INFORMED CONSENT FORM: CONCEPTS THAT THE ULTRASONOGRAPHIST SHOULD KNOW

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ABSTRACT

OBJECTIVE: The goal is to present concepts about the informed consent form that are important to the medical daily practice.
METHOD: This is a narrative literature review about the informed consent form. The concepts discussed were selected from articles available freely online, legal doctrine books, Brazilian law, as well as guidelines and resolutions of the Federal Council of Medicine.
RESULTS: The practice or obtention of informed consent in the practice of medicine is typical of the last decades and characterizes the improvement of biomedical ethics. Brazilian legislation, guidelines and resolutions governing the doctor-patient relationship and informed consent form should be followed. However, there are no established rules that define the form of this term.
CONCLUSION: The validity of the informed consent form will depend on the professional to inform and clarify it, in addition to the willingness of the patient.

KEYWORDS: INFORMED CONSENT FORM; BRAZILIAN LEGISLATION; MEDICAL ETHICS; BIOETHICS; MEDICAL LAW

INTRODUCTION

Since ancient times, few and sparse reports and references of situations have been observed in which the patient was informed and enlightened about medical procedures that were indicated to him. There is also little mention of the doctor's consideration and importance given to the patient's willingness to comply with the recommended procedure or to refuse it.

In the 1950s, some major legal events took place in the United States, resulting in behavioral changes in the doctor-patient relationship. The expression informed consent came from the judicial decision in the Salgo v. Leland Stanford Jr. University Board of Trustees, in 1957.[1]

It is also observed that the most expressive ethical and legal documents were realized from the 1970s, coinciding with the fall of dictatorial regimes in Europe. Among these documents the following stand out: the Nuremberg Code (1947), the Belmont Report (1978), the Helsinki Declaration (1964) and the Universal Declaration of Human Rights (1948).

In the current reality, health professionals rely on both the Medical Code of Ethics and national legislation to better ensure patient autonomy.

The Code of Medical Ethics refers to the patient's informed consent on several occasions: it qualifies the patient's autonomy, in the choices related to medical care, as a fundamental deontological principle of medical ethics, and prevents the doctor from not obtaining consent of the patient, or his legal representative, after informing him about the procedure to be performed, except in case of imminent risk of death. [2]

Therefore, it is important to mention that the main cause of the litigation labeled as medical error comes from the unsatisfactory doctor-patient relationship, resulting from the professional's inability to provide adequate interpersonal communication and excel in good quality care. Today, this relationship tends to be impersonal, distrTFUSul, mutual and reciprocal. [3]

The elaboration of the informed consent form is an obligation of the health professional who will provide the service, being a medical act and not from the hospital, clinic or laboratory, where the patient will be informed about the benefits, risks of the procedures and medical treatments to which he will be submitted, which strengthens his confidence. [3]

What is certain is that, failing to do so, the professional can be characterized as an agent of bad faith, by guilt or intention, because only from the exact knowledge of what is offered to him, as well as the risks and benefits to which he will be submitted - it is that the patient agrees or not with the performance of the procedure, thus contemplating the bioethical principle of autonomy. [4]

It is worth mentioning that, the failure of the duty to in-

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form or to obtain consent, today, become the main point of the lawsuits against doctors in many countries. [5]

When dealing with an invasive procedure, especially those performed through interventional imaging, which can cause the patient, in addition to anxiety also discomfort, it is extremely necessary that the side effects listed in the medical literature are very well clarified[5], thus motivating doctors of the importance of learning and retraining through this article.

OBJECTIVE

To present concepts about the informed consent form which are important to the daily practice of sonographer doctors.

METHOD

This is a narrative literature review about the informed consent form. Articles available for free online access, books of legal doctrine, Brazilian legislation, as well as guidelines and resolutions of the Federal Council of Medicine were selected.

RESULTS AND DISCUSSION

The Federal Council of Medicine provided Recommendation 1/2016 to the medical class, which deals about obtaining consent in medical care, justifying the initiative to develop guidelines for doctors on the subject, by the following facts:

a) The evolution, development and expansion of the human rights catalog, remade based on the knowledge of the atrocities perpetrated during the Second World War, including experiments on human beings;[6]

b) Documents that support and stipulate guarantees, rights, duties and ethical references in relation to human beings;[6]

c) The four basic references of bioethics: the principles of (i) autonomy, (ii) non-maleficence, (iii) beneficence and (iv) justice;[6]

d) The guarantee of the dignity of the human person;[6]

f) The need to establish, for all health professionals and institutions, the fact that patients have rights, including to right to decide, freely and autonomously, after being sufficiently informed and clarified, about his submission to any therapy , clinical or surgical procedure that is recommended.[7]

Thus, informed consent has become a mandatory medical practice, equaling to the legal status of freedom, equality and human dignity, since it is a fundamental right of the patient. [8]

In the doctor-patient dialogue, the doctor will elucidate all information about the treatment to which the patient will be submitted, informing all the risks, side effects and consequences of the treatment. In addition, it is necessary for the doctor to not only report one treatment, but to provide information about other possible procedures or even for the patient to receive a second opinion.[10]

For the informed consent term to be complete, it is necessary that the patient obtains the right to choose the form of intervention based on the information received during the dialogue.[10]

The 1947 Nuremberg Court ruling specifically summarizes what the informed and voluntary consent term is, demonstrating that this is essential, since it is the means by which the patient exercises his right of choice after receiving all the information of the procedure he will undergo. [10]

Therefore, the informed consent form constitutes the patient's right to participate in the relevant decisions to his treatment and the physician must alert him about the benefits and risks of the procedure. [11]

Given the subjectivity of this relationship, the form becomes secondary to the real objective of the institute. However, in view of the need for documentary defense in a judicial process, the usual practice of requiring written forms in health institutions must be taken into account. [12]

Thus, taking into consideration the need for documentary evidence, the main characteristics are[13]:

a) Written - containing all written risks and benefits, not just containing the information "the patient was aware of all the risks and benefits ";

b) Understandable - understandable to the patient (to be clear, by the principle of information - without purely technical terms);

c) Informative - with risks and benefits of reaching the different cultures and social classes of patients;

d) Absence of addictions - free from any kind of deception, coercion, intimidation, threat, injury, simulation, error, etc. The term informed consent aims to protect: (i) human dignity, (ii) private autonomy, (iii) beneficence, (iv) non-maleficence and (v) justice; these principles should be used as molds in the physician's performance. [14]

The principle of autonomy is the essence of the informed consent form, since it prescribes respect for the legitimate autonomy of people, for their choices and decisions; these must be truly autonomous or free. Thus, in order to have autonomy, the person's free will is necessary, without defects or vices that may tarnish his will. [14]

The principle of beneficence, on the other hand, describes that the doctor must seek the best treatment without considering the personal manifestations of patients and the principle of non-maleficence implies doing only what is good for the patient. [15]

The term informed consent, from the perspective of the principles of human dignity and justice, aims to exercise the fundamental right to the physical and moral integrity of the person /patient. [15]

It is discussable, when the patient cannot speak for himself or is unable to understand the act to be performed, being the doctor obliged to obtain the consent of his legal guardians, whose name is the substitute consent.

The civil capacity defined as aptitude to perform acts of civil life is defined in articles 3 and 4 of the Brazilian Civil Code, which absolutely excludes minors under 16 years old and those with mental illnesses and in a relative way over minors that are16 and under 18 years old. In the absence of civilian capacity, it is necessary to obtain substitute consent

for the performance of medical procedures. The holder of this right varies according to the factual situation presented and not every kind of relationship gives such a prerogative. [16]

If the minor has been emancipated by his parents, by means of a public instrument or sentence of the judge, he will no longer depend on those responsible to consent. The minor's participation in obtaining consent must be encouraged. It is even suggested that the consent should be obtained in a playful way, with figures and comics, to exercise the better understanding of the patient. [17]

In other cases of disability, the participation of those involved should also be encouraged, based on the assessment of the degree of impairment of the patients' ability to understand.

Patients who, for any reason, have greater difficulty in understanding the information should receive more detailed explanations and adequate to their degree of understanding. The criteria for determining the ability to consent, or even to refuse, includes the assessment of the individual's ability to, upon receiving information, process them in order to understand the questions posed and rationally evaluate the possibilities presented, that is, evaluate values, understand risks, consequences and benefits of the surgical or therapeutic treatment to which he will be submitted. [18]

There may be situations in which the patient denies his consent to perform a certain medical procedure, with serious consequences for his health. In these cases, if there are doubts about his decision-making ability, the doctor should request a specialized evaluation. If the patient is capable to decide and denies consent, the doctor

must register his decision in paper; propose alternatives, if any; give the patient time for reflection; explain the prognosis and consequences; and finally, fill out a refusal form.

Regarding legislation, the following articles stand out:

a) Article 1 of the Federal Constitution: The Federative Republic of Brazil, formed by the indissoluble union of States and Municipalities and the Federal District, constitutes a Democratic State of Law and is based on: (...) III - the dignity of the human person. [19]

b) Article 5, item X, of the Federal Constitution: All are equal before the law, without distinction of any kind, guaranteeing to Brazilians and foreigners residing in the country the inviolability of the right to life, freedom, equality, security and property, in the following terms: (...)

X - intimacy, private life, honor and image of people are inviolable, ensuring the right to compensation for material or moral damage resulting from their violation. [19]

c) Article 15 of the Civil Code: No one can be constrained to undergo, at risk of death, medical treatment or surgical intervention. [20]

d) Article 6 of the Consumer Protection Code: Basic consumer rights are: (...) III - adequate and clear information about the different products and services, with correct specification of quantity, characteristics, composition, quality, incident taxes and price, as well as on the risks they present. [21]

e) Article. 22 of CFM Resolution no. 2.217/2018: The doctor is prohibited from: Failing to obtain consent from the patient or his legal representative after informing him about the procedure to be performed, except in case of imminent risk of death. [22]

f) Article. 24 of CFM Resolution no. 2.217/2018: The doctor is prohibited from: Failing to guarantee the patient the exercise of the right to freely decide on his person or his well-being, as well as exercising his authority to limit him. [22]

g) Article. 31 of CFM Resolution no. 2.217/2018: It is forbidden for the doctor to: Disrespect the right of the patient or his legal representative to freely decide on the execution of diagnostic or therapeutic practices, except in case of imminent risk of death. [22]

CONCLUSIONS

Therefore, consent to the medical act is the acceptance given by the patient to the professional who observes the above requirements. Thus, its validity will depend on the fulfillment of the professional's duty to inform and the clarification and will of the patient.

There is no specific form, in a specific law or in the Code of Medical Ethics, for informed consent in a general manner. This is based on the idea of providing contact between the professional and the patient, thus strengthening their relationship.

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