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Perception of resident physicians about the informed consent form

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Abstract

The right to information about medical procedures is the basis of a good physician-patient relationship and, together with bioethical principles, ensures respect for patient autonomy. From this perspective, this descriptive research with a qualitative approach sought to understand the perception of resident physicians about the informed consent form. Data were collected using remote semi-structured individual interviews. Complying with the methodological criteria, the information obtained was classified into three categories: 1) perception, knowledge, and construction of the informed consent form for medical procedures; 2) social and legal function of the informed consent form; and 3) relevance of the patient's capacity, temporality, and provision of the form to the patient. The importance of bioethics, legislation, and the preparation of medical consent in a practical and theoretical environment was highlighted to consolidate an adequate physician-patient relationship.

Keywords: Physician-patient relations. Duty to warn. Informed consent. Principle-based ethics. Medical staff, hospital.

Resumo

Percepção de médicos residentes sobre o termo de consentimento esclarecido

O direito à informação sobre atos médicos sustenta a boa relação médico-paciente e, juntamente com os princípios bioéticos, garante o respeito à autonomia do paciente. Considerando isso, esta pesquisa descritiva de abordagem qualitativa buscou apreender a percepção de médicos residentes sobre o termo de consentimento esclarecido. A coleta de dados ocorreu mediante entrevista individual semiestruturada aplicada à distância. Em conformidade com os critérios metodológicos, as informações obtidas foram classificadas em três categorias: 1) percepção, conhecimento e construção do termo de consentimento esclarecido para atos médicos; 2) função social e legal do termo de consentimento médico esclarecido; e 3) relevância da capacidade do paciente, da temporalidade e do fornecimento do termo ao paciente. Ressaltou-se a importância da bioética, da legislação e da elaboração de consentimento médico em meio prático e não só teórico, a fim de consolidar um adequado relacionamento médico-paciente.

Palavras-chave: Relações médico-paciente. Responsabilidade pela informação. Consentimento livre e esclarecido. Ética baseada em princípios. Corpo clínico hospitalar.

Resumen

Percepción de médicos residentes sobre el formulario de consentimiento informado

El derecho a la información sobre actos médicos apoya una buena relación médico-paciente y, junto con los principios bioéticos, asegura el respeto a la autonomía del paciente. Teniendo eso en cuenta, esta investigación descriptiva con enfoque cualitativo buscó comprender la percepción de médicos residentes sobre el formulario de consentimiento informado. La recopilación de datos se realizó a través de entrevista individual semiestructurada aplicada de forma remota. Cumpliendo con los criterios metodológicos, las informaciones obtenidas se clasificaron en tres categorías: 1) percepción, conocimiento y construcción del formulario de consentimiento informado para actos médicos; 2) función social y legal del formulario de consentimiento médico informado; y 3) relevancia de la capacidad del paciente, temporalidad y entrega del formulario al paciente. Se resaltó la importancia de la bioética, la legislación y la elaboración del consentimiento médico de forma práctica y no solo teórica, para consolidar una relación médico-paciente adecuada.

Palabras clave: Relaciones médico-paciente. Deber de advertencia. Consentimiento informado. Ética basada en principios. Cuerpo médico de hospitales.

Research

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Informed consent expresses the action of consenting and means allowing a particular act to be performed or granting permission or authorization [1]. It is a way of agreeing and granting approval to the act of someone you trust because you believe they have the skills and technical knowledge to enable them to perform a professional act with the most predictable results possible [2]. Informed consent for medical procedures consists of the professional explaining all the therapies to which the patient may be subjected, informing the probable risks and benefits in accessible language so that the patient can freely choose whether or not to undergo a particular treatment [3].

Consent must preferably be given in writing, with the patient's or legal guardian's permission, free of any defects, such as coercion. It must be preceded by exhaustive explanations about the medical intervention, including its nature, objectives, methods, duration, justification, possible harms, risks, and benefits. Alternative methods must also be presented as a means of choice for the patient and their complete freedom to refuse or interrupt the procedure at any time [3].

Clarification encourages trust and the expression of the patient's will, which are the best foundations for building an adequate physician-patient relationship. Once the patient understands the information provided and demonstrates a willingness to follow the treatment, consent can be formalized through an informed consent form, which must be signed by those involved.

To be valid, the consent form must meet specific requirements, such as being formulated in accessible language, describing the procedures or therapies that will be used, objectives and justifications, discomforts, possible risks, expected benefits, and alternative methods. In addition, it is necessary to clarify the patient's freedom to refuse or withdraw their consent without any penalty or prejudice to their medical and hospital care. Finally, the patient's or their legal representative's signature or fingerprint identification is required, according to attorney Maria Helena Diniz [3].

The author also states that obtaining the patient's consent after receiving medical information is guaranteed by their right to self-determination, i.e., to make decisions regarding their own life, health, and physical and mental integrity, and to be able to refuse or not preventive, diagnostic, or therapeutic proposals. The patient has the right to oppose a therapy, opt for a more appropriate or less rigorous treatment, accept or not a surgical intervention, and change or not physician or hospital [3].

Far beyond protecting the professional by proving that they provided the information to the patient, the consent form aims to clarify all doubts and dispel the patient's insecurities related to their treatment. Therefore, the information given to the patient or his/her guardian must be clear, objective, and understandable.

Informed consent, whether oral or written, is the expression of recognition of the patient's autonomy to choose whether or not to undergo medical research, prevention, diagnostic, and treatment techniques. Thus, their beliefs and moral values are respected, as they are considered rights of personality, as described in Art. 15 of the Civil Code [4]. This is a free, voluntary, considered, autonomous, non-induced decision taken after an informative and deliberative process on the biomedical procedure or procedures to be adopted under the forms informed.

As Borges [5] states, today, the patient is no longer seen as the one who consents but rather the one who requests, demands, and participates in the decision-making process regarding their health, being the agent of their own will.

Consent is not an inexorable and permanent act, so if there are significant changes in therapeutic procedures, it must be obtained continuously since the permission given previously has a defined time and act, following the principle of temporality. It is also accepted that, at any time, the patient has the right to no longer consent to a specific practice or conduct, even if they have already consented in writing, thus revoking the permission granted, following the principle of revocability [6].

In other words, the first consent, called primary consent, does not exclude the need for so-called secondary consent. Thus, for example, a patient who allows hospital admission does not authorize any means of treatment or procedure that has not been duly explained [6]. Therefore, informed consent is the required ethical and legal

validity of medical procedures, recognizing the person's self-determination as one of its pillars.

Since physicians are the holders of the knowledge of the science they have studied, it is up to them to provide all the necessary information and to have the moral conscience that the patient's understanding allows full consent. On the other hand, the lack of informed consent increases the number of lawsuits against physicians, regardless of whether or not there was a medical error.

It is also worth noting that, unfortunately, many physicians do not provide the form promptly so that it can be effectively explained to the patient. Neglecting the act of informing, which is of utmost importance to patients, may result from the slight emphasis on the preparation of medical students, who are focused mainly on developing clinical skills and are little concerned with the social, ethical, and legal repercussions of medical procedures. This study aims to understand resident physicians' perceptions about informed consent for medical procedures in this scenario.

Method

Before its execution, the study was forwarded to the Ethics Committee (IEC/IRB) following Resolution 466/2012 of the National Health Council (CNS)[7]. The research information was collected only after obtaining a favorable opinion. The study consisted of descriptive research with a qualitative approach, which allowed us to work with the universe of meanings protected by values, aspirations, beliefs, and customs, thus enabling the analysis of variables that should not be quantified[8].

Content analysis is a set of communication analysis techniques that aim to go beyond uncertainties and enhance the content of reading the collected data[9]. As Chizzotti states, "The objective of content analysis is to critically understand the meaning of communications, their manifest or latent content, explicit or hidden meanings"[10]. Thus, this method considers the meaning and the language, not the word[11].

It is important to note that the study design followed the eight "big tent" criteria for excellence in qualitative research and the Consolidated Criteria for Reporting Qualitative Research (COREQ) qualitative research checklist to support the fundamental elements of qualitative analysis[12,13].

The research was conducted at an institution with a medical residency program recognized by the Ministry of Education (MEC), with a team composed of resident physicians in surgical and clinical specialties. This teaching hospital performs minor-, medium-, and high-complexity surgeries, such as oncological and cardiac surgeries and organ transplants, among others, within the scope of the Unified Health System (SUS) and private complementary health care.

The institution was chosen because it performs several interventional medical procedures daily, in which written consent is required rather than verbal consent.

Twenty-five resident physicians from five areas (urology, orthopedics, anesthesiology, otorhinolaryngology, and general surgery) were invited to participate—the lead author personally invited first-year residents. Participants perform invasive medical procedures with prior approval and consent from their respective medical preceptors in each area. There was also communication and acceptance from the medical residency coordinators of the specialty services.

Nineteen resident physicians responded to the invitation. However, those who had worked as independent physicians or had been on call outside of their medical residency, those who graduated more than two years ago, and those who graduated outside Brazil and had their diplomas revalidated were excluded from the study. Thus, the interviews of ten residents were evaluated: four in anesthesiology, four in general surgery, and two in otorhinolaryngology.

The participants were between 24 and 27 years old, 80% male, and all had graduated in medicine in Brazil less than two years earlier. They were enrolled in the Medical Residency Commission of the Brazilian Ministry of Education and agreed to participate in the research by signing an informed consent form (ICF).

The number of people interviewed was sufficient for the construction of categorizations and subsequent analysis of the responses to be consistent. Minayo[14] explains that some care must be taken with the sampling process to reflect the totality in its multiple dimensions. Such care would

include prioritizing subjects with the information and experiences that the researcher wishes to know, considering a sufficient number for the recurrence of information, and choosing a set of informants that would allow the apprehension of similarities and differences.

Regarding the interview, the following triggering questions were asked:

1. What do you know about informed consent forms?
2. What is your perception of the use of informed medical consent forms for medical procedures?
3. What does the consent form represent for you and the patient?
4. Do you believe the informed consent form provided to the patient can or does provide clarification about the medical procedure?
5. How far before the medical procedure is the consent form provided to the patient to clarify the procedure?

The interview was conducted remotely following the national legislation in force during the pandemic period [15]. The research instrument consisted of an individual and semi-structured interview applied using the Google Forms research platform. The responses were sent directly to the researcher via Google Drive.

This method allowed greater comfort and security for the researcher and the resident physician participating in the research. It allowed complete freedom of response within available hours and at home, without interference or embarrassment from third parties. The Bardin technique was used to analyze the information, which organizes the data into three phases: pre-analysis, exploration of the material and treatment of results, inference, and interpretation [11].

Results

The guiding questions sought to meet the study's objectives and enable a dialectical movement between theoretical knowledge and empirical reality. After being read in-depth, some responses were transcribed and qualified according to thematic composition, grouped, and condensed by the semantic nuclear similarity of recording units.

Thus, ten responses were obtained, which were classified into three main categories: 1) perception, knowledge, and construction of the informed consent form for medical procedures; 2) social and legal function of the informed consent form for medical procedures; and 3) relevance of the patient's competence, temporality and provision of the consent form to the patient. Each category is constituted by its own reflective or rational elements that characterize or embody the subcategories. These, in turn, can be understood as a refined thematic substrate that fills the main category together.

Therefore, several pieces of information are clustered around larger pillars of main categories in a unifying logic. However, it is necessary to emphasize that one category can encompass elements of another since social processes conducted by a plurality of individuals are variably dependent on each other and are, therefore, not exhaustive or isolated. However, each individual record is preserved through acronyms, mainly descriptive, since, although similar in their partiality, they are not identical in all facets [11, 14].

The design of the five fundamental instrumental questions presented to the resident physicians in the interviews contributed to the additional finding that the three main categories have a relationship of precedence among themselves concerning the determinants declared or perceived significantly regarding the importance, applicability, and language of the consent form. Thus, the methodological reflection on the evidence pointed to three categories arising from the participants' discourses, which will be discussed in detail.

Discussion

Category 1: perception, knowledge, and construction of the consent form

The analysis of this category, related to the perception and knowledge about the medical consent form, indicates that the form is frequently used by the participants, considering the aspect defined as a legal document.

"It is a document that records that the patient has been informed about the procedure to which they

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will be subjected and sign if they understand and agree with what will be done" (Resident C).

"It explains and describes to the patient, in terms that are easy to understand, the proposed procedure and anesthesia, as well as inherent risks and possible complications, in addition to clarifying any doubts. The physician and patient must sign" (Resident D).

"A text given to the patient explaining the circumstances of the procedure, risks, and possible complications. In accessible and non-technical language" (Resident F).

The duty to inform the patient is a fundamental and inaugural deontological principle of a good physician-patient relationship, and it is not always necessary to use the form as in a legal document. This is because information is a fundamental right of the patient. There is no doubt in the doctrine as to its constitutional basis, whether as a reflection of the principle of equality or as a reflection of the principle of dignity; *therefore, the highest principle of human dignity is the basis for all other personality rights, including the right to information, especially in consumer relations* [16].

This duty must comply with two principles: simplicity and sufficiency. Simplicity is configured as accessible expressions for a coherent understanding, with language devoid of technical-scientific terminology. Sufficiency consists of the quantitative limit of information, aiming to allow the patient to make a decision that is the true manifestation of his/her will, as it contains essential data considering its clarification [17].

Therefore, mere acknowledging, without internalizing knowledge, does not satisfy due clarification, and the physician must provide clarifying information to the patient. By doing so, the professional will respect one of the main pillars of the physician-patient relationship and one of the most essential bioethics principles: autonomy. This involves offering the person the right to decide their destiny and which treatment to follow based on the information provided by the physician. Autonomy, therefore, derives from the understanding of the consent form described by the interviewees.

Category 2: social and legal function of the consent form

In the contractual relationship between physician and patient, providing information is essential to protect the principle of objective good faith [18]. Signing this document is one way to prove that the physician or other healthcare professional fulfilled their duty to explain the proposed treatment. The clauses that make up the information document must prove that the dialogue between physician and patient took place, with the clarification of all the risks and benefits of the proposed procedure, as well as the care that the patient must take for the success of the treatment.

"For us, it represents that we can act, as well as legal protection. For the patient, it represents the autonomy to decide whether or not to undergo a procedure" (Resident A).

"It is a guarantee that both parties, when they are aware of and in agreement with the proposed procedure and especially with its possible complications. It is a legal backing" (Resident G).

Brazilian law does not explicitly regulate the informed consent form. However, in its absence, general principles of law, constitutional principles, and consumer protection legislation can be used to regulate the contractual relationship between physician and patient.

Unsurprisingly, many recently graduated students and physicians with years of professional experience interpret the consent form as legal protection, a subcategory of social and legal function. If its real need is not met, the document can be contaminated by defects and may be voidable, so what should serve to fulfill an obligation becomes worthless.

Given the growing use of legal actions in medicine, applying the Consumer Protection Code in the physician-patient relationship itself leads many medical professors to instruct their students, albeit intuitively, to adopt a protective and legally preventive medicine from an early age. On the other hand, the consent form merely proves that the duty to inform has been fulfilled and is not supported by specific legal standards.

Therefore, the consent form is not simply a document to be signed; it goes beyond that. It is a form of information that is discussed and strengthens the physician-patient relationship. However, its absence or, what is worse, its preparation for the exclusive purpose of defense ceases to be relevant in legal decisions. A coherently described medical record is more valuable, demonstrating that the medical care provided information pertinent to inform the patient entirely.

Once all the essential principles in constructing a consent form, supported by the essential pillars of the duty to inform, are upheld, the document assumes the role for which it is intended, maintaining its essence: guaranteeing the patient's well-being and decision-making power.

Category 3: relevance of the patient's capacity and temporality

Actual capacity is the ability necessary for a person to make decisions and be responsible for their choices in civil life. Thus, when a person is wholly deprived of this capacity, they are represented in cases of absolute incapacity and assisted in situations of relative incapacity to make their acts valid. Therefore, the informed consent form can be personally signed if the subject has total civil capacity. On the other hand, the incapacitated and relatively incapacitated patient, in turn, will be respectively represented and assisted in their decisions [19].

The capacity to consent to a specific health treatment concerns the possibility of the patient discerning values freely and rationally and understanding the benefits and risks of the proposed treatment.

"Even if the patient is capable, we have to deliver the form in advance, so that they can assimilate it and question what they do not understand, and can cancel it if they are not sure" (Resident C).

"For children and incapacitated people, it has to be delivered to the guardian" (Resident J).

As for the timing, there is concern about the advance provision and formal acceptance by signing the consent form. Despite this, it is also clear that there is a lack of awareness that defects in this aspect can cause the document to be annulled, as can be seen in the following statements:

"The form delivered on the day can pressure the patient into not having a choice but to sign. Delivered in advance allows the patient to think more carefully about whether or not to undergo surgery" (Resident I).

"I believe that on the day of the procedure, the patient is more anxious and may not properly understand what is being proposed. In a controlled environment such as the outpatient clinic, there is a greater possibility of dialogue between the physician and the patient to clarify doubts" (Resident H).

The physician must inform the patient in detail of all the risks and benefits related to the procedure as far in advance as possible, allowing the patient to reflect and decide whether they truly accept the potential consequences explicitly stated in the consent form [20].

For the consent form to fulfill its ethical and informative duty, respecting the principle of good faith, among others, the patient must have sufficient time before the medical procedure to which they will be subjected to resolve all possible doubts and, if necessary, seek the opinion of other professionals. Thus, an abusive act that would invalidate the information document is disqualified because it did not fulfill its intended function. Failure to observe the timeliness regarding providing information and consent vitiates the legal agreement between the physician and the patient, as it restricts the latter's autonomy and understanding.

If the resident physician does not understand the essentiality of providing the consent form before the date of the invasive procedure that may result in foreseeable complications, the consent may be defective. These failures may result not only in the nullification of the means of proof but mainly in the breach of essential guiding principles of bioethics that safeguard the construction and maintenance of a good physician-patient relationship.

Final considerations

This qualitative analysis brought to light vital reflections on the principles involved in bioethics and the legislation that guides the preparation of medical consent to further consolidate a good physician-patient relationship. The categorization

made it possible to understand that the interviewed physicians are concerned about the consent form, whether due to taking legal actions in medicine, increasing lawsuits for damages against physicians, or the training encouraged by medical schools.

The evolution of medicine and law has made professionals pay attention to their attitude towards patients, respecting the bioethical principles, the law, and the Code of Medical Ethics that govern the physician-patient relationship. Informed medical consent is a form of respect for this relationship. It is achieved when the patient accepts the relevant facts, implications, and consequences of the medical procedure to which they will be subjected. It is a professional duty to inform and ensure that the information is enlightening and fulfills its social function.

The residents' statements about the consent form highlighted theoretical aspects more strongly than the real experience. Thus, it is necessary to hold discussions and reflections with teams in medical residency programs in the face of real situations so that residents can internalize the broader meaning of the form and, above all, use it not only as a self-defense tool but also as a way to promote patient autonomy.

Likewise, in medical graduation, it is essential to promote the study and debate regarding the fundamental principles that involve the right to be informed, whose guarantees are based on fundamental principles of law provided for in the legislation. Thus, the dignity of each patient is also protected by the right to autonomy, free from any defects of choice that may lead to the nullity of consent without clarification.

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