

# The patient's right to information and consent in the execution of medical procedures: The legal and sociological dimension

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## ABSTRACT

The increasing penetration of medical science in the everyday life of modern man presents a particular need to maintain an ethical framework (program), which places high priority on the protection of patients and efforts to codify their rights and obligations.

The laws that fortify and safeguard the rights of patients are concrete actions that incorporate specific measures and clear provisions and afford patients - who feel as if they are being ignored or that their rights are being violated - legal rights and legal remedies.

Rights such as the safeguarding of their health, respectful treatment in the provision of health services, the prohibition of discrimination, the right to information, the right to informed consent, the right to confidentiality and privacy, the right to freedom of choice and the right of access to medical confidentiality affect critical issues of our age, while protecting the sensitive aspects of each citizen's personal data.

These rights constitute fundamental ethical questions in the establishment of an equal doctor-patient relationship, which is regarded as a prerequisite for effective communication on both sides, with the main objective being the success of the therapeutic process, the maximisation of patient satisfaction, compliance with the proposed treatment, the reduction of anxiety and faster recovery.

This paper aims to outline the patient's rights and analyze the patient's right to information and consent to medical treatment.

**Key words:** health, patient, right, patient's rights, medical responsibility, informed consent, doctor-patient relationship.

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## INTRODUCTION

In recent years, the patient's rights increasingly offer considerable scope for the development of legislative initiatives in many countries. Their application is directly linked to ensuring the highest possible quality of service in the field of healthcare and maximum

user satisfaction in relation to these services.

Inspired by universal human values and ideals, they keep pace with the modern-day needs of the patient who is better informed and often more categorical when it comes to decisions that affect their medical care.

The patient, no matter how uninformed, has the right to have their opinion heard, to be informed on all relevant parameters relating to their health, to make choices, to feel secure when it comes to matters that affect their medical care and to receive assurances that the therapy they are undertaking is appropriate and affective. When they feel that the care they are receiving is not the best, they do not hesitate to choose another doctor or, in the case of medical mistakes, take legal action.

The doctor is obliged to assist the patient in taking the correct decision, fully informing them of the nature, risks and benefits of the specific medical procedure.

### **The right to health – a constitutional foundation**

The “right” is a legislative institution through which justice systemised the private relationship between members of society. It is the power that the justice system provides to an individual or categories of individuals in order to serve an interest, to which a legal foundation is afforded (D. Tsatsos, 1988).

One of the most basic rights is the right to health, a right that constitutes a basic fundamental principle and duty which the state is obliged to provide to its citizens through an effective and efficient healthcare system that reflects human values, is socially just and offers universal coverage to the population. According to Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), the right to health is defined as “the right of everyone to the highest possible standard of physical and mental health”. It primarily concerns the right to healthcare and individuals’ free access to healthcare while it incorporates a special interest in “disadvantaged” individuals and those living in poverty (Universal Declaration of Human Rights, 1948).

Nevertheless, although significant advances in this direction have been achieved in recent years, health cannot yet be considered a vested good that is provided without discrimination.

Reference must be made to the applicable constitutional provisions. A simple reading of the provisions relating to the rights of citizens convinces one of their absolute power in the field of healthcare service provision, be they of a public or private nature.

The Constitution offers objective protection of one’s health in Articles 5§5, 7§2 and 2§3. Health is guaranteed not only as a good but as a right. Article 4, paragraph 1 states that “the Greeks are equal before the law”. Article 9A states that “everyone has the right to protection against the collection, processing and use of personal data, particularly by electronic media, as defined by the law” (2472/1997).

If, however, we consider the state’s entrenched constitutional obligations to take measures to safeguard

life and health (Article 5 paragraphs 2 and 21, paragraph 3 Abbr.) in relation to the constitutional principles of protecting human dignity and the free development of one’s personality (article 2 paragraph 1 and 5, paragraph 1 Abbr.), we could characterise it as a fundamental and social right. (G. Papadimitriou, 2005). In order to ensure a high quality level of health for all, countries must enforce the right to healthcare and the safeguarding of health through the formation of a national plan within the framework of available resources with the aim of ensuring this right is common to all individuals and does not discriminate (BMA, 2006)

### **The existing legal framework**

The Hippocratic Oath (460-370 BC) could be considered the first charter of patient rights in the history of civilized humanity. “Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.”

No progress was made in this particular matter between Hippocrates’ era and the mid-20th century. On the contrary, the patient’s rights had the same fate of all other human rights throughout the millennia of barbarity that followed the demise of the ancient Greek world (A. Koutselinis, 1999).

This state of affairs continued until the end of World War II. In 1948 the Geneva Declaration set out the obligation of doctors to provide services to patients regardless of gender, nationality, social or political position, race or illness and to respect the patient’s confidentiality and safeguard all of the patient’s confidentiality, even after their death (The Geneva Declaration, 1948).

A year later the International Code of Medical Ethics spelled out the need to respect the patient’s confidential information, the patient’s right to be informed and the right to a humane and dignified life.

Political and social processes initially resulted in the adoption of the Code of Patient Rights by the American Hospital Association in 1973.

France proved to be the pioneer in Europe with the introduction of the Charter of Rights and Obligations of Patients in 1974. The same year the European Communities Hospital Committee adopted the European Charter of Patients’ Rights.

The Lisbon Declaration was announced several years later, in 1981. Greece was the first country in Europe to introduce the law (L. 2071/92, article 47) on the “Rights of Hospital Patients”, followed by Ireland. The law was clearly influenced by the Lisbon Declaration (C. Spyraiki, E. Fragiadaki, 2006)

The regulations of Law 2071/1992 on the “modernization and organization of the healthcare system” replaced

a series of legal provisions which established the National Healthcare System and altered the general approach and ideological direction of legal canons that were rooted in the Constitution and safeguarded the right to good health.

In 1997 Law 2519 established the Patient Right Protection Agencies, which led to the promotion and dissemination of the institution.

In accordance with this law, a recommendation is made to the Health and Welfare Ministry for:

- a) The Independent Patient Rights Protection Unit which is administered directly by the ministry's General Secretary and
- b) The Protection of Patient Rights Audit Committee, which possesses the main responsibility for monitoring and developing the institution

An important step in the regulation was the Greek Parliament's ratification (Law 2619/98) of the Council of Europe Convention on Human Rights and Biomedicine (Oviedo, 1997).

In 1999, via Law 2716/99, the following were introduced to hospitals and began operating:

- a) A Citizen Communication Office and
- b) A Citizens Rights Protection Committee

If we attempt to evaluate the establishment of these agencies at hospital level, we will see that they played an important role in the change of attitude among healthcare professionals.

The creation of these agencies meant that the patient was no longer weak and all were made aware of this. The result was the right to good health, the respect of this right and the observance of the law and eradication of poor management. Hospital administration and organization gradually improved in qualitative terms (X. Kontiadis, 1995)

### **An initial approach to the problem**

One of the basic operational problems faced by hospitals in the past was the lack of a bill of hospital patient rights and the protection of these rights. As previously noted, the matter of patient rights was of serious concern to all societies. However, they tried to fill this gap via operating regulations relating to healthcare service personnel and, in this way, the fundamental rights of hospital patients were adopted in a direct manner.

The lack of these rights had caused serious problems of dysfunction in healthcare services due to the fact that the patient raised concerns relating to matters that affected them and the healthcare services could not solve these problems. This occurred due to the lack of a specific legal framework of patients' rights and obligations and led to conflict and friction in the

healthcare field. This situation created a climate of insecurity among patients at hospitals and other healthcare units and a consistent upheaval at hospitals (A.D. Alexiadis, 1999).

No official at these institutions knew how far the demands of hospitalized patients should be met and what their rights were in terms of healthcare matters. Meanwhile, patients, who were unaware of their rights, often made excessive demands, insisting they be met immediately, which created serious problems. The State considered it was necessary to examine the particularly sensitive field of health and establish a framework of principles that would constitute the bill of hospital patient rights.

A legal framework of rights was adopted so that all hospital patients could address the appropriate department, where necessary, and seek protection and a solution to their problem. In this way a solution was found for a problem facing the healthcare sector. It was deemed that, in the long term, there was a need for legislation to guarantee these rights, to solve all the unclear elements, to educate and raise awareness of all medical personnel and to improve the level of our society by improving the level of education and awareness of citizens so that citizens and patients were aware of their rights and demanded the necessary respect from all medical personnel in the provision of healthcare services (Akinosoglou et al 2007).

### **The rights of hospital patients (L.2071/1992)**

- 1 The patient has the right of access to hospital services most suited to the nature of their illness
- 2 The patient has the right to care with due respect for human dignity. This care includes not only the general practice of medicine and nursing and paramedical services but also suitable accommodation, adequate treatment and effective administrative and technical support
- 3 The patient has the right to consent to or refuse any diagnostic or therapeutic procedure. In the case of a patient with reduced or total mental incapacity, this right is exercised by an individual legally entitled to act on their behalf.
- 4 The patient may request to be informed on their state of health
- 5 The patient's interests are crucial and depend on the completeness and accuracy of the information provided. The patient should be presented with the full picture of the medical, social and economic aspects of their state of health in order to be able to take decisions or participate in decisions that may affect their life.
- 6 The patient or their representative, in the event of the application of paragraph 3, has the right to be fully informed and in advance of the risks that may arise or occur in the case of the application of unusual

or experimental diagnostic or therapeutic procedures. Such procedures may only be applied if the patient approves of them. The patient may withdraw their consent at any time.

**7** The patient should feel completely free in making a decision to accept or reject any cooperation whose purpose is research or training. Consent to participation is a right and may be withdrawn at any time.

**8** The patient has the right to safeguard their personal life. The confidential nature of the information contained in documents that concern them and their medical file and findings must be guaranteed.

**9** The patient's religious and ideological beliefs must be respected

**10** The patient has the right to present and lodge complaints and objections and be fully informed of the actions taken and consequences

### **THE PATIENT'S RIGHT TO INFORMED CONSENT TO MEDICAL PROCEDURES**

#### **The concept of prior informed consent**

The patient's right to consent to a medical procedure constitutes the basic tenet of the ethics of medicine, legitimizing every possible intervention to the patient (K. Fountedaki, 2007).

The term "consent" in medical procure refers to the agreement and acceptance on the part of the patient to the therapy proposed by the doctor, which aims to improve their health and quality of life.

Up until the mid-20th century, the concept of concept was unknown. In medical procedure influenced by Hippocratic tradition, the doctor was in power and, at the same time, had the ethical obligation to define the interests of the uneducated patient and decide on the course of their health and quality of life.

It was not until the 1960s that serious concerns were raised in terms of the ethical and legal implications of the doctor's super-powers which transgresses the autonomy and self-determination of the human personality (Varka-Adami, 2008).

Following the Lisbon Declaration in 1981, the patient's right to information on their health as a condition of their consent to or disagreement with proposed therapy was institutionalized.

In Greece, this right was established by the provisions of articles 2, paragraphs 1, 5 and 7, paragraph 2 of the Constitution which protects human dignity and the freedom to develop one's personality and prohibit any form of bodily harm or harm to one's health and, generally, any affront to one's dignity.

For the first time, via paragraph 4 of Law 2071/92, the law makes reference to the right of the hospital patient to be informed by hospital doctors on the state of their health as well as the possible risks to their health posed by the application of experimental

diagnostic or therapeutic procedures (Voultsos, Hatzitolios, 2008).

The right to information was extended to all individuals and not just hospital patients via Law 2619/98, through which the Council of Europe Charter for the protection of human rights and the dignity of the individual with relation to the application of biology and medicine was ratified. Article 10 of this law defines the rights of all individuals to be informed on the state of their health while it also incorporates the obligation of respect for the wishes of those who choose not to be informed (Varka-Adami, 2008).

Additionally, article 5 of Law 2619/98 strictly defines the free consent of the patient as a condition of every procedure and the informing of the individual who will undergo the procedure as to its aim and nature, as well as the consequences and risks involved. If the full revelation of the truth may have a negative impact on the psychology of the patient and family members, that may adversely affect therapy or the procedure, then the doctor may not be so clear and may not disclose certain cases (I. Androulidaki-Dimitriadi, 1993).

In emergency situations, the doctor can carry out a therapy or procedure without prior consent. These cases refer to the patient's probable will.

The persons who consent are: the patient themselves, their close family members only in the case that the patient themselves cannot take such a decision due to the state of their health. In the absence of family members and in emergency cases, the doctor is obliged to act in accordance with probable will.

Apart from Laws 2071/92 and 2619/98, the obligation for sound and timely information is also established by article 8 of Law 2251/94. Based on these provisions, the doctor providing their services is liable for all harm caused to the patient where the patient has not been legally informed in a timely manner (M. Mitrosyli, 2000). The new Code of Ethics of Medicine (Law 3418/2005) is fully harmonized with these abovementioned provisions. Articles 11 and 12 refer to the obligation to inform the patient and for the informed patient's consent as a condition for the application of any form of medical procedure.

Apart from the abovementioned provisions, the right to be informed as a condition of consent in the carrying out of medical procedures is foreseen by specific laws that regulate specialized operations such as transplants of human tissue and organs or medical assistance in human reproduction.

#### **The industrialisation of information**

Aware of the fact that informing patients about therapy is one of their basic obligations, doctors are concerned about the content and extent of this information. The generalized consent forms that the patient – or a

family member - signs in a panicked state when their health, physical state or life is at risk do not constitute documents of irrefutable presumption in the courts. The "industrialization" of information, which is most commonly observed in major hospitals and justified by their operating conditions, does not make up for the possible lack of information nor the verbal briefing that the patient may have received and prompted them to provide their written consent.

The doctor is obliged to inform the patient on:

- The diagnostic methods, the results of the diagnosis, the type of illness, the means used, the course and stages of the therapy
- The need for the proposed therapeutic procedure and the consequences in the case of its possible delay [Kanellopoulou-Boti, 1999]
- The risks and possible implications of the medical procedure (E. Anaplioutou-Vazeou, 1993)
- The cost of the therapy and financial implications of the illness

Complete, objective information should be provided using simple, comprehensible words, without omitting basic medical terms, without excess, without the alteration of the truth, in a calm manner and a certainty that arises from the doctor's scientific training and experience.

The obligation to inform the patient and the obligation to obtain their consent constitute independent provisions fully harmonized with contemporary international perspectives and they further contribute to the sovereignty of forensic support relating to failure to inform the patient (P. Manti, 2000).

Most likely, it will reinforce judicial disputes concerning failure to inform or the incorrect informing of the patient. On the other hand, it will act as a safety valve in the case of unjust claims leveled by patients against doctors, while it seeks to protect the doctor throughout the course of a civil, criminal or disciplinary procedure.

#### **The right of prior informed consent within the doctor-patient relationship. Ethical dimensions**

The nature of the doctor-patient relationship lies at the heart of modern-day medicine and involves the upgrading of the patient's role to ensure they are more active participants in decision-making that affects their health.

The creation of an equal relationship is considered a vital prerequisite for substantive communication between the two sides. The ultimate goal is to ensure the therapeutic process is successful. This relationship contributes to the maximization of the patient's satisfaction, better adaptation to the proposed therapy, a reduction in anxiety and faster recovery.

On the other hand, a problematic relationship will most likely have a negative impact on the therapeutic

process and, as a result, the patient will not reap the greatest possible benefits.

The ties that develop between the doctor and their patients are influenced by the theoretical model relating to health matters which each patient adopts. The biomedical model, on which contemporary medical practice is primarily based, places emphasis on the biological status of the patient, who does not bear social and psychological characteristics but is considered a biological case.

The relationship between doctor and patient could be characterized as impersonal and unequal as the patient is being called upon to follow the instructions of an individual receiving therapy without participating in the taking of decisions that affect them (G.K. Tountas, 2007). At the other end is the biopsychosocial model within the framework of which the patient is able to actively participate in all procedures and decisions that affect their health. The doctor not only places emphasis on the biological characteristics but also the social and psychological elements. The biopsychosocial model is based on a holistic approach to health. According to this model the doctor considers their relationship with the patient as equal as willingness exists for effective cooperation (G.K. Tountas, 2007).

#### **The key elements of the ideal doctor-patient relationship**

The doctor-patient relationship is an unequal one. Despite that, many theorists believe that a reciprocal relationship can exist if each party respects the rights of the other and recognizes their obligations.

On a theoretical level there are some conditions that fulfil the prerequisites of what could be considered an "ideal" doctor-patient relationship.

In reality, an ideal relationship cannot exist as its nature and quality is influenced by a series of factors that are different in every case, such as the doctor's personality, the patient's ability to comprehend, the level of education etc.

Initially, each medical procedure and the doctor-patient relationship, as a result, should be governed by the principles of Bioethics which can be summarized as follows: the principle of benefit, the principle of autonomy, the principle of justice, the principle of parity (Akinosoglou, 2007).

Additionally, the basic elements of the ideal doctor-patient relationship could be summarized in the following way:

- A lack of conflicting interests
- The doctor's ability to communicate
- The patient's ability to choose
- Medical capability
- Compassion
- The duration of the relationship

The doctor's personal sensitivities and theoretical

training in bioethics matters, the patient's personality and the type of relationship they have combined with the environment in which this relationship develops can influence the form and quality of this relationship and the strength of each party in this relationship, which impacts on the patient's level of autonomy in decision-making.

The personal awareness of the physician, the theoretical education in bioethics, the personality of the patient, the type of relationship which, in conjunction with the environment in which this relationship develops can affect the type and quality of relationship and strength of each side in this relationship, affecting the degree of patient autonomy in decision-making.

### **The doctor-patient relationship in the 21st century**

At the start of the 21st century, the doctor-patient relationship lay at the heart of contemporary medicine. The changes that have occurred in the medical field and outside it, the appearance of new medical technology, the internet, the increase in chronic illnesses, the ever-increasing costs and the changing social models are constantly reshaping the behaviour of the doctor and patients, making their relationship ever more complex while defining its essential elements at the same time. The two basic models we see in the doctor-patient relationship are the paternalistic and informative models.

According to the model in which the doctor is in power, the doctor is the one who takes decision on behalf of the patient as the doctor is the only person who knows what is good or bad for the person receiving treatment (P. Ziroyiannis, 2009)

This paternalistic model dominated the course and evolution of medicine up until the occurrence of social developments that led to the appearance of new models in the doctor-patient relationship.

The "partnership" or shared model is considered easier to implement. According to this model, the patient participates in medical decision-making so that a relationship based on equal partnership can develop between the patient and doctor and not a relationship of dependence (EJ Emanuel, 1992). The deep-seated changes that have occurred the doctor-patient relationship in recent decades, whose aim is to ensure respect of the patient's rights, resulted in the distancing of the doctor from their paternalistic role and the patient's participation in the healing process. Today's doctor offers their knowledge of the latest information concerning diagnostic techniques, the causes, prognosis, therapeutic choices and prevention strategies relating to the health problem faced by the patient.

The patient, for their part, provides their personal experience of the illness, their position on the various risks and, finally, their personal values and preferences.

The doctor-patient relationship must be a relationship of autonomy. This means that both parties must have rights and obligations and that when ethical values conflict, they should resolve any issues in the relationship on the condition that a new, more favourable one will be established (Papadimitriou, Papakostas, 2002). While science verifies the strength of a therapeutic relationship of this kind, other powers conspire to undermine it. The existing healthcare system causes both doctors and patients to feel a sense of anxiety and isolated from one another.

Human relationships need time and time is never sufficient in the world of organised care. Today's healthcare system, in the worst-case scenario, can turn the contact between doctor and patient into a purely commercial relationship (E. Panagopoulou, A. Benos, 2004).

To conclude, the relationship between doctor and patient is experiencing a transitional period and change is anticipated arising from the increased use of technology in medical procedures and the emphasis which is being given to the promotion of healthcare at the collective rather than individual level, among other factors. The value of the doctor-patient relationship cannot easily be measured but it is, nevertheless, invaluable.

### **Conclusions and Proposals**

The transition to a model that places the patient at the centre of contemporary medical practice and aims for their active participation in decision-making demands a new way of thinking on both the part of the patient and the doctor.

In Greece patient's rights is a relatively new matter in terms of guaranteeing them via the Greek justice system while the obligation to inform the patient is a concept virtually unknown in the medical world and among patients.

The patient's informed consent is chiefly limited to procedures that are considered serious and, oftentimes, pose a risk to the patient's life. The main reason consent is sought derives mainly from doctors who do not wish to carry out the procedures, rather than allowing the patient to exercise the right to self-determination. Clearly, effort is required on the part of both doctors as well as the state and patients themselves in order to secure their rights at the level of day-to-day practice.

The training of young doctors in medical ethics and etiquette and the organisation of awareness-raising seminars are considered necessary to the comprehension and solution of problems faced by patients.

Promoting awareness among citizens of their rights as patients and their ability to demand respect from any medical professional in the course of their use of healthcare services are also considered essential. All of the abovementioned should be founded in the

principles that relate to respect for the individuality of each patient as well as the evaluation of their ability to manage their health, thereby establishing new bases for the practice of medicine and the position of patients at the start of the 21st century.

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