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MEDICAL CONSENT IN INTERWAR ROMANIA

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Informed consent represents nowadays one of the most important elements of the patient-physician relationship, based on the fundamental bioethical principle of autonomy. Most articles and books about the consent for medical procedures, and especially about the beginnings of the informed consent, are found in the Anglo-Saxon literature. Little is known about the evolution of the concept in other parts of the world, and even less about the history of medical ethics in Romania. The purpose of this article is to summarize the most important landmarks regarding the evolution of the concept of consent in medicine in interwar Romania. We will summarize the main characteristics of the informed consent, from the legal and medical difficulties that had appeared when trying to implement them in clinical practice to the main characteristics and this concept in the national context.

Keywords: Medical consent; history of informed consent; interwar Romania.

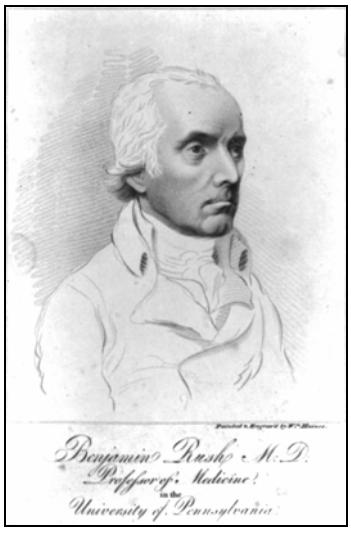
INTRODUCTION

Informed consent represents nowadays one of the most important elements of the patient-physician relationship, based on the fundamental bioethical principle of autonomy[1]. In bioethics autonomy is defined as personal self-governance – the capacity to make choices voluntarily, and independent of external constrains, to be your own master[2] – regarding the medical choices one must made. Even if most authors consider that the current concept of informed consent has appeared in the middle of the 20th century[3], there is a plethora of data suggesting that its roots, at least in Continental Europe date since the 19th century[4], even if we were to use the classical criteria differentiating informed from simple, medical consent[1].

Before that, we could not talk about an actual consent; however, physicians sometimes required the agreement of their patients in order to perform certain medical procedures; this requirement was derived from the need of the physicians to do good to their patients: they made use of the information with beneficence in a paternalist relationship in order to maximize the beneficence of the patient within the framework of their professional independence and responsibility. The beneficence based consent was directly derived from the Hippocratic principles, that considered the good of the patient to the most important duty of the physicians: *"the physician must be able to tell the antecedents, know the present, and foretell the future … The art consists in three things – the disease, the patient, and the physician. The physician is the servant of the art, and the patient must combat the disease along with the physician"*[5], *or "Whenever a doctor cannot do good, he must be kept from doing harm"*[5] *or "Whatsoever house I may enter, my visit shall be for the convenience and advantage of the patient… With regard to healing the sick, I will devise and order for them the best diet, according to my judgment and means"*[6]. The physicians respected the whishes of the patients, and subsequently their autonomy, only if by that they could do more good than by using other means[7–8]. This type of agreement from the patients was coined by later historians of medical ethics as simple consent, or

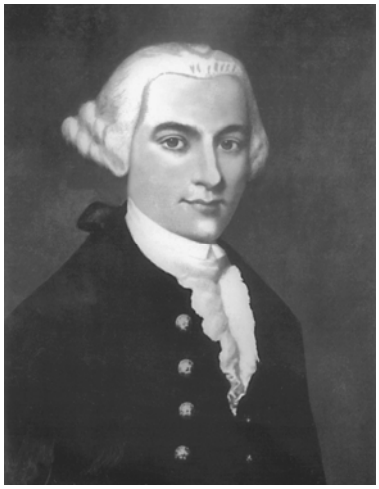
beneficence based consent[1,3]. Actually Hippocratic consent is an implied consent, a native form of the demand for medical care or subsequent to sufferance and asking for help. Thousands of years the responsibility for the medical care rested upon the shoulders of doctors especially because they did not ask the patients to contribute to their own care, the relationship doctor-patient being binomial. This does not imply the concept of an open team for medical care (the Doctor-Patient-Family relationship sometimes had implement a compensatory alliance due to lack of consensus with the patient's family), a because is moral and professional (professional independence) for the physician to take his own decisions – all these values were already expressed in the Hippocratic Oath: "If I faithfully observe this oath, may I thrive and prosper in my fortune and profession, and live in the estimation of posterity; or on breach thereof, may the reverse be my fate"[6].

According to this model, informing the patient and telling him the truth about the disease or possible treatments was ethically permissible only if by that the patient received a material, health-care related benefice. This model was partially modified by the illuminist ideas of John Gregory[9] and Benjamin Rush[10] who considered that physicians must inform patients as happiness and self-governance aid them in treating the sick. If informing was mandatory, the authorization of the physicians by the patients was considered however considered useless, as they should never oppose or judge the inclinations of the physicians[8].



BENJAMIN RUSH
(1746–1813)

Thomas Percival, the one who coined the term medical ethics in his highly influential book that stayed at the base of the moral codes of physicians in the US for more than 150 years, had a slightly different approach – he believed that telling the truth was a duty while beneficence was a virtue[11]. Whenever virtues are opposing duties, the former should prevail[11]. This approach was taken by the American Medical Association in its Code of Ethics and remained there until the second half of the 20th century.



THOMAS PERCIVAL
(1740–1804)

This approach, with the physician being the undisputed authority and the patient seen only as a recipient of medical procedures, was however attenuated by a number of legal ruling that decreed a more limited liberty of the physician in relation with his patients – this limitation became progressively more and more preeminent, making physicians feel obliged, and finally being de facto obliged to obtain a written consent from their patients before performing invasive procedures. These consent forms are not considered however as truly informed consent forms, as the proper information for the patient to take the right medical decisions often was lacking, the main purpose of those papers being to protect the physicians from battery law suits[1].

Currently, the legal framework of the informed consent is based on a series of famous cases, amongst which are *Salgo v Leland Stanford Jr. University Board of Trustees* case (1957) in which the court decided that the physician had the duty to present to the patient all information that was needed for him to make an informed decision: „consistent with the full disclosure of facts necessary to an informed consent"[12] *Canterbury v.*

Spence, 464 F.2d 772 (1975), ruling that "A physician should convey the risks of an operation when a reasonable person would be likely to attach significance to the risk in deciding whether or not to forgo the proposed therapy[13]" *or Sidaway vs Board of Governors of the Bethlem Royal Hospital (1985), stating that* "The degree of disclosure required to assist a patient to make rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment"[14].

To be noted that currently, at least in EU, it is considered that beneficence and non-maleficence stay together with the autonomy of the patient at the basis of informed consent within the principles of bioethics and within framework of the physician-patient relationship, the specific type of physician-patient relationship being freely chosen by the physician based on his/her professional experience and independence, and by choosing a specific type of physician-patient relationship the physician optimizes the medical care. Most articles and books about the consent for medical procedures, and especially the beginnings of the informed consent, are found in the Anglo-Saxon literature. Little is known about the evolution of the concept in other parts of the world, and even less about the history of medical ethics in Romania. The purpose of this article is to summarize the most important landmarks regarding the evolution of the concept of consent in medicine in interwar Romania.

Before the 20th century the physician-patient relationship in Romania was similar to any other country highly paternalistic, the main causes of this approach being presented elsewhere[15–18]. The physicians were regarded as absolute authorities, whose decisions were never disputed. Moreover there were only a handful of cases in which physicians were brought to court, and in most of them the allegations were not directly determined by the medical act.

In interwar Romania the medical practice was starting to align with the one from the Western Europe, and especially with the one from France. This led to the entrance in Romanian medicine of concepts like deontology, consents, medical confidentiality, and so on.

Regarding the concept of medical consent, it posed a few significant difficulties – both legal, represented by a limited amount of legal norms (seen as compared with today's legislation) – regulating the personal rights and uncertainties regarding the nature of the legal report between physician and patients, and medical norms – represented by the strong paternalism of the physicians, and especially by the doctrine of the right to treat that we will analyze succinctly.

LEGAL NORMS REGULATING THE PERSONAL RIGHTS

The Civil Code from 1864 detailed family rights, and protection of the persons unable to take care of themselves; however, little is detailed about the personal rights, a situation similar to other Civil Codes derived from the Napoleonic Civil Code.

The Constitution from 1866 included, in the list of fundamental individual right: freedom of conscience, of the education, of the press and of the meetings. The freedom of conscience however was related to religious self-governance[19]. The approach is highly similar to the one found in the France (and other Roman law countries), from which most of the general norms regarding the civil rights were taken.

UNCERTAINTIES REGARDING THE NATURE OF THE LEGAL REPORT BETWEEN PHYSICIANS AND PATIENTS

The legal aspects of the physician-patient relationship seemed in a general matter unregulated. According to Teişanu, this has caused the judicial system to consider it being either explained by:

- The mandate (proxy) theory. According to it, the physician-patient relationship is viewed as a mandate contract, in which the patient mandates the physician to take medical decisions on his behalf. The Civil Code stated that, once the mandatary (patient) empowered the mandant (physician) he had no obligation regarding the execution of the mandate contract; therefore the consent was needed only for the physician to act; once she/he obtained the approval, was free to do whatever as deemed necessary to treat the patient[19–21].
- The contract for services theory. According to this theory the medical act was considered a service; being a service, the parts must employ a contract either written or oral whose object was the medical act (either diagnostic or therapeutic)[21].

- The unnamed contract theory. According to this theory the physician-patient relationship was based on an unnamed contract (contract unregulated by a specific law, and lacking a legal name, that must only obey the general validity criteria for civil contracts)[21].

THE RIGHT TO TREAT DOCTRINE

A direct consequence of the paternalistic physician-patient relationship, this doctrine considered that the physician has not only a duty, but even more, a right to treat his patients. J-L Faure, a French physician (1863–1944) for example, said: "*the will of the surgeon must be above the one of an ignorant sick person. When it is no emergency, the physician must convince the patient; but there are instances when the individual freedom is in opposition with the interests of the collectivity*"[22]. This doctrine was often found in clinical practice, even if sometimes was contrary to the civil law.

PARTICULARITIES OF THE CONSENT IN INTERWAR ROMANIA

The difference between civil capacity and the capacity to consent to treatment. The Civil Code specifically stated that some social categories, like minors, people with psychiatric diseases, or married women had limited or no civil capacity, meaning they couldn't sign the consent for a medical procedure. They were however the only ones unable legally to sign the consent form; in order for a patient to be able to sign the consent, was only needed for him to know what he was doing (receiving medical care), what were the consequences of accepting a certain medical procedure (having decisional capacity), and to have an idea about the risks of the surgical intervention[23].

The right to refuse the treatment. The right to personal, corporeal integrity stated that no one cannot affect the physical integrity of a person; however, except for illegal purposes, one could dispose freely of his/hers body, including by doing bodily harm[24]. Therefore the physician should have obtained the consent for any kind of procedure able to affect the physical integrity of the patient. In Continental Europe (courts in France (Paris, Montpellier, Aix, Nice), Italy or Belgium) were cited a number of court decisions stating the mandatory character for consent in surgery, anesthesia, X-Ray imaging, or any other type of medical or surgical procedure associated with possible risks for the patient. For a detailed list see[21]. When the refusal was considered as causing harm to the patient however, the attitude was more nuanced – many physicians used to consider that they had the right to treat, irrespective of the whishes of the patient. In Romania the right to treat was however viewed as an absolute right of the physicians, which could not be restricted by the autonomy of the patients.

Proxy consent. According to Teişanu, if a patient was unable to give consent, it should have been obtained from a proxy. There were two types of incapacity causing impossibility to give the consent: natural and legal. Natural incapacity referred to the instances when the patient lacked decisional capacity because of a natural state – very young persons, psychiatric patients, acute alcohol intoxication, etc. In these instances the physician should have assessed the decisional capacity and take medical decisions accordingly. If there was no emergency, the physician ought to wait until the person became lucid again. However, if there was an emergency, the physician could intervene without consent, even if the patient was at least partially decisional competent. For example, if a drunk person came to the emergency room by his own will, the physician could still treat him without being required to ask for the consent of the patient[21]. Therefore, unlike today, the mere presence of an instance that could cause decisional incapacity was enough to consider the patient as naturally incapacitated and to release the physician from the obligation to require him to obtain the consent. Another instance in which the person was naturally incompetent to sign the consent was represented by the unconscious patient (serious accidents, patients under anesthesia, coma, or agonic). In these cases the physicians were allowed to treat the patient without the need for a signed consent, as ruled by courts in Bordeaux (1895) or Chateau-Thierry (1905)[25]. Judicial incapacity referred to the instances when the patient lacked the civil capacity to sign legal documents (consent included). There were three main instances of judicial incapacity: minors, interdicted persons and married women. First two had associated, judicial and natural incapacity, and in their case the consent should had been given by a proxy. For minors however, was done a distinction between minors with insight and

those without. In minors without insight the custodian was the one who ought to sign the consent, and per prima facie this was the father. The mother was considered a proxy only if the father was dead, lapsed from civil or parental rights, or unable to express his consent. If the fatherless child had another legal guardian than the mother, she was still the one who ought to sign the informed consent, as the legal guardian had only patrimonial attributions. Was therefore made a clear distinction between the father, as a tutor and legal guardian of the child, and the mother, whose right to sign the consent was only applicable if the father was unable to do so[21,26,27]. Regarding patients with psychiatric disorders there were also two possible options: if the patient was in a lucid interval, he was the one who should have signed the consent to treatment; if however he was not lucid, and subsequently decisional incompetent, the family should have consented to the treatment. If the family did not took the best decisions, as deemed by the physician, he could always override the decisions of the family[21]. Regarding the married women, an article from the Romanian Civil Code of 1865 stated that the consent of the husband is always necessary in instances where the collective interests of the family were at stake. This article however was considered archaic and not taken into consideration except for particular cases in obstetrics, when the physician could not save both the mother and the child[20].

APPLICABILITY OF THE CONSENT PROCEDURE

Nowadays informed consent is required for most diagnostic, curative or preventive measures, irrespective of the invasiveness of the procedure. The instances when the informed consent is not required are life-threatening emergencies, patient's will to nominate another person to receive information, whenever medical care in the benefice of the patient require interdisciplinary care, and so on[28]. For example, is not needed an informed consent when the patient comes to the physician for a consult, as it is implied that he wants to be consulted. In interwar Romania consent was sought for a more limited number of procedures. The Law regarding the organization and functioning of the Romanian College Board from 1930 considered as an act against the deontological norms of the medical profession "avoiding to obtain the consent of the sick or his family for surgical interventions"[29]. Therefore the only medical procedures for which the Code specifically required the physicians to obtain consent were the surgical ones. As seen above in the rest of the continental Europe the applicability of the consent was wider, including medical imaging, anesthesia, treating psychiatric patients, and so on. The Romanian approach was most likely caused by the fact that physicians were still viewed as highly authoritative figures, and their science as above all others[27,30].

CONCLUSION

During interwar Romania the medical consent started to be an important topic in healthcare even if highly disputed. Most physicians defended and still defend their professional independence and responsibility when patient's autonomy was overruling the professional recommendation. However increasing of awareness concerning human rights and patient's rights forced all Romanian physicians and legislators to take into consideration patient's will and his best interests regarded as his will and desire. Therefore the need of consent for surgical procedures became stipulated in 1930's in the law regulating the Romanian College Board and its deontological norms. Doing so, Romanian regulations proved to be modern, harmonized with other codes and regulations especially those arising from France.

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