consent, although this is an *ad abundantiam* requirement and by no means a substitute for the doctor-patient information dialogue.

Both the Spanish Supreme Court and the Constitutional Court grant informed consent the status of a fundamental right as "a necessary consequence or explanation of the classical rights to life, physical integrity and freedom of conscience" or, in other words, because of the inherent nature of these rights. Thus, despite the fact that the Spanish Constitution does not include informed consent in the list of fundamental rights, case law nevertheless elevates it to the category of a fundamental right derived from the right to life, physical integrity and freedom of conscience, so that "informed consent constitutes a mechanism for guaranteeing the right to physical and moral integrity, and its omission implies a violation of the fundamental right" (Cadenas Osuna, 2018).

The Spanish doctrine refers to the concept of informed consent through a personalist view, in relation to the provisions of Law 1/1982 on the protection of honour, image and privacy published in the spanish Official Gazette no.115 of 14 may 1982. Consent does not

have to be in writing, it is not a formal contract, but it must be conclusive and express, so it can even be verbal.

It has already been mentioned that the right to privacy can be the subject of a profit or the subject of a contract, unlike the right to honour, since is not available.

Consent may be revoked at any time, but any damage caused must be compensated, including any justified losses (Law 1/1982 on the protection of honour, image and privacy, art. 2.2).[vi]

The consent of minors and incapacitated persons is given by them if their conditions of maturity allows it, in accordance with the civil law. In all other cases, consent must be given in writing by the legal representative, who is obliged to inform the Public Ministry of the consent given. If, within eight days, the Public Prosecutor's Office objects, the judge will decide. The exercise of the civil protection of the honour of a deceased person corresponds to the person designated for this purpose in the will, who may even be a legal person. If there are no testamentary heirs, then descendants, living ascendants will be legitimated. In default. It is the Public Prosecutor's Office that will be entitled to act ex officio in the interests of the deceased (Encabo Vera, 2012).

Conclusion

The respect of the dignity of the human person is the universal principle on which the consent before any medical act is based. Consent is one of the pillars of this famous and noble relationship between physician and patient and it is based on respect for life and human dignity.

Consent is a *sine qua non* condition for the validity of the medical contract. In France, the Court of Cassation has declared that "an intervention that affects the integrity of the person constitutes in itself an act of violence that can only be legitimate under the criminal law, if it has been done in a medical interest" (Stoeklé et al., 2022).

Obtaining the patient's consent before any medical act is a legal obligation, the failure of which can be considered as an infringement of the patient's physical integrity. In all situations where the health professional proposes a diagnostic or therapeutic procedure, he must ensure free and informed consent. The obligation to obtain consent stems from the principle of respect for the individual's will to consent or not to a medical act.

The principle is reflected in national and international legal texts, reinforcing the need for consent before any medical act. The consent is linked to the possession by the patient of all the information allowing him to take the adequate decisions for him (Jandou et al, 2020).

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[i] For more details, see https://gdpr.eu/gdpr-consent-requirements/ .

[ii] In this regard, the provisions of Articles 13-25 of Romanian Law 46/2003 on patients' rights.

[iii] Exceptions to this rule relate to explicit patient consent to the disclosure of such sensitive information or if required by law. Exceptions to intrusion into privacy are also considered to be cases where such intrusion is positive for the treatment and health of the patient or where there is a danger to the patient or to public health.

[iv] In 1942: the Teyssier decision insisted on the doctor's obligation to inform his client about the exact nature of the operation and its consequences as well as the possible alternatives, and the whole thing must be practiced under a very serious medical reason, except in exceptional cases.

[v] With reference to the autonomous regions of Andalucia. Galicia, Comunidad Valenciana and Extremadura.

[vi] See official website: https://www.boe.es/buscar/act.php?id=BOE-A-1982-11196 .