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Social and Legal Perspectives on Informed Consent. A Bioethical Approach

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Abstract: *In the biolaw literature, the concept of valid consent is sought to be accredited instead of informed consent when discussing medical responsibility and doctor's obligation to inform the patient, as part of their professional obligation, to provide them with treatment/care. In this paper we present a few cases related to ECHR and also a current case of possible malpraxis presented to the Romanian Court, not yet solved at this date.*

The central ethical problem *represents the discussion on valid consent from the perspective of the theory of international human rights law.*

Keywords: *informed consent; doctor-patient relationship; legal perspective.*

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Introduction

Informed consent appears in bioethics and in the doctrine related to medical law both as a process of informing the patient and making a decision regarding the therapeutic approach or the research of which he is to be part, as well as an administrative tool - form or set of forms - with contractual value justifying the patient's consent and excusing the doctor for possible injuries to the patient that occur during the therapeutic process or research on human subjects and which are not due to the doctor's fault or his ignorance, risks of which the patient has been advised and to which he consented. Also, informed consent (abbreviated from now on as I.C.) also covers risks of which the doctor was not and could not have been aware - and, as such, did not communicate them to the patient - therefore consent forms also include risks that cannot ordinarily be foreseen.

The case Atudorei v. Romania

The European Court of Human Rights was referred to the case of Atudorei vs Romania - in which the object of the case was involuntary psychiatric hospitalization (ECHR, 2014). The plaintiff has been hospitalized involuntarily, at the request of her family, when they noticed that the plaintiff was practicing yoga - which was considered by her parents as a religious deviation. The involuntary hospitalization occurred when the plaintiff, being of consent age, wanted to marry a person she knew at the respective yoga classes and who was not approved by her parents.

The motivation of the plaintiff's parents for hospitalization was their desire to remove their daughter from the harmful influence of the practice of yoga and especially of those who led this group of yogis. In the anti-cult context, it is often invoked that the person under the psychological influence of some religious practices, and especially of some charismatic leaders, can lose their potential in the ability to exercise their autonomy and give their consent. In this context, the parents and the psychiatrists who carried out the hospitalization chose the solution of involuntary hospitalization, considering *ab initio* that the plaintiff was incapable of consent.

In the debate that took place at the ECHR and including from the applicant's initial letter, submitted to the Court, it was noted that, from an early age, the applicant was subjected to repeated physical and psychological abuse, by her family, even before she begins practicing yoga and being affiliated with this supposed cult. Ever since she was a child, she was monitored excessively, not being allowed to move anywhere alone. This

called into question the basic reason for hospitalization - namely, if the plaintiff really developed the mental disorders invoked by her parents, if they appeared as a result of yoga practice, if she manifested them because of the abusive behavior of her parents, from before the yoga practice, or if because of these supposed disorders the parents chose to have a hyperprotective behavior since her childhood.

In this case, the Court finds that the plaintiff's right to private life was violated by the involuntary hospitalization, as it was assumed - based on a single medical examination and the parents' statements - the plaintiff's incapacity to consent. This incapacity had to be ascertained by a medical team, and the patient would have had the right to a second medical opinion, especially given that the hospitalization was not justified by anti-social behavior of the plaintiff. The only aspect considered anti-social by the parents and by the doctor chosen by them was the adherence to that yoga group, named by them as "sect" and which had a negative reputation among the public from which the parents came. The Court finally considered that this did not justify the deprivation of liberty of the applicant and her involuntary hospitalization, despite the repeated expression of her lack of consent (Sandu, 2024a).

The case Mockute v. Lituania

In the case of Mockute vs. Lithuania, regarding the violation of the right to private life, ECHR found, on 27.02.2018, the violation of art. 8 and 9 of the European Convention of Human Rights when the applicant Mockute, being hospitalized in a state psychiatric hospital, had some information about her private life made public in the press, the data being taken from the hospital's archives. The disclosure of personal information, including those related to the applicant's state of health to her mother - the applicant being of age and not giving her consent for this disclosure - constitutes a violation of the right to private life. It is, in the Court's understanding, a transmission to third parties of information about a person's private life, a transmission which, in the Court's view, must be based on a legal framework, "the existence of a legitimate purpose or a proportional character not being sufficient".

In the Court's interpretation, the communication of some information about private life, especially regarding the state of health, without consent, represents a violation of the Convention (art.8), even if this disclosure is made to close people - parents - of the patient, a patient who is capable of consent, and consent should not be sought from relatives (Bogdan & Micu, 2018).

The case under discussion is essential not only for clarifying the importance of informed consent as a tool for the protection of human rights (Năsui, 2024) and limiting the circumstances in which private life information - in this case health - can be disclosed even to persons who might ordinarily be expected to be interested in that information and possibly entitled to receive them, of the fact that the assumption of entitlement does not diminish the importance of consent, including when the person's competence to consent is limited, but without being officially declared incompetent.

The case is also important in order to understand the limits of communicating such information to the media or generally by publication, even if it can be assumed that the way the information is communicated cannot ordinarily lead to the identification of the person to whom I refer. This situation of masking the person's identity is encountered in many situations in the case of publishing medical information for scientific purposes, when care is taken only to hide the information about the person - their image included - but the obtaining of informed consent is not considered for the publication of that information.

The case Lambert v. France

With regard to the *withdrawal of artificial life-sustaining treatment*, the European Court of Human Rights formulated the following opinion in the case of Lambert and others v. France: "there is no consensus among Council of Europe member states in favor of allowing the withdrawal of artificial life-sustaining treatment" despite the fact that most member states "seem to allow it". There is a consensus noted by the ECHR judges (ECHR, 2022) among the member states regarding the primary importance of the patient's wishes regarding the decisions taken regarding the end of life - such as the case of non-resuscitation or euthanasia - and therefore states should have the freedom to allow or not to withdraw artificial life-sustaining treatment and to establish the regulations regarding this withdrawal, with a view to establishing a balance between the right to life of patients and "the protection of their right to respect for private life and their personal autonomy". The Court reserves the right to examine compliance with the obligations of the states, based on Art. 2 of the Convention, both through national legislation and through practical activity and through national jurisprudence. In other words, the states' margin of appreciation is very wide.

Regarding compliance with art. 2 of the Convention, when medical treatment, including life-saving treatment, is administered or decided to be withdrawn, ECHR (ECHR, 2017) primarily considers the analysis of national law and regulations and its compatibility with the Convention and

its Article 2, if in practice the will of the patient's or of his/her relatives has been taken into account, including the will previously expressed - in the form of an *in advance directive* or a *do-not-resuscitate order* [n.n.] – and how the professional opinions of other medical personnel involved or not in the patient's therapy were consulted and taken into account. Also, ECHR (ECHR, 2021) analyzes the existence of the possibility of the patient or of the relative to address a national court regarding possible doubts regarding the medical decision and the fact that it was "the best decision to be taken in the interest of the patient" (ECHR, 2022).

The case Csoma v. Romania

The plaintiff Csoma became pregnant, the progress of the pregnancy being monitored by the gynecologist P.C. from the city hospital Covasna, the fetus being diagnosed, in the sixteenth week, with hydrocephalus, and termination of the pregnancy was proposed. The doctor administered the patient a perfusion and an abdominal injection with glucose, to determine the death of the fetus. During the night of 15.05.2002, the plaintiff developed fever and chills, the fetus being expelled during the following morning, as a result of which the patient presented hemorrhage. The two subsequent curettages were not effective, the patient's bleeding continued, so the patient was urgently transferred to the Sfântu-Gheorghe County Hospital. In the ambulance, she was assisted only by a nurse, and not by a doctor. Arriving at the County Hospital, the doctors had to perform a total hysterectomy and bilateral adnexectomy to save her life.

Following the complaint submitted to the College of Doctors against the doctor who initially treated her at the Hospital in Covasna, the College of Doctors found that it was necessary to monitor the termination of the pregnancy with the help of an ultrasound, the proof of which was missing from the medical file of the petitioner. The method chosen for terminating the pregnancy would have required, in the opinion of the College of Doctors, additional information on the risks and complications and a written informed consent, specific for this procedure. This consent is also absent from the file, which is why the preclinical investigations that would normally have been carried out are also missing. In the opinion of the College, these deficiencies are considered minor irregularities of a procedural nature, these observations not leading, however, to the conclusion of medical negligence. On 09.12.2002, the plaintiff filed a criminal complaint against the doctor, also filing claims as a civil party. The Institute of Forensic Medicine, analyzing the case, also believes that there was no medical fault. Against these observations, the plaintiff formulates objections, questioning, among other things, about alternative

methods of terminating the pregnancy, and whether an ultrasound monitoring would not have reduced the risks of the procedure. Following this appeal, the Institute also notes the lack of documents in the medical file, including the lack of informed consent from the patient, but that there was no medical negligence, even though the doctor failed to talk to the patient and obtain her consent. The prosecutor's office attached to the Covasna Court decided to remove Dr. P.C. from criminal prosecution, prior to the issuance of the opinion by the Institute of Forensic Medicine.

Following the exhaustion of all national appeals, the plaintiff addresses the ECHR, claiming that her rights provided by the Convention under art. 2, art. 6 and art. 13 have been violated – in that she was not properly informed about the risks of the intervention, claiming that due to medical negligence her life was endangered and her family life was affected by her impossibility of carrying another pregnancy. The plaintiff also claims that, despite her quality as a nurse - which implies the existence of wider medical knowledge than a person outside the medical system -, this did not exempt the doctor from the obligation to inform her about the risks of the procedure nor obtaining informed consent, the pregnancy termination procedure not being likely to require an emergency intervention, which would make it impossible to prepare it through clinical and preclinical tests. In its defense, the Romanian State states that its responsibility cannot be invoked, as long as the investigative bodies have established that it is not medical fault and that the lack of procedures such as the one for obtaining consent cannot be interpreted in the sense of the patient's ignorance of her medical conditions and risks, given her professional qualification.

The European Court of Human Rights reiterated its principles, according to which states must take all measures, including those of a legislative nature, to ensure that "public and private hospitals are obliged to resort to measures capable of protecting the lives of patients". Furthermore, the Court points out that if a foreseeable health risk was not properly presented to the patient and his consent obtained, the state party to the Convention is liable for this omission. Regarding the exhaustion of all domestic appeals, the Court found that, although it was possible for the plaintiff to go to a civil court to obtain compensation, the fact that she has formulated civil claims in the criminal complaint covers this requirement that, prior to addressing the ECHR, the plaintiff has exhausted the national appeals, the existence of a mechanism that allows the continuation of the trial of the civil claims after the rejection of the criminal action being necessary. The Court upholds the petition and condemns Romania to pay the sum of 6,000 euros as moral damages.

Therapeutic non-obstinacy and elements of bioethics in palliation

Romanian society is, at the time of writing this paper, confronted with a public scandal (Realitatea.net, 2024) following the arrest of two medical staff from the Intensive Care Unit of a well-known hospital in the Capital of Romania, following the complaint received by public Prosecutor's Office where it was stated that the respective medical personnel deliberately decreased the dose of a drug administered to some patients in intensive care and that this decrease in the dose led to the death of the patients. The Institute of Forensic Medicine specifies that the decrease in the dose of the respective medicine can cause the person's death, while other specialists in the field of intensive therapy have shown that the decrease in the respective dose is in accordance with international protocols, when the patient shows no signs of reacting to the respective medicine, and the patient's vital functions are incompatible with life, reducing the dose does not represent medical fault, nor can it be considered premeditated murder.

In fact, due to the poor development of palliative medicine in Romania, but also the exaggerated desire of the relatives to give the patient the maximum therapeutic possible, until the last moment of life, even if the therapy does not give results, could constitute as many reasons for debate among the mass media and the public, starting from this controversial case, starting from the fact that at the national and European level there is no unified, legally established vision regarding the suspension of the therapeutic act seen to be ineffective, even if in the term this short suspension causes the death of the patient.

From the point of view of the I.C. issue, which is the object of interest of this paper, we point out the need for a coherent ethics policy regarding bioethical issues at the end of life - specifically, in the present case, the medical will (do not resuscitate order, do not treat order, advance directive). Also, the medical will must nominate a person, among the relatives, to make decisions on behalf of the patient as long as he is unable to consent, even if this person is not the closest in terms of the degree of kinship. As long as the legal opinion stipulating the obligation of therapeutic non-obstinacy, at national and European level, is not clear, I.C. or delegated consent (and not presumed consent in a negative way) should be the instrument that makes the difference between people at the end of life, who continue to receive treatment, and not to be included in palliation programs and the people who will benefit from the non-inheritance of therapy. The task of triaging people who should be stopped from therapy that, in the medical opinion, does not produce results - should not be left exclusively to

the medical staff. The decision previously expressed by the patient or by the designated caregiver should be taken into account, even with the caregivers assuming the cost of the therapeutic obstinacy.

Therapeutic non-obstinacy can also occur in the case of other diseases considered incurable, but which are not accompanied by deep coma. In such a situation, the patient is transferred - with the consent of the relatives - to palliative care wards. We are not talking about a person's lack of treatment, but only the replacement of curative treatment with palliative treatment in the event that it is considered that the curative treatment can no longer be effective. The informed consent of the patient - less often - or of the relatives is necessary for hospitalization in palliation wards, and for obtaining this I.C. the person giving consent must understand the irreversible nature of the patient's medical condition. In such a situation, in the form of I.C. for admission to palliation, there are also elements related to the do-not-resuscitate order that basically asks the medical staff of the palliation ward not to intervene or call other specialists to treat other medical conditions that would appear to be at risk of death for the patient, even if they are other than the chronic illness that led to the palliative care admission. Even though some palliative care clinics offer this care that consists of providing medico-pharmaceutical substances to limit the perception of pain, counseling and psycho-emotional support, along with therapeutic care for conditions other than the one in palliation and to which the patient becomes unresponsive, emergency resuscitation is generally avoided for palliative patients.

For example, a patient admitted to the palliative care unit should not be resuscitated in case of cardiac arrest, even if that cardiac arrest is not proven to be related to the oncological disease from which the patient suffers. Medical considerations are related to saving resources, as long as the patient in palliation has a negative prognosis in terms of life expectancy, but also from the perspective of the person's dignity, who would be subjected to trauma related to various medical interventions that would be added to his condition as person at the end of his life.

The I.C. form that we have analyzed, used in the palliative care section of Paşcani Municipal Hospital shows that "medical investigations or treatments requested by the patient or by his guardian from the perspective of active medicine will not be carried out" (Paşcani Municipal Emergency Hospital). Also, the same form stipulates the following: "It is important to understand that cardio-respiratory resuscitation maneuvers will not be practiced in advanced stages of the disease, as they are contraindicated." Although we are not medically competent to discuss to what extent cardio-

vascular resuscitation maneuvers are contraindicated in all terminal illnesses, we believe, from a bioethical and legal perspective, that such a statement included in the informed consent represents an implicit *do not resuscitate order* and that it is introduced from economic or bio-psycho-social reasons rather than from a strictly clinical perspective.

Practically, having a non-resuscitation value, it prevents the performance of any cardio-vascular reanimation maneuvers of the person under palliation, even if we are not talking about a comatose state of the said patient. However, we can talk about respect for the patient's dignity, which occurs when the patient is not subjected to additional maneuvers that, although they would prolong life, would put them in a situation of additional discomfort. On the other hand, the obligation to consent to non-cardio-vascular resuscitation when in palliation for other types of illnesses can be interpreted as forcing the patient to renounce the right to life in advance, since the palliative situation can last months or even years and the cardio-respiratory arrest to occur at a time when the disease, even in a terminal state, would not cause immediate death.

The fact that the statement regarding non-resuscitation or the non-performance of curative treatments have the role of do not resuscitate orders is indicated by the fact that the patient in the palliative ward gives "informed" consent to follow the treatment prescribed by the doctor, including the necessary tests, according to the General Form of I.C. of the hospital, even if he agreed that he would not benefit from any treatment. More specifically, the patient consents or does not consent in advance to follow or not a perfusion/injectable/investigational treatment ("investigations" not representing a proper treatment) which was previously specified that they will not be given, at least not upon request to him, but which were clearly and comprehensibly explained to him - although at the time of hospitalization in palliation it cannot be a question of such therapeutic operations: "I consent/do not consent to follow the following investigation/treatment: PERFUSABLE, INJECTABLE TREATMENT, INVESTIGATIONS. The nature and purpose, benefits and risks of performing/not performing the explorations/treatment, as well as the other therapeutic operations, were explained to me to my understanding by Dr. X."

A bioethical approach

There are number of elements that make informed consent invalid: coercion, fraud or manipulation. As long as a moral norm is only idealized, not having the constraining force of the legal norm, its application represents a pure virtue, which often remains without object in the social

world. Ethics based on justice and equity, because it has benefited from normative transposition, codified by laws, has punitive force and, as such, represents a behavior adopted and imposed at society level.

Informed consent can be valid even if it is not complete - that is, the patient did not have access to all available information, but only to those that the doctor considered the patient competent to understand. The consent is not valid even if it is fully informed, as long as the patient is asked to exceed his powers to consent in favor of the doctor, exonerating him from a responsibility that falls to him as a professional task. There are a number of elements that make informed consent invalid: coercion, fraud or manipulation.

As long as a moral norm is only idealized, not having the constraining force of the legal norm, its application represents a pure virtue, which often remains without object in the social world. Ethics based on justice and equity, because it has benefited from normative transposition, codified by laws, has punitive force and, as such, represents a behavior adopted and imposed at society level. The acceptance of cultural relativism brings with it the acceptance of some practices considered here and now immoral and, therefore, ethical particularism aims at acceptability in a socio-cultural context, while normative ethics identifies principles and methods of their implementation with potential for universalization.

We formulated the opinion that in practice there is a possible contradiction between the two roles of the previously mentioned I.C. – the decision-making and the administrative one – when the forms of the I.C. (administrative activity), signed at admission, tend to cover all aspects of the patient's activity in the respective clinical institution, even before the diagnostic process allows the doctor to propose a therapeutic approach to which the patient seems to be obliged to consent, thus leaving the burden of medical risk exclusively on the doctor (Sandu, 2024b).

Informed consent is a multidimensional tool for legal protection of the right to life and privacy, both from the perspective of international human rights law and national law - from Romania or from other countries. Starting from the medicalization of social life and the tradition - widespread in Civil Law - of consent, the idea of informed consent, treated in a manner analogous to that of medicine, was taken up in other fields generically united under the name of helping professions - such as psychology, social work, paliative care, alternative therapies, nursing, physical therapy, etc. and also in non-medical research, correlated with the previously mentioned professional fields and especially with the behavioral sciences.

Conclusions

The acceptance of cultural relativism brings with it the acceptance of some practices considered here and now immoral and, therefore, ethical particularism aims at acceptability in a socio-cultural context, while normative ethics identifies principles and methods of their implementation with potential for universalization.

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