The development of the concept of the patients informed consent

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Abstract

Background: The European Convention on Human Rights is the key legal document that outlines the basic human rights and freedoms. It’s a comprehensive, universal document with broad regulation despite its laconic nature. Its context is quite broad and, among other things, it deals with a whole range of the so called “medical rights”, such as the availability of medical care and its timeliness, including on specialized treatment and medical research, informed consent to medical procedures and its results, etc. The article reviews the history of the concept of informed consent in the light of various cases from the practice of different states. After that, it analyses Article 8 of the European Convention on Human Rights (ECHR) and the judicial practice of the European Court of Human Rights with regard to informed consent to medical intervention.

Method: The method of doctrinal research is used to make conclusions on the above-mentioned topics.

Conclusions: It is argued that article 8 of the convention encompasses “the right to be free from non-consensual medical treatment or examination, holding that “a compulsory medical intervention, even if it is of minor importance”, as well as the imposition of a medical examination, constitute an interference with the right to private life”6. It’s shown that the ECHR is the powerful instrument to protect the medical rights of the patients and to ensure their informed consent to various medical procedures.

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Introduction

The issue of informed consent to medical intervention is the central issue with regard to medical rights of the patients. Voluntary informed consent of the patient is a necessary precondition of any medical intervention. In most medical cases there are errors in the procedure for obtaining informed consent1,2,3,4. From the standpoint of law, informed consent is the voluntary acceptance to the proposed medical treatment by the patient based on the complete, objective and comprehensive information about the treatment, its possible complications and alternative therapies5.

The requirement to obtain a patient’s consent to medical intervention was formulated in the XVIII century in England.

In 1900, the German Ministry of Health has made it mandatory for university hospitals to carry out all medical experiments involving human subjects with obligatory receipt of their written consent and permission of the human health department. It was forbidden to conduct medical experiments to patients who were not informed about medical procedures.

Chronologically, the first case dealing with the issue of informed consent was the Modlinsky Case. Dr. Modlinsky during the surgery of 18 years old girl, additionally removed the cystic tumor, which neither the patient nor her parents did not know. As a result of postoperative complications, the patient died. On 15 of November 1901, the Moscow regional court, based its judgment on Article 1468 of the Statute on punishment in Russia, judged Modlinsky to be guilty of having performed surgery without obtaining the patient’s consent. Although, there was no indication of the patient’s informed consent in the above mentioned document, on 19 of November 1902 the Criminal Court of Appeal of the Senate of Russia affirmed the decision of the lower court, stating that “not obtaining the patient’s consent for surgery deprives medicine of its legal character and is the sign of overt neglect, giving the doctor’s deed the status of a criminally culpable act”.

In Rauhfus Case, Professor K.A. Rauhfus did a tracheotomy to a child and instructed the assistant to tie up the parents who were against the operation. As a result, the child was safe and the child’s parents were sincerely grateful to the professor. This case was considered at the meeting of the St. Petersburgs Law Society, and the behavior of K.A. Rauhfus was qualified as a double crime: the infliction of bodily injury to a child and the deprivation of his parent’s liberty. In response to these accusations, K.A. Rauhfus said that he had no other choice, because
the child would have died shortly without this operation.

In the USA, medical intervention without the consent of the patient was considered as battery and is reflected in Schloendorff v. The Society of the New York Hospital Case. In this case a patient underwent surgery “against her expressed wishes and vociferous protests. She successfully sued the surgeon and the hospital and in so doing began an inevitable erosion in medicine’s attitude of paternalism”. The decision made by the justice Cordazo reinforced the principle of autonomy. The justice noted that “every human being of adult years and sound mind shall have the right to determine what shall be done with his own body and a surgeon who performs an operation without his patient’s consent, commits an assault, for which he is liable in damages”.

The concept of informed consent evolved in the 2nd half of the 20th century. The Nuremberg Code established ten basic principles that were mandatory for everyone conducting research with human beings. The concept of informed consent was established as a result of these principles. The Nuremberg Code provides that “1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity”.

The concept developed in 1957 following the decision of California District Court of Appeals for the First District in Salgo v. Leland Stanford, Jr. University of Trustees. In this case “the plaintiff who became paraplegic following a procedure for a circulatory problem, alleged that his physician did not properly disclose ahead of time essential information concerning risks”. In this case the court said: “A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment”.

In Natanson v. Kline Case the court emphasized on the professional standards for disclosure of information. In this case the patient claimed that he had not been sufficiently informed of the adverse effects of cobalt irradiation therapy, which was then a relatively new procedure. However, because the patient did not produce expert witnesses to show that other practitioners would have disclosed more than the defendant-physician, the court refused to improve liability.

An important aspect of the concept of informed consent lies in the fact that the information provided to the patient must be adequate in the sense that an “average patient” should be able to comprehend it (awareness of the information). The so-called “reasonable man approach” was endorsed in Canterbury v. Spence Case. In this case the court described two standards: a) Professional Custom Rule (Natanson v. Kline Case); b) Patient-Oriented Rule. The decision of the court is significant with this regard because it makes a shift from professionally based standards for disclosure by physicians to their patients. The court held that the “demand for the patient’s right to self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves”. The court goes much further and states that: “...true consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each... it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie”.

Overall, it can be said that the development of judicial practice prompted the development of the concept of informed consent and the decision-making process became more patient-oriented. As the California Supreme Court noted: “...we employ several postulates. The first is that patients are generally persons unlearned in the medical sciences and therefore, except in rare cases, courts may safely assume the knowledge of patient and physician are not in parity. The second is that a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment. The third is that the patient’s consent to treatment, to be effective, must be an informed consent. And the fourth is that the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the physician that transcends arms-length transactions. From the foregoing axiomatic ingredients emerges a necessity, and a resultant requirement, for divulgence by the physician to his patient of all information relevant to a meaningful decisional process”.

Informed consent and the ECHR

Article 8 of the European Convention on Human Rights – General Overview

Article 8 of the European Convention on Human Rights provides: “1 Everyone has the right to respect for his private and family life, his home and his correspondence. 2 There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the
interests of national security, public safety or the economic well being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”

Article 8 of the convention protects private life, home and correspondence of the person. Moreover, the content of Article 8 is more broad and, among other things, it refers to a number of the so called „medical rights.” It should be noted, that the Convention is a living instrument, that should be interpreted in accordance with modern requirements and developments of law.

Article 8 of the Convention and the principle of informed consent

Some scholars argue that article 8 of the convention encompasses „the right to be free from non-consensual medical treatment or examination, holding that „a compulsory medical intervention, even if it is of minor importance”, as well as the imposition of a medical examination, constitute an interference with the right to private life”. In Y.F. v Turkey Case the court notes that „The Court observes that Article 8 is clearly applicable to these complaints, which concern a matter of „private life”, a concept which covers the physical and psychological integrity of a person (see X and Y v. the Netherlands, judgment of 26 March 1985, Series A no. 91, p.11, § 22). It reiterates in this connection that a person's body concerns the most intimate aspect of private life. Thus, a compulsory medical intervention, even if it is of minor importance, constitutes an interference with this right (see X v. Austria, no. 8278/78, Commission decision of 13 December 1979, Decisions and Reports (DR) 18, p. 155, and Acmanne and Others v. Belgium, no.10435/83, Commission decision of 10 December 1984, DR 40, p. 254)”.

In some occasions the court distinguishes different categories of persons with regard to the importance of the informed consent to medical intervention. More precisely, in Pretty v. UK Case the court noted that the imposition of medical treatment, without the consent of a mentally competent adult patient, would interfere with a person's physical integrity in a manner capable of engaging the rights protected under Article 8 § 1 of the Convention. In the case of M.A.K. and R.K. v. UK, the court found the violation of a minor’s rights due to the taking of blood samples and photographs without parental consent.

Furthermore, the court accentuates on the importance of having access to information concerning health-related risks, hence concluding that if a foreseeable risk materializes without the patient having been duly informed in advance by doctors, and if those doctors work in a public hospital, the State Party concerned may be directly liable under Article 8 for this lack of information.

Case-law of the European Court on Human Rights

RR v. Poland (2011). The applicant was a woman who had the right of abortion granted by domestic law. Nevertheless, she was not given the opportunity to use this right, because the Polish doctors and hospitals refused to carry out genetic testing. The doctors said that the applicant did not meet the requirements which were established by law. It should be noted, that Polish laws and regulations were weak and ineffective imposing strict requirements for those who wanted abortion. Finally, the applicant gave birth to a child with Turner syndrome. The applicant’s request for the initiation of criminal proceedings against the doctor had been denied. In 2011 the court issued decision establishing that Poland violated articles 3 and 8 of the European Court of Human Rights. The court noted that a woman was denied access to genetic examinations „which would have enabled her to decide whether or not to seek a legal abortion in Poland”.

Similarly, in the case of VC v. Slovakia, the court found a violation of article 8 of the convention. In particular, the court noted that medical procedure was carried out without the informed consent of the applicant. That is to say, the woman had not understood the nature of the medical procedure and its effects. In fact, the applicant had no other choice, but to agree to a medical procedure. The court stated that the woman’s informed consent was necessary, that it would guarantee her physical and moral autonomy. The court also found that the sterilization procedure violated the physical integrity of a person, because the procedure was carried out when the girl was only 20 years old starting reproductive life. Consequently, the doctors’ actions caused the girl psychological and social problems. The VC v Slovakia ruling is the first of its kind issued by the European Court of Human Rights, but there are multiple similar cases pending. These cases can have a major impact in the lives of women who have had their fertility taken away from them. The court’s recognition of forced sterilization as a severe human rights abuse will hopefully bring some sense of justice to victims, as it has to VC. Judgments on discrimination would send a strong message that governments can no longer use racial stereotypes to defend abuse masquerading as medicine.

A.S. v. Hungary (2004) Roman woman of Hungarian origin had a caesarian section operation. Hospital doctors asked her to sign a consent form for the operation, while she was in the operating table. Medical records confirm that during the signing of the form the applicant was in a bad medical condition and was not able to express her own will. Also the Latin terminology used in the document containing the consent of the person, was unclear for the applicant. Only after the surgery the applicant understood that she underwent a sterilization procedure and, as the result, lost her reproductive function. In this case, the applicant argued that the medical staff did not provide her with detailed information on the nature of the medical procedure, its risks and possible consequences relying on articles 10 and 12 of the convention. The Committee on the Elimination of Discrimination against Woman (CEDAW) found the following violations of law: 1) the right to information about family planning; 2) the person’s informed consent to medical procedures; 3) the right to information about the medical services.

The committee adopted a recommendation asking the
state to compensate the applicant. Finally, based on the recommendation in February 2009, the applicant received appropriate compensation from the state.18

Article 3 of the convention comprises a wide range of acts. The distinction of these rights is useful to define the total amount of compensation for their violations.19

Conclusion

As we have seen, the informed consent of the patients has several centuries of history. Starting from 1900-ies the judicial decisions of different countries gradually established and developed the concept. The European Court on Human Rights played a key role in the development of the concept. Article 8 of the convention encompasses “the right to be free from non-consensual medical treatment or examination, holding that „a compulsory medical intervention, even if it is of minor importance”, as well as the imposition of a medical examination, constitute an interference with the right to private life”. This right is closely linked to the right to self-determination. The European Court on Human rights is the powerful instrument which considers informed consent as the part of human dignity and provides that any conduct that interferes with a person’s integrity or sense of self-worth might be viewed as an attack on that person’s dignity.

References

9. The Nuremberg Code