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Medicine from the blackboard

Ethics for physicians and surgeons: consent

Ética para clínicos e cirurgiões: consentimento

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Introduction

The obligation of the physician to obtain the patient's consent to a certain proposed treatment rests on the ethical principle of autonomy of the patient.¹ In this context, the consent is an "autonomous authorization for a medical intervention," and authorization is given by the patient him/herself.² Accordingly, obtaining the patient's consent should not be an isolated act, but part of the dynamics of the doctor-patient relationship, which include a frank and honest exchange of information between both parties involved, and does not necessarily include the acceptance of the treatment proposed – but also the possibility of refusal.³ Etchells et al. refer to this dynamic as the "consent process".¹

In Brazil, there is a distorted view that obtaining a consent from the patient for a certain procedure or therapy is the best way for the physician to protect him/herself against future legal actions, in case of an unfavorable outcome. This view is not only distorted, it is erroneous: the nature of the doctor-patient relationship allows for several interpretations when it comes to defining professional liability in court. Some authors define it

as contractual, through the duty of diligence,⁴ i.e., professional commitment.

To França,⁵ it is a rental service agreement. However, the topic is controversial. Bueres⁶ acknowledges the divergences in this respect; however, he does not accept the "rental service" idea, as there is no legal subordination in the doctor-patient relationship. Thus, in an area with so many divergent ideas, it shall not be the signature of the patient on a document that he/she hurriedly or improperly read that will protect the doctor. Undoubtedly, the moral aspect of the topic itself is much more important.

After all, what is consent? As previously stated, consent is the "autonomous authorization of a medical intervention[...] given by the patient on an individual basis."² Or, in simpler words, the term refers to the action of an autonomous individual, informed with respect to the procedure or treatment to which he/she will be submitted, agreeing to submit himself/herself to such treatment or experiment (in the case of research).⁷ In short: patients must have the right to decide on their medical treatment and must have the right to receive all information necessary and relevant to make these decisions.

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The concept of “consent”, according to Vaughn, involves some assumptions to be validated. “Typically, an informed consent only exists if, necessarily, the patient is competent to decide; if he/she is properly provided with information; if he/she understands the information provided; if he/she voluntarily decides on the treatment; and finally, if he/she consents to be submitted to the procedure proposed.”⁷

The “competence to decide” roughly refers to the capacity of the individual to render decisions on medical interventions. Individuals incapable in this regard cannot provide an informed consent, and are replaced by a legal guardian. Most of the times, however, it is assumed that adults are competent, unless there are reasons that strongly evidence the contrary.⁸

Generally, minors, patients with mental retardation or dementia, psychoses, and alcoholics are deemed incapable.⁷ But any patient may also be deemed incapable in less clear situations, in which he/she is overwhelmed by fear or pain, for example. Additionally, sometimes patients may be deemed incapable due to loss of some mental functions – as, for example, the ability to communicate their decisions (aphasia), to understand the implications of their choice (or the information received), or to reasonably justify them.⁷ Vaughn states that the incapability can be total or partial. The author often mentions the example of a woman deemed incapable to manage her financial life, but who may be capable to consent to a medical procedure.⁷

It is important to note that obtaining the consent of the patient, as Etchells et al.¹ affirm, is not a superficial event; in fact, it is a process that results from a good doctor-patient relationship. And, although consent holds an apparent meaning of “acceptance” of what is proposed to the patient, the term is also applied to the refusal to receive the treatment offered – and all information relevant to such refusal should be provided to the patient by the doctor.¹ As Bernard Knight states, “freedom against physical interference is one of the basic human rights, and a person with sufficient maturity and mental capacity can choose whether or not he/she wants to receive the medical treatments proposed. With few exceptions, consent to be examined or treated is an absolute prior requirement before the doctor approaches the patient.”⁹

It is necessary to remember that the consent may be expressed or may be implied in the doctor-patient relationship. The express consent may be given orally or in writing. Consent will be implied when indicated by the behavior of the patient when submitted to a procedure. Etchells et al. mention, for example, the case of the patient that extends the arm when a blood sample for laboratory analysis is requested.¹ Knight reminds that, when the patient arrives at the hospital to be submitted to a surgery, he/she is implicitly agreeing with the procedure.⁴

However, for Etchells et al., procedures involving higher risk require a consent, both express and implied¹ they remind that informed consent forms do not replace in any way the “consent process”. Conversely, Knight states that the written consent should be obtained in cases of major diagnostic procedures, general anesthesia, and surgical interventions. He states: “It is important to note that the consent should be obtained for each specific procedure, and the practice of obtaining the permission through a general ‘blank’ form at admission in the

hospital covering the entire length of hospital stay does not have any legal validity.”⁹

There are no fixed rules to obtain the consent in all medical procedures or proper forms for all of them, but in cases in which the risk exists and there is no proper form, the doctor should, as good practice, record in the patient’s medical records that the “consent process” was established.

The importance of the consent

As Knight states, consent is a basic human right.⁹ Additionally, Etchells et al. emphasize that “the notion of consent is based on the ethical principle of patient autonomy. ‘Autonomy’ refers to the right of the patient to make free decisions on his/her medical treatment. Respect for people requires that healthcare professionals do not proceed with non-desired interventions and enable the patients to have control over their own lives.”¹

The legal issue in this regard is more subject to controversies. Some countries, such as Canada and the United States, have accurate laws on the subject. To treat patients without their consent constitutes abuse and imprudence, and to treat based on an improper informed consent constitutes negligence.¹

In Brazil, the Resolution 196 of the Federal Medical Council is specific regarding the requirement to obtain an informed consent from research subjects. For the typical patient, in everyday life, the Code of Medical Ethics, in the section related to human rights, establishes that “the physician may not fail to obtain consent from the patient or his/her legal guardian after explaining to him/her the procedure to be performed, except in case of imminent risk of death” and also “[the physician may not] fail to ensure to the patient the exercise of the right to freely decide regarding himself/herself or his/her welfare, and [the physician may not] exercise his/her authority to limit it”.¹⁰ However, this issue is not very clear in the Penal and Civil Codes, even though the Consumer Protection Code (Law 8078 of September 11, 1990) – if we accept, as mentioned above, that the doctor-patient relationship is a “rental service” relationship – in its article 6, item III, determines that “proper and clear information on the different services” that shall be rendered to him/her is a basic consumer right, as well as the forbiddance to (in tem IV) “execute services without express authorization of the consumer” .

Consent in the doctor-patient relationship

There are empirical studies that reinforce the need to properly obtain the patient’s consent to the procedures to which he/she will be submitted. In a review on this topic, published in 1995, Stewart demonstrated that good communication between the patient and his/her doctor improved the patient’s emotional state, the resolution of symptoms and functions affected, as well as the pain control and reduction in stress and negative feelings.¹¹

In spite of that, a lot of doctors found it difficult to find the right way to approach the patient in order to obtain his/her consent, including regarding which information should be

provided. Vaughn⁷ proposes that, despite the difficulties, in general, some points are mandatory among those that should be informed to patients, namely:

- 1) Type of procedure (e.g., if it is an examination or a therapeutic procedure, whether it is invasive, and how long it takes to be performed);
- 2) Risks of the procedure (what type of risks are involved, their severity, probability of occurrence, and when they may occur);
- 3) Alternatives to the proposed procedure – including the option not to treat (also include information about the nature and risk/benefit of these options);
- 4) Expected benefits of the proposed treatment – including the extent, and how these benefits will be obtained.

Conversely, the doctor should remember that when the patient looks for a doctor, he/she feels like (as Engelhardt Jr. says) “a stranger in a strange land”.¹² The author states: “when the patient looks for a healthcare professional, he/she is in an unfamiliar territory. In this context, he/she is a stranger, an individual in an unfamiliar territory, who does not know what to expect or how to control the environment. Therefore, the patient’s usual way of thinking should be properly followed or changed in order to include the physician’s theories and explanations and the medical and hospital environment routine. (...) Like a stranger in a strange land, the patient is at risk of becoming a marginal individual”.¹²

Nonetheless, there appears to be a certain consensus that doctors are not required to obtain their patients’ prior consent in all situations: “the doctor duty to obtain an informed consent has exceptions”, Vaughn states.⁷

“The consent is frequently not required in emergency situations, when stopping to obtain the consent may cause severe damage to the patient”. By law, “an emergency happens when it requires immediate treatment in order to save a person’s life or preserve his/her health”.¹ However, the “exception in case of emergency” has limits. Doctors should not perform emergency treatment without consent if they have reasons to believe the patient would refuse it if he/she was able to choose.

A patient’s eventual disability does not exempt the doctor from obtaining consent. Etchells et al. affirm that “if a patient is mentally incapable of taking medical decisions, the physician or surgeon must obtain a substitute’s or his/her legal guardian’s consent”.¹ This point of view differs from that expressed by Vaughn, who suggests that the “informed consent is not necessary when the patient is disabled”.⁷ The position of Etchells et al. is believed to be much more suitable for the Brazilian reality.

Conversely, it is also not necessary to obtain consent when the patient waives his/her right to express willingness, relinquishing relevant information on his/her case. “It is an exercise of autonomous decision the choice of not choosing or deciding. The authority to decide which is the correct choice is transferred to the physicians or to the legal guardians by the patient”.⁷

Another controversial exception is the “therapeutic privilege” i.e.: failure to supply relevant information to the patient when the physician believes such information may

cause damage to the patient. “The idea behind this conduct is that some patients are so distracted, depressed or weak that such information may aggravate the disease”.⁷ This exception, demands restricted, careful use. Despite acknowledging that the doctor’s intuition (and his/her autonomy to decide whether or not a certain fact should be disclosed to the patient) should be considered, misuse of the “therapeutic privilege” merely to avoid the obligation of giving bad news to the patient or to prevent a potential rejection of the proposed treatment does not appear to be a morally acceptable attitude in the medical practice.

It also appears to be obvious that an informed consent cannot be considered as such unless the patient clearly understands the information provided. The patient’s understanding is crucial for a valid consent. It is important both for physicians, on a daily basis, and for researchers. Costa Miranda et al., referring to research subjects (which may probably be applied to common patients) and also to the informed consent form used, concluded that “the level of difficulty of the informed consent forms is inconsistent with the education of our population”.¹³

Less obvious is how much “understanding” is necessary. For Vaughn, “the informed consent requires, at least, that the patient receives the relevant information and evaluates it so he/she can understand the consequences of his/her choice. Patients are not required to fully analyze the information received, but to understand what is most relevant to make their decisions. And their refusal to the treatment proposed should not be deemed an evidence that they did not understand the issue.”⁷

The obstacles to an easy understanding by the patients are numerous. It may be a result of the patient’s lack of intellectual capacity to understand what is explained. But it may also result from a deficiency of the doctor him/herself, who expressed the information in an incomprehensible manner or through jargon incomprehensible to the layman. Or further, the information to be transmitted may be “unevenly balanced” (e.g., overstating the risks and mitigating the benefits of a certain procedure, or vice-versa). Additionally, the patient’s ability to process the information received may be negatively affected by fear, psychological mechanisms of denial, illusions, or false beliefs. At this point, Kuczewski and Pinkus recommend: to allow the family be with the patient throughout the treatment, which may be useful to make the correct decision, and also to keep the patient calm and less afraid during the therapeutic process.⁸

It is important to mention that these aspects do not invalidate in any way the informed consent, nor allow the doctor to simply “provide information to the patient” – they only make the process slower, requiring extra care to be successfully completed.

Lastly, the decision to consent should be voluntary. The consent of an informed and capable patient that understood the information received “cannot be validated unless provided voluntarily”⁷ – i.e.: freely, under no external pressures. Coercion and manipulation are the most common external pressures,⁷ according to Vaughn. Some philosophers, he continues, define coercion as the intentional use of a severe threat to produce damage or force control over another person.

The following are forms of coercion: threat of abandonment, unless the patient undergoes the treatment proposed; threat of discharging the patient in case he/she does not agree with what was proposed, etc. Manipulation refers to different non-coercive ways to control the actions of another person – as, for example, providing false or overstated information, or even omitting relevant facts regarding the proposed treatment/procedure. The use of the “therapeutic privilege” to control the patient’s decision is, obviously, a form of manipulation and, according to Vaughn, has a negative impact on the informed consent.⁷

Final considerations

The everyday life of doctors and patients is full of social influences on the acts of each person, his/her beliefs, and ways of thinking. However, these influences cannot prevail over the autonomy of each individual. Doctors may influence their patients through rational arguments, emotional appeals, or even scientific authority. Under any of these situations, the line that separates voluntary consent from involuntary consent is very tenuous. Ideally, to consent is much more than to agree. When a patient authorizes his/her doctor to perform a certain therapeutic procedures/diagnoses, “he/she is not only saying yes”,⁷ but he/she is also becoming responsible for the autonomously taken decision and for understanding the facts. It is very different from the simple act of signing a paper that he/she has barely read. And, by participating in the decision-making process, he/she greatly increases his/her chances of success.

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