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UPDATE

The doctor-patient relationship in the perspective of the CFM 1/2016 Recommendation

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Abstract

For a long time, the doctor-patient relationship has presented strong signs of paternalism, in which the physician assumed his or her paternalistic role, directing the patient and deciding on the treatment. The paternalistic nature of this relationship has been weakened with the evolution of the principle of patient autonomy, making it necessary to establish a more horizontal communication. Recommendation 1/2016 on free and informed consent published by the Conselho Federal de Medicina (the Brazilian Federal Council of Medicine) in 2016, makes the physician responsible for developing an intersubjective relationship with the patient, in order to establish a more symmetrical and egalitarian connection. This article proposes to analyze the concepts of autonomy and capacity according to the Civil Code and bioethics and how intersubjective communication between doctors and patients can help in the secure obtaining of consent.
Keywords: Bioethics. Physician-patient relations. Informed consent. Personal autonomy.

Resumo

A relação médico-paciente na perspectiva da Recomendação CFM 1/2016

Por muito tempo, a relação médico-paciente apresentou fortes traços de paternalismo, com o médico dirigindo o paciente e decidindo sobre o tratamento. Com a evolução do princípio da autonomia do paciente, o paternalismo dessa relação se fragilizou, tornando-se necessária comunicação mais horizontal. A Recomendação do Conselho Federal de Medicina 1/2016, que trata do consentimento livre e esclarecido, atribui ao médico a responsabilidade de desenvolver relação intersubjetiva com o paciente, estabelecendo conexões mais simétricas e igualitárias. Este artigo propôs analisar, a partir do Código Civil e da bioética, os conceitos de autonomia e capacidade, buscando entender como a comunicação intersubjetiva entre médico e paciente pode auxiliar a obtenção segura do consentimento.
Palavras-chave: Bioética. Relações médico-paciente. Consentimento informado. Autonomia pessoal.

Resumen

La relación médico-paciente en la perspectiva de la Recomendación CFM 1/2016

Por mucho tiempo, la relación médico-paciente presentó fuertes rasgos de paternalismo, con el médico dirigiendo al paciente y decidiendo sobre el tratamiento. Con la evolución del principio de autonomía del paciente, el paternalismo de esta relación se fragilizó, tornándose necesaria una comunicación más horizontal. La Recomendación del Consejo Federal de Medicina 1/2016, acerca del consentimiento libre e informado, atribuye al médico la responsabilidad de desarrollar una relación intersubjetiva con el paciente, estableciendo conexiones más simétricas e igualitarias. Este artículo propuso analizar, a partir del Código Civil y de la bioética, los conceptos de autonomía y capacidad, procurando entender cómo la comunicación intersubjetiva entre médicos y pacientes puede ayudar en la obtención segura del consentimiento.
Palabras clave: Bioética. Relaciones médico-paciente. Consentimiento informado. Autonomía personal.

Declara não haver conflito de interesse.

Patient capacity and autonomy

In 2016 the Conselho Federal de Medicina - CFM (Brazilian Federal Council of Medicine) published CFM Recommendation 1/2016 [1] on the free and informed consent for medical assistance. The recommendation suggests to the physician to remove, from the relationship with the patient, the paternalistic character that has defined it for a long time, proposing a closer, horizontal relationship. In this way, the autonomy of the patient, subject of rights and who must be aware of diagnoses, prognoses and indicated treatments, would be respected. The idea is that clear and objective information ensure more safety to the medical act and allow the patient to consent or decline the proposed therapy.

The 2018 Código de Ética Médica - CEM (Code of Medical Ethics) [2] this and some resolutions of the CFM and regional councils had already dealt patient autonomy and the ethics of the termo de consentimento livre e esclarecido - TCLE (free informed consent form) applied to the medical practice. However, CFM Recommendation 1/2016 [1] is one of the few Brazilian regulations that sets out in detail the process for obtaining patient consent. Likewise, there is no ordinary regulation in the legal system regarding free and informed consent, as in other countries such as Spain, for example [3].

The Código de Defesa do Consumidor (Brazilian Consumer Defense Code) [4] considers the nature of the doctor-patient relationship to be contractual; however, care should be taken in judging this relationship from the commercial perspective, considering the need to consider the idiosyncrasies and vulnerabilities of the subjects. The physician-patient relationship should not be treated in a simplistic and normative way, as a mere contract. Ethical reflection that respects the subjects involved is necessary to ensure that the patient's will is protected and the medical performance safeguarded. Likewise, when judging lawsuits, the magistrate must make a transdisciplinary analysis of the subject, taking into account the Brazilian legislation, the guidelines of the medical councils and the principles of bioethics.

In the preamble to CFM Recommendation 1/2016, "free consent" is defined as the *act of decision, agreement and approval of the patient or his or her representative, after the necessary information and explanations under the responsibility of the physician regarding the diagnostic or therapeutic procedures that are indicated* [1]. To practice an act of decision, agreement and approval, it is assumed that the patient has the capacity and autonomy to understand the information received about their health and to deliberate freely.

As explained in section 7.2 of the annex to this recommendation, "capacity" is the basic element of consent and can be defined as the necessary fitness for a person to personally perform the acts of civil life [1]. Maria Helena Diniz [5] points out the fact that *capacity is the legal measure of personality, that is, to be able to act by oneself, the person must meet requirements of the Brazilian legal system. In this way*, if they have any legal restrictions on the acts of civil life, they must rely on assistance or representation, depending on your age or disability.

As regulated by art. 1 of the Civil Code, every person is capable of rights and duties in civil order [6]. For this reason, disability is an exception, with hypotheses always provided for by law and must be strictly considered. Articles 3 and 4 describe absolute and relative hypotheses of incapacity, constituting norms of public order since the restriction imposed prevents the incapable person from performing certain acts of life, which would be left to the individual will for the capable persons [5].

In the civil field, "capacity" means aptitude to practice legal acts - the legislator imposed in the Brazilian Civil Code of 2002, in its article 3, that subjects under 16 years of age are absolutely incapacitated; and, in Article 4, that those over 16 and under 18 years of age are relatively incapacitated. In the same article, it is also stated that the following are incapable, in relation to certain acts or the way of exercising them, habitual drunks, drug addicts, prodigals and those who, because of transitory or permanent cause, can not express their will [6].

Considering that subjects under the age of 18 can not manifest themselves in relation to their own health is a remnant of the patriarchal society, given that, at present, young people mature earlier due to greater access to information and to the very evolution of society. Thus, adolescents of 12 or 13 years are often able and have the autonomy to decide on their bodies and quality of life [7]. In addition, it must be considered that even the right to vote is available to young people from the age of 16 years.

When we take into account the incapacity imposed by the Civil Code, we are, at the outset, violating the autonomy of the patient. Segre, Silva, and Schramm argue that *the intervention of the physician on the patient, or, extending the reach,*

of the health worker on the patient, can only be admitted - in the autonomistic view - when the latter asks for help [8]. Otherwise, can parental authority prevail over minors, or the social interest of the state over persons in need of legal intervention, such as drunks and drug addicts? [8]

To the claim that drug use, religious fanaticism or a brain tumor are already, in the first instance, obstacles to autonomy, we will respond that each of us surely obeys the most varied influences on our own conduct and that therefore, within the reality of each individual (and this is what counts), autonomy must, at the very least, be understood [8].

In the book Direitos do Paciente ("Patient Rights"), Rachel Sztajn points out that, for bioethicists, autonomy is the person's ability to decide on their life without any coercion. However, it is worrisome to transform the power of self-government toward health into an obligation. By changing the physician-patient relationship, previously paternalistic, in a purely contractual relationship, the health professional can see the patient simply as a consumer. What used to be a relationship of trust turns into banal consumption, converting the obligation of means into the obligation of a result [7].

Considering the rules about capacity of the Civil Code as a synonym of autonomy may not be enough for the patient to decide on their treatment. To adhere only to legal rules is to underestimate the meaning of free and informed consent, which is not only legal regulation, but the patient's right and the moral obligation of the physician, who must try to establish effective communication to make his relationship with the patients symmetrical [9].

In turn, Rui Nunes conceptualizes autonomy as *the perspective that every human being should be truly free, having the minimum conditions to self-realization* [10]. However, he understands that autonomy is not limited to the patient, especially in the case of children, adolescents and people who have reduced discernment. Consideration should also be given to family autonomy, which extends to other family members the power to decide on interventions that require free and informed consent [11].

For the physician to consider an individual autonomous, the person must understand the material facts, the prognosis of the disease, the alternatives of treatment and their consequences. The doctor must explain the risks involved, even if remote, so the patient can consent or refuse the options offered. In addition, in order for consent to be clearly informed, it is important that the health professional clearly states the individual's illness [7].

It is a recent understanding that there must be more interaction in the communication between doctors and patients, prioritizing respect for autonomy. Before, paternalism was prioritized, based on the Hippocratic understanding that the physician, holder of the scientific knowledge, could and even should decide on the most appropriate treatment. Thus, in the past, asymmetry in the physician-patient relationship was natural and evident. In order to decide the "best", the physician determined the treatment to be adopted, often contradicting the patient's own will [7].

In the hippocratic relation, analyzing the question of ability has no meaning, since the physician assumes the main role, determining the treatment, while the patient remains submissive within the hierarchical relation. However, when establishing the autonomy of the patient, the professional must investigate their will and work with understandable information, without making their indication prevail, so that the patients manifest themselves freely [7].

In the introduction to its annex, CFM Recommendation 1/2016 specifies that *the principle of respect for patient's autonomy has become, in the last decades, one of the main conceptual tools of applied ethics, being used in opposition to the so-called medical paternalism* [1]. However, conceptualizing "autonomy" is not the easiest task, since its definition is broader than that of civil capacity, but, in bioethics, we find some important guidelines and principles for the analysis of the theme.

According to Goldim, perhaps the earliest record of the word "bioethics" dates back to the German Fritz Jahr, who, in 1927, characterized it as the recognition of ethical obligations, not only in relation to the human being but to all living beings [12], proposing the bioethical imperative, according to which every living being should be respected and treated as an end in itself.

Diniz and Guilhem [13] report that in 1971 the American oncologist and biologist Van Rensselaer Potter published the book "Bioethics: a bridge to the future", considered to date the historical milestone of the origin of this field of knowledge. Also at that time, in which studies in the field of human reproduction were being developed, André Hellegers related the term "bioethics" to biomedical ethics, using it institutionally when founding, in

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1971, the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics [14].

In 1974, the US Congress, concerned with the control of research on human beings, set up a national commission to study the ethical principles that should underpin scientific research. Three important cases had an impact on public opinion and influenced this study: in 1963, live cancer cells were injected into sick elderly patients at the Israelite Hospital in New York; between 1950 and 1970, the hepatitis virus was injected into mentally ill children at Willowbrook State Hospital, New York; and from 1940 to 1972 (despite the discovery of penicillin in 1945) in Alabama, four hundred blacks with syphilis were left untreated for the natural course of the disease to be studied [15].

In 1978 the results of the study of the commission, known as the Belmont Report, were published, with wide repercussions in the medical-scientific community. However, this report concerned issues relating to research with humans, and its focus was not the clinical practice.

In 1979, in their "Principles of Biomedical Ethics", Tom Beauchamp and James Childress [15] established as guidelines the respect for autonomy, beneficence, non-maleficence and justice. Initially, these principles were conceived without hierarchy, applying the most appropriate one according to the study of the concrete case. However, because the United States is a country that understands the doctor-patient relationship as contractual, the principle of autonomy has been prioritized. As Beauchamp and Childress state:

There is in medicine the temptation to use the authority of the physician role to foster or perpetuate patient dependency, rather than to promote autonomy. The fulfillment of the obligation to respect the autonomy of the patient, however, requires empowering them to overcome their sense of dependence and obtain the greatest possible control or the control they desire [16].

Rui Nunes points out that the principles established by Beauchamp and Childress *reflect the secularization characteristic of Western societies, which seem to imply a prevalence of individual self-determination over other fundamental human values such as social responsibility or human solidarity* [17]. These ethics focused on the right to self-determination and the dignity of the person was one of the major cultural changes of the late twentieth century. Therefore, one of the criticisms of principlism is that it would not embrace classical ethics. However, as Nunes explains:

The formulation of the principles aims to meet the plural collection of modern Western societies and the ethical minimum that cuts across the different cultures of humanity. Ethical construction and reflection are discussed, and the concept of common morality is suggested, not a systematized ethical theory. This is a less ambitious goal than has been hoped for in the past, but more in line with the multicultural consecration of human rights [18].

From the book "Principles of Biomedical Ethics", bioethics has been restricted from its original conception, of being more concerned with the human being and the environment, to limit itself to the field of biomedicine. And, as Volnei Garrafa states, *the theme of autonomy was maximized hierarchically in relation to the other three, becoming a kind of super-principle* [19].

This idea of maximizing autonomy was disseminated internationally from the 1970s and was consolidated around the world in the 1990s. Although relevant, the other three principles did not have the same importance, and the notion that it was important to treat conflicts individually and not collectively, as the principle of justice proposed.

With this understanding settled, in order to avoid judicial demands in care relations and scientific research, the application of the free informed consent form has become fundamental. In addition, this understanding instrumented industries, universities and corporations, which began to apply terms of informed consent specific to each situation, distorting the initial concept of bioethics, which provided for the protection of the most vulnerable. In the early 1990s, the principlist theory came to be questioned, but only since 1998, with the IV World Congress of Bioethics, have new ideas been incorporated:

At the end of the twentieth century, therefore, the discipline began to expand its field of study and action, including, in the analyses of the question of the quality of human life, subjects that until then only touched its agenda, such as the preservation of biodiversity, the finitude of natural resources, the balance of ecosystems, genetically modified foods, racism and other forms of discrimination, as well as the issue of prioritization in the allocation of scarce resources, the access of people to public health systems and medicines, etc. [20]

A major milestone in bioethics was the development in 2005 of the *Universal Declaration on Bioethics and Human Rights* (UDBRH) [21], a document that brought together fifteen principles applicable in medicine and scientific research, based on the dignity of the individual, respect for human rights and in the defense of individual freedoms. These universal principles have come to guide practitioners especially in cases where moral dilemmas prevail. In addition, it is important to point out that ethical reflection should be part of scientific development and medicine, with bioethics having a fundamental role in evaluating the characteristics and vulnerabilities of each society, and particularly of each individual.

Articles 5, 6 and 7 of the UDBRH deal with autonomy and consent. Article 5 deals with autonomy and individual responsibility, establishing that the autonomy of the subject must be respected; in the case of persons incapable of exercising it, their rights will be protected. Article 6, which deals with consent, establishes that in any medical or scientific intervention the prior, free and informed consent of the individual is necessary, after due clarification. Article 7 provides special protection for those unable to express their will. The Declaration of the United Nations Educational, Scientific and Cultural Organization (Unesco) [21] also provides, in Article 8, for respect for human vulnerability and for personal integrity.

The CFM Recommendation 1/2016 [1] is based on the principles outlined by Beauchamp and Childress [16]. Currently, intervention bioethics recommends that concrete cases be evaluated also in accordance with the principles established by the UDBRH [21], taking into account the vulnerabilities of each subject and the country in which the medicine is being practiced. In Brazil, where there is profound social inequality, it is fundamental to consider the material, social and intellectual vulnerability of the subjects in order to overcome the barrier of ignorance and to enable effective and efficient communication between the physician and the patient.

The physician must inform the patient about their health condition, diagnosis, prognosis and indicated therapeutics. This obligation does not transfer to the patient the responsibility for the medical act but gives them the possibility to interfere in the treatment, to give an opinion about what will be done with their body and, consequently, to make choices that will define their quality of life. When this is the case, the patient should request help from relatives or caretakers and even the intervention of the very physician, so that the physician prescribes specific treatment, respecting the principles of beneficence and non-maleficence.

It is the duty of the physician to assess the autonomy of the patient, considering their vulnerabilities. However, obtaining free and informed consent will depend on the subjective view of the health professional, who may consider the patient autonomous or non-autonomous. When they consider the patient to be non-autonomous, the physician risks underestimating them, not informing the facts clearly.

In addition, due to the vulnerabilities and stages of the disease, it is possible that during treatment, the patient may lose part of their autonomy, losing the ability to deliberate on the next steps. In these cases, the subjective look of the physician will be an important factor.

In any case, the shortcoming of the Brazilian legislation regarding TCLE causes legal uncertainty to those involved, since the physician may be held liable for unforeseen or unwanted results, and the patient may undergo non-consenting procedures, therapeutics or surgeries.

Free and informed consent and consent form

Free consent is the result of the respectful relationship between physician and patient, free from flaws such as coercion or embarrassment. To consent is to allow, to approve, to agree - it is presumed that the patient voluntarily agrees to the proposed treatment after receiving the proper explanations about his illness and the possibilities of treatment and cure. For this consent, the patient must be considered fully capable and autonomous, that is, they must be in possession of their mental faculties, without any legal impediment.

It is important to differentiate free and informed consent from the TCLE. While the former results from good medical care, in which the health professional establishes assertive and effective communication with the patient, the latter is a formal term signed by both the patient and the health professional in medical practice and in scientific research.

The Conselho Regional de Medicina do Estado de São Paulo - CREMESP (Regional Council of Medicine of the State of São Paulo), in its opinion 124.460 / 2011 [22], presents two interpretations

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on the TCLE. The first has a legal character and understands the term as a practice of defensive medicine, a formal document signed by the physician and patient, which may be evidence for the benefit of the physician in eventual judicial or ethical lawsuits. The second interpretation is based on bioethics and good communication between the two parties, developing an intersubjective relationship that aims to protect the patient and encourage them to participate in decisions about their health, respecting the principle of dignity.

The disease causes vulnerabilities and the subject often feels diminished in relation to other people. When one perceives oneself ill, that is, with diminished productive capacity in all areas, the person seeks help. At that moment, the physician, that is, the one to whom the institutions assigned technical competence, takes control of this fragile relationship since he is the agent with the power to diagnose and propose therapies. The subject, in accepting this relationship, becomes a patient and, in this way, loses part of the control of their life, since they must entrust it to the physician, following the behaviors prescribed:

If one can speak of the dignity of the human person somewhere - this is the case. The body torn by disease must find in the pragmatic-semantic environment a relief valve. It needs to be recognized as another plan of motives and desires. They need to receive an education that allows them to learn their new state - the therapist leads them from the point of departure of doubt, insecurity and fear, and transforms them into a clinical subject, that is, in a subject capable of understanding their state, the possible evolutions, and participant in the decisions that lead to the possible outcome of this state of affairs, since this is where lies the limited human freedom [23].

Becoming aware of the importance of communication between the physician and the patient is essential if the barriers between the physician's scientific knowledge and the patient's need to better know their condition are overcome. Sending clear information to the patient allows them to feel more confident in making decisions about treatment, and can deliberate with the confidence and the desired autonomy, from which they will take responsibility for his choices.

The professional does not have all the information about how the treatment can evolve, there are always uncertainties and risks. The unknown is the subjective probability, and the risk is the objective probability, which opens the possibility for several situations. José Roberto Goldim explains that *to consider the unknown risk as being null is an unfortunately used misapprehension. If the risk is unknown it is because it has not yet been reported. This is not to say that it will not occur* [24]. It is presumed, therefore, that sharing the ignorance of unpredictable situations with the patient is the moral responsibility of the physician.

In Brazil, the Legislative Branch has not yet regulated TCLE in medical practice, as has already occurred in countries such as Spain [3], which made the term mandatory in surgical procedures and invasive examinations. The available documents that guide the consent term are CFM Recommendation 1/2016 [1], the Code of Medical Ethics [2], CFM Resolution 1995/25 [25] and Resolution 466/2012 of the Conselho Nacional de Saúde – CNS (National Health Council) [26], edited by the Ministry of Health, which regulated it in scientific research with human beings.

Resolution CNS 466/2012 [26] defines the free and informed consent in scientific research as the consent of the participant or their legal representative, without any flaws, after the necessary clarifications regarding the research objectives, nature, methods, benefits, and risks. For the consent to be accepted, the resolution establishes a set of steps. The first one consists of clarifying the research, in clear and accessible language, respecting the characteristics of each volunteer, such as age, limitations, autonomy, etc. After the necessary explanations and the necessary time for the deliberation of the volunteer, they can read and sign the document. In item "c" of section IV.4, the resolution establishes that it clauses are forbidden in which the participant waives the right to compensation for eventual damages.

In turn, Resolution CFM 1995/2012 [25] deals with the anticipated will directives. The patient, while capable and autonomous, manifests their desire to receive or not receive certain treatment and, when a situation of incapacity occurs in which they can not express themselves, their directives should be considered by the doctor. This patient statement will prevail over any non-medical opinion, including that of family members. However, if the directives are in disagreement with the precepts dictated by CEM, the physician should disregard the patient's will.

The 2018 CEM [2] briefly addressed the patient's consent without going into too much depth as Recommendation 1/2016 did. The Code - in the

"Fundamental Principles", item XXI - provides that the patient can propose diagnostic and therapeutic procedures, and the physician must accept these choices if they are appropriate to the case and scientifically recognized, respecting their conscience and legal provisions.

In "Chapter IV – Human Rights", article 22 states that the physician is prohibited from not obtaining consent from the patient or his legal representative after clarifying the procedure to be performed, except in case of imminent risk of death [2]. Article 24 of the same chapter prohibits the doctor to contradict the patient's right to decide freely about their person and well-being or to exercise their authority to limit it. There are also other references in the CEM regarding consent, making it mandatory in the medical practice, with registration in medical records and a written form when necessary.

The Federal Council of Medicine [1] it considered, in developing CFM Recommendation 1/2016, the little information available on consent, the timing of the consent, and how to document it. The text mentions the Federal Constitution of 1988 and recognizes in the introduction of its annex the principle of the dignity of the human person as the foundation of the Brazilian State itself:

Under the ethical-legal prism, human dignity is the autonomy of the human being, that is to say, it consists in the intrinsic freedom, proper to the nature of the person, who is endowed with reason, to be able to decide freely and by oneself (free will) about matters that concern them, especially about their intimacy and privacy. The individual is a shaper of oneself and of their life, according to their own spiritual project [1].

The CFM recommendation considers free and informed consent as the duty of the physician and the right of the patient, and the process for obtaining it should not be seen as a bureaucratic act, but as a stage of communication between the two, having a triple function.

The first is to respect the freedom of choice of the patient, translating this freedom as autonomy. After the necessary clarifications regarding the diagnosis, the indicated procedures and the suggested therapy, the patient can then decide autonomously. The second function is to foster the intersubjective relationship between the two parties, narrowing the bond between the two. Finally, the third function is to define parameters of professional performance, also based on this communication.

According to CFM Recommendation 1/2016 [1], initial elements, information elements, and understanding of information are necessary for obtaining consent. Initial elements are considered in evaluating the patient's behavior: whether they are able to receive the information, whether they are prepared to receive it, and whether the situation is favorable to the autonomous decision. If the patient is not fully prepared, the doctor can "fractionate" the information in order to protect them. If there are doubts about the autonomy of the patient, the professional should consider whether, in a general way, the proposed therapy and the risks and benefits of the treatment were understood.

Informative elements refer to the presentation of the situation, the diagnosis, the indicated therapies, the risks of the treatment and other information that may arise in the doctor-patient interaction. The professional must be sensitive to clarify the patient's doubts so that autonomous decisions are possible, not attaching to technical and unnecessary details for the understanding of the case. The CFM [1] recommends that the physician be clear and include, in addition to information on the disease and the justification of the treatment, the exposure of the risks, side effects and possible therapeutic complications. In addition to the material information, in cases with a negative prognosis, the physician should be prepared to listen to the patient and, respecting their momentary fragility, to clarify their doubts with interest and tolerance.

Understanding the information depends on the previous steps. If the initial and informative elements were well considered, the patient will then be able to understand their condition and accept or decline the proposed therapy or choose other suitable alternatives.

In emergency situations, it may not be possible to obtain the consent of the patient. In these cases, the physician must observe the principles of beneficence and not maleficence and, if appropriate, the anticipated directives of will. There are cases where the patient refuses to decide or maintain intersubjective communication with the physician. In these situations, if it is the will of the patient that the physician decides, the same principles must be respected.

There are also situations of serious risk to public health, such as patients diagnosed with a communicable disease who neglect or refuse

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medical treatment. In such cases, if there is no agreement of the patient, after all attempts have been frustrated, compulsory treatment is justified, which must be reported in medical records and, when necessary, to the competent authority. CFM Resolution 2.057/2013 [27] allows for the treatment without consent in exceptional situations, for example, compulsory hospitalization of patients with mental disorders, which may be requested by the family, by the physician or judicially determined.

Consent may be verbal or written. When written, the patient should have the opportunity to read the document calmly, talk to family members, write down questions, and return to the doctor for further explanation. It is also possible that consent is recorded as a complementary instrument. For invasive exams, surgeries, and other more complex procedures, the CFM recommends that the physician use the TCLE.

In any case, consent should only be given when there are no doubts that could affect the treatment. The validation of the information, i.e., the medical initiative to confirm the understanding of the message, asking and repeating some words that demonstrate the understanding of the patient, is also part of the process. It is the validation that allows the physician to make sure the assimilation of what was agreed in the communication.

CFM Recommendation 1/2016 [1] directs the TCLE to have clear, easy-to-understand language and avoid technical terms and foreign words. It is recommended that the TCLE be printed and that the font size be readable, with spacing between rows for more comfortable viewing and whitespace for the patient to fill, or alternatives they may point out. After signed by the patient, the blanks must be invalidated so that subsequent fill-ups do not invalidate the entire document. In accordance with subsection 9.1.3 of the recommendation, it shall be stated in the TCLE:

a) Justification, objectives and brief, clear and objective description, in accessible language, of the procedure recommended to the patient; b) Duration and description of possible discomforts in the course of the procedure; c) Expected benefits, risks, alternative methods and possible consequences of not carrying out the procedure; d) Care that the patient must adopt after the procedure; e) Patient's statement that he is duly informed and clarified about the procedure, with his signature; f) Declaration that the patient is free not to consent to the procedure, without any penalty or without prejudice to their care; g) The physician's statement that they clearly explained the whole procedure; h) Full name of the patient and the physician, as well as, when applicable, of members of the team, the physicians address and telephone contact, so that they can be easily located by the patient; i) Signature or identification by fingerprint printing of the patient or their legal representative and signature of the physician; j) Two copies, one to be kept by the patient and one to be filed in the medical record [1].

Final considerations

The CFM recommendation 1/2016, which deals with the process of obtaining free and informed consent in medical care [1], is the most complete orientation on assertive communication between the physician and the patient in Brazil. This recommendation is not intended to encourage the practice of defensive medicine, but to encourage good communication and the intersubjective relationship between both parties.

The current precariousness of Brazilian medicine and health should not justify the deterioration of the physician-patient relationship. It is important that the professional tries to establish communication channels, developing empathy and trust, to minimize the natural asymmetry of this relationship.

Based on the constitutional principles, every patient has the right to express himself or herself in relation to the treatment proposed by his physician, putting into practice the free and informed consent after the science of diagnosis and prognosis of his disease.

As a continuous process, involving direct interaction between the physician and the patient, doubts should be clarified at any stage of the treatment, whenever they arise. The patient, as a subject of rights, can also revoke their consent, without being penalized by the choice.

As stated, this free and informed consent is different from the TCLE. According to the Code of Medical Ethics [2], free consent is mandatory in medical practice and the process and result of a trust relationship between professionals and patients. It can be verbal or written and should be registered in medical records. On the other hand, the TCLE is recommended by the CFM in more complex procedures, such as invasive examinations and surgeries, among others, not being necessary in all cases.

By considering communication and trust as essential elements of the physician-patient relationship, the natural gaps and asymmetries of this relationship can be overcome, and subjects, with their vulnerabilities and insecurities, can have their dignity respected. Patient empowerment - obtained with information about the disease, treatment alternatives, and prognosis - allows decision making in a safer, more confident and autonomous way, which can facilitate treatment evolution and restore health, as well as providing more credibility to the medical act.

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