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RESEARCH

Informed consent form in healthcare

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Abstract

Bioethics has among its principles autonomy, the basis of informed consent, which is confirmed by the informed consent form. In this document, the health team clarifies the diagnosis, prognosis, risks and objectives of the treatment suggested to the patient. A literature review was conducted to select articles focusing on this document, and the resulting *corpus* shows that health teams struggle to use the informed consent form, especially regarding its purpose, the language used and how to present it. It was also noted that has often been applied for purposes other than its original one, such as the legal protection of healthcare providers, especially physicians, in case of technical errors.
Keywords: Bioethics. Informed consent. Personal autonomy.

Resumo

Termo de consentimento livre e esclarecido na assistência à saúde

A bioética tem entre seus princípios a autonomia, base do consentimento informado, o qual é comprovado pelo termo de consentimento livre e esclarecido. Nesse documento a equipe de saúde esclarece o diagnóstico, prognóstico, os riscos e objetivos do tratamento sugerido ao paciente. Por meio de revisão de literatura, foram selecionados artigos que focalizam esse termo, e pela leitura do *corpus* percebem-se dificuldades da equipe de saúde em seu uso, sobretudo no que concerne ao seu objetivo, à linguagem utilizada e à maneira de apresentá-lo. Ademais, notou-se que o documento vem sendo aplicado visando a prevenção jurídica dos profissionais da saúde, principalmente médicos, em caso de erro técnico, uso que foge à proposta inicial.
Palavras-chave: Bioética. Consentimento livre e esclarecido. Autonomia pessoal.

Resumen

Formulario de consentimiento informado en la asistencia sanitaria

La bioética tiene entre sus principios la autonomía, base del consentimiento informado, que se confirma con el formulario de consentimiento libre e informado, documento en el que el equipo de salud aclara el diagnóstico, pronóstico, riesgos y objetivos del tratamiento sugerido al paciente. A través de una revisión literaria, se seleccionaron artículos que tratan del formulario de consentimiento. Al leer el corpus, se notó que los equipos de salud tienen dificultades con el documento, especialmente en lo que respecta a su objetivo, el lenguaje utilizado y el modo de presentación. Además, se constató que el formulario se ha aplicado con el objetivo de proteger legalmente a los profesionales de salud –sobre todo médicos– en caso de error técnico, uso que difiere de la propuesta inicial.
Palabras clave: Bioética. Consentimiento informado. Autonomía personal.

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In healthcare, the informed consent is not an isolated act, but a constant process of information exchange between doctor and patient, to promote the latter's active participation in the treatment [1,2]. Every decision, to be autonomous, must be conscious, and therefore the act of consent can only be considered valid if the medical team clearly explains the benefits and risks of a certain procedure [3].

In its article 22, the Brazilian Code of Medical Ethics (CEM) [4] obliges the health professional to obtain the consent of the patient or responsible family member after elucidating them on the procedure to be performed, except in cases of imminent risk of death. Article 34 also obliges health professionals to inform patients about their diagnosis, treatment objectives, risks and prognosis, except when such information may bring them harm, situation in which the communication is directed to the legal representative. Patients have the right to be informed about their health status and to make decisions [5].

The informed consent form (ICF) must contain all information relevant to the clinical case. The document aims to ensure patient autonomy and prove that the information was relayed to them. Moser [6] also points out that decision-making requires that the patients be properly informed not only about their diagnosis, but also about therapeutic alternatives. In the literature, two approaches to the ICF exist: in healthcare (used in this study) and in research involving human beings.

In healthcare, the ICF has two purposes: legal, for eventual defense of the professional, and ethical, as a continuous process of clarification in the doctor-patient relationship, protecting the latter's self-determination [2]. In studies with human beings, the principles of consent, as defined in item II.5 of Resolution 466/2012 of the National Health Council (CNS) [7], are similar to those of assistance. It involves the *assent of the research participant and/or their legal representative, free from vices (simulation, fraud or error), dependence, subordination or intimidation, after full and detailed clarification about the nature of the research, its objectives, methods, expected benefits, potential risks and the discomfort that it may cause* [7].

The ICF used in healthcare must also clarify medical interventions, treatments and possible failures and risks of procedures – one of the main difficulties encountered. Health professionals often have doubts about what information they have to give to the patient and how to obtain informed consent [8].

Considering the relevance of the ICF for the doctor-patient relationship, one must take into account how the document is written. A study focusing on research concluded that, in Brazil, many individuals are unable to fully read and understand the consent form, which can also be observed in healthcare [9]. Another study also stressed the complexity of the information, the use of technical terms and the large number of pages as factors that impair the understanding of the ICF [10].

A research with nurses working in critical situations indicated ethical problems in the information transmission, linked to decision-making and the patient's self-determination [11]. The author draws attention to the relevance of clarification, since deliberations are based on the information provided. Another study highlights the communication problems between the multidisciplinary team and the patient, especially involving difficult news, which, despite being constant in the work routine, generate discomfort for many doctors, who feel unprepared to disclose them properly [12].

Given the importance of the ICF for professionals and patients, this research aims to encourage discussions in training spaces of the hospital and academic community, to promote advances and give visibility to the meaning of this document. For that, we seek to understand how healthcare perceives and uses the informed consent form.

Method

This is a literature review whose bibliographic survey covered the period from January 2013 to April 2018. The Scientific Electronic Library Online, PubMed and Latin American and Caribbean Health Sciences Literature databases were searched for articles that focused on the ICF, using "free and informed consent" and "informed consent" as keywords.

The search resulted in 40 articles, 11 published in 2013, 9 in 2014, 9 in 2015, 7 in 2016 and 4 in 2017. Articles in which ICF was mentioned but not the main subject were disregarded. To analyze the selected texts, we considered the work of authors who developed important concepts for thinking about the topic, even in publications prior to 2013.

Theoretical references

Bioethical principles and literature

In the hospital setting, specialized care for treating chronic or acute conditions requires the communication of difficult news. In this scenario, bioethics and ethics guide care towards respect for human dignity, with responsibility and prudence, guaranteeing patients' rights.

According to Goldim [13], the word "bioethics" first appeared in 1927 in an article published by Fritz Jahr, who described it as the recognition that every living being must be respected as an end in itself. Later, as pointed out by Oliveira, Oliveira and Oliveira [14], the word is used by Potter in the 1970s to refer to a multi and transdisciplinary science that considers human beings as fully capable of deciding on the best conduct to develop their life project.

The advent of bioethics relates to human rights achievements and the need to control abuses and to resolve moral conflicts arising from scientific and technological advances [15]. From the reflection on these issues, documents began to be developed to guide the conduct in research and medical procedures.

The *Nüremberg Code* [16], released in 1947, appeared as a response to the brutal experiments carried out with human beings in World War II. The text, the first to ponder ethical issues for scientific research, states that the individual's voluntary consent is essential. Subsequently, other documents were developed, such as the *Declaration of Helsinki* [17]. With continued updates, this is the most important international statement in the ethical control of research with human beings, being used as a basis for the editorial guidelines of the main scientific journals [15].

Currently, four principles govern bioethics: beneficence (the professional must act for the sake of life and health); non-maleficence (not causing harm to another person); justice (every human being has the right to be cared for according to their needs); and autonomy (right of the patient or legal representative to make their own decisions regarding diagnostic and therapeutic procedures) [14].

In Brazil, one of the documents that govern ethics in medical procedures is the CEM [4], which provides guarantees for both the medical staff and the patient, no longer admitting unique and peremptory decisions on the part of the professional. Following the manifestation of conscious and bilateral acceptance, the clarification of the patient and the documentation give transparency to the medical intervention, recording its extent and the possible failures of the procedure performed [14].

The Federal Council of Medicine (CFM) Recommendation 1/2016 [1] validates and makes the ICF fundamental for obtaining consent without vices or influences. The recommendation [1] also provides complementary ethical guidelines for emergency situations, refusals, the possibility of psychological disorders caused by information, risks to public health and the pre-existence of mental disorders.

Another important document is Resolution CNS 466/2012 [7], based on respect for human dignity and the protection of research participants, recognizing their vulnerability and ensuring that their contribution and permanence in the study occur by free and express manifestation. All these documents highlight the clarification and registration of procedures as a means to enhance the bioethical principle of autonomy, essential in health practices.

Autonomy

When seeking help, patients are physically and mentally fragile, becoming vulnerable, coerced into making decisions and accepting treatments that they might not otherwise choose [18]. In this sense, the principle of autonomy is an attempt to prevent citizens from being subjected to atrocities, violence and abuse in times of fragility [19]. The hospitalized individual, when moving away from their social network, which gives them confidence and security, becomes even more vulnerable. The professionals who provide them with the necessary care ignore their history, expectations, desires and life projects, which compromises their ability to decide on treatment-related issues [18,20].

Vulnerability is associated with the patients' lack of autonomy during hospitalization, the disease itself, the lack of information and treatment options, besides the lack of control over their own body and mind [20]. Moreover, the possibility of being considered incapable of making decisions and choosing treatments compatible with their life projects can further increase their fragility. Each individual knows what affects them the most, is aware of their physical and emotional limits before a medical procedure and, therefore, it is up to them to decide which discomforts are valid compared to possible benefits [21]. Despite the passivity, impotence and fragility experienced in hospitalizations and treatments, it is the patient's right to choose, accepting or refusing any procedure [22].

The autonomous subject is the individual who can decide by considering their principles, values,

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beliefs and perceptions, examining all the factors that interfere with their ability to choose [23]. With accurate information, patients have the power to guarantee respect for their autonomy [24]. Therefore, from the very first contact, it is important that the medical team relay true and complete information, complying with the due process of free and informed consent [25].

A study on knowledge and willingness to participate in research concluded that inadequate understanding or lack of knowledge of specific information contained in the ICF impairs the individual's autonomy [26]. In healthcare, the lack of clarification harms the doctor-patient relationship, since the patient's free and autonomous choice depends on the possibilities that are presented to them. If only one possibility is highlighted, decision becomes peremptory, since the only alternative is the refusal of treatment [14].

However, there are exceptions in clinical practice – for example, when the patient rejects blood transfusion. In this case, the individual with the possibility of cure, at risk of death and without therapeutic alternatives, has no right to decide, since the doctor has the legal and ethical obligation to perform the procedure. The São Paulo State Regional Council of Medicine, in Consultation 35,605/2010, with an opinion signed by counselor Caio Rosenthal, advises:

For older patients adherent of the Jehovah's Witness faith, minors, with or without discernment to express their will, when there is no alternative other than blood transfusion, and risk of death, the attending physician and the hospital have the legal and ethical duty to perform the transfusion, regardless of the refusal of patients or legal guardians [27].

That is, the patient's autonomy can be rejected when there is an imminent risk of death and chances of cure, in which case their consent need not be obtained. In such situations, disregarding the patient's will is legitimized, as *healthcare providers and community would even condemn the conduct of the doctor who, in the face of the patient's denial, stays at their bedside, in a caring attitude, waiting for the moment of death. The doctor is not a comforter, but a professional trained to manage the patient's health conditions and perform fast and safe intervention procedures. He is, so to speak, the professional of life* [28].

If the patients lack the conditions for self-government and self-determination – such as minors or patients in a coma –, they must be legally represented by family members or legitimate third parties [14]. For ethical reasons, even if in these cases the request for consent is made to legal representatives, no one replaces the persons themselves in deciding any conduct, even though the responsibility extends to all those involved, including society and the State [29]. For this reason, with persons of legal age, when the patient and their representative manifest different decisions, the right of the former prevails. The will of the patient shall only be overridden if it comes up against the precepts of the Code of Medical Ethics, if the patient authorizes the representative to decide, or if the health professional believes that the patient is not in his right mind to make decisions [14].

At the time of admission and treatment, some individuals lack the cognitive and physical conditions to consent, which is even worse in the case of patients experiencing pain and fear [8]. The latter influences decision-making, limiting autonomy and voluntariness, since the patient may feel coerced by the fear of being left without treatment [18]. That is, there is a prospect of coercion in the doctor-patient relationship, especially in the case of Brazilian Unified Health System users, who may feel obliged to accept therapy for fear of losing follow-up if they disagree [3].

Health education can improve the care decision-making process, being crucial in cases where the professional or the institution needs to give the patient as much information as possible about the prospects. With knowledge, patients can think, make decisions and take their stand [30]. This education must prioritize respect for human rights and the construction of values, functioning as a cultural action to emancipate and empower subjects [20].

By properly understanding the information and ICF, patients can express their voice, history and needs, becoming subjects of rights [31]. This is important because, when the consent form is poorly understood, the voluntariness of the process is impaired [32]. To exercise their autonomy, individuals must receive information clearly and accurately, with simple vocabulary and elucidation of possible doubts [14].

Informed consent form

Informed consent is a central part of bioethics and its rigor in demanding respect for the patient's freedom, autonomy and self-determination [33]. It gained strength by ensuring that, if the patients have minimal conditions, no one can decide for them – and if they

cannot, that right passes to a family member or legal representative, but not to doctors.

The ICF includes rights of freedom, privacy and individual choice [5]. Its aim is to promote informed, active and autonomous patience participation and authorization [34], providing appropriate information, such as benefits, risks, consequences and therapeutic alternatives [20]. As Sousa, Araújo and Matos point out, *true informed consent, in which there is patient involvement and consciously shared responsibility, is the only way to quality medicine and to defend the rights of patients and health professionals* [35].

The free and informed consent process goes beyond the document signed by the patient. It must guarantee the exercise of autonomy through knowledge of indications and therapeutic alternatives. Behind the formality of the informed consent form, there must be full respect for the patients, allowing them to fully understand their health status and that their treatment decisions are respected, even if they differ from the position of the medical staff [20].

In scientific studies, according to CNS Resolution No. 510/2016, item XX of article 2, the consent process is *based on building a relationship of trust between researcher and research participant, in accordance with their culture and continuously open to dialogue and questioning, and the record of its obtainment is not necessarily written* [36]. Rodrigues Filho, Prado and Prudente state that the ICF *is a complex document, which unfolds into several elements, transforming its proposition into a process of clarification and respect for the dignity of the human person* [37]. One must ensure that the information has been understood or if additional information is needed [33], since the ability to consent depends on the patient's understanding [20].

A study on the ICF in research concluded that not all participants who signed the document really understood all the information, which impairs autonomous decisions [38]. The signature alone does not guarantee that the consent was free, autonomous and voluntary, and that the patient understood all the risks and benefits [39]. Factors such as stress, educational level, economic vulnerability and access to health services interfere in the process.

Consent is only effective if it is done freely, without physical, moral constraints or limited time for reflection, which does not mean that the doctor cannot advise the patients so that they can better understand their situation [33]. Consent can also be implicit or explicit [8]. The former can be given using non-verbal language, such as gestures that manifest an autonomous movement towards procedures and treatment; the latter is given verbally or in writing. Even in telehealth, already authorized by some councils, the ICF must be requested, as to maintain ethical and legal principles in healthcare [40].

As Miziara points out, *there are no fixed rules for obtaining consent for all medical procedures, nor proper forms for all of them, but in cases where the risk exists and no adequate form exists, the doctor should, as a good practice, note in the patient's record that the "consent process" was established* [41]. In addition, the ICF can be revised, readjusted or revoked at any time, if the patient so wishes. If the subject remains silent, without approving or disapproving any decision, the judgment regarding the procedures must be transferred to the physician [14].

The most common mistake in the consent process is to use technical terms, inaccessible to the patient or to a lay research participant [42]. Several reasons can prevent proper understanding, such as the patient's intellectual limitations or the doctor's difficulty in explaining medical jargon. Fear can also influence the process, with defense mechanisms like denial, illusions or false beliefs [8].

Contextualizing information, adjusting it to the individual's ability to understand, is the best method to obtain informed consent [43]. As such, writing up the ICF is a challenging task since patients have their particularities. Writing requires knowledge, sensibility and teamwork, so that the text is enlightening and careful with the human beings involved [42].

To facilitate the understanding of the ICF, audiovisual resources can be added, such as educational videos that help the patient to comprehend the proposed procedure [44]. CNS Resolution 510/2016 provides, in its article 5, for the use of alternative means, allowing consent to be *carried out by its oral, written, sign language or other forms of expression that prove to be appropriate, considering the individual, social, economic and cultural characteristics of the person* [36]. Ensuring a welcoming environment is also imperative, since the physician's commitment to promote a discussion with the patient facilitates the understanding of important points [3].

In Brazil, the ICF is often seen in a distorted way, considered as a way to prevent lawsuits in case of bad outcomes from the medical procedure [2,8,32,45]. However, the document cannot

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be transformed into a set of technical terms for the protection of the physician; it must be clear and foster solidarity with the patient at all stages of treatment [46]. An adequate way to avoid legal proceedings is to develop clear communication with the patient [46].

When the relationship is based on the perspective that the professional is the authority and the patient should only obey, the cooperation between the parties is affected, making the treatment something imposed by the medical team [18]. Until recently, the physician was seen as a unilateral provider of the patient's well-being, but in the current conception the patient is a co-author and shares responsibilities in the choices [15]. In a proper doctor-patient relationship, decisions are taken together [46].

Consent is the patient's moral right and an obligation for the healthcare professional. As Clotet states, *since the interaction between doctor and patient is a contractual relationship that implies rights and duties for both parties, the doctor cannot dispense with the patients decisions whenever their state allows them to express them, and must recognize the patient as an autonomous and free being* [47]. Given this patient autonomy, bureaucratic issues arise, and it is in this sense that the ICF can have a heavy legal burden, protecting patients and doctors.

However, in the hospital, away from social and family life, with physical and work limitations, the subject experiences fear and feelings of incapacity [20]. In this context, *the very biomedical language, imbued with specific jargon and scientific terminology, makes it difficult for the patients to completely grasp the aspects related to their health status* [48], often unbalancing the doctor-patient relationship. The lack of dialogue between health professionals and patients shows that communication is often overlooked in the care relationship [18].

Doctor and patient have different languages, and the patient's modes of expression are often undervalued in healthcare settings. But this asymmetry cannot be used to deny the individual's freedom of decision, disregarding their life projects and ability to act [20]. Thus, the doctor-patient relationship must consider the patient's wishes and give security to the professional, avoiding confrontations and legal actions [2], the consent form being part of this process [45].

Despite the ethical and legal requirement, it is neither necessary nor advisable for the ICF to be signed for all procedures, since, besides there being no guarantees that the written document would avoid legal claims, it can also distance the patient and create distrust. If properly written and updated, recording the information given and the patient's participation in therapeutic decisions, the medical record can serve as proof that the duty to inform has been fulfilled. Its ethical and legal value is analogous to that of the ICF, which fails to foresee all the possibilities of intercurrences or complications of a case [2]. As an essential document in medical practice, the medical record must contain all the facts, results of clinical and complementary exams, and diagnostic hypotheses [49].

Although often used for the purpose of legally protecting the doctor, the ICF was created to preserve the fundamental principle of bioethics: autonomy. However, valuing this principle is not restricted to this document; autonomy is the foundation of the doctor-patient relationship and must be present throughout the treatment.

Final considerations

CEM [4] requires clarification and consent from the patients, who must have autonomy over their health. However, since it depends on the professionals' duty to provide relevant information in an comprehensible manner, this autonomy can be limited, impairing the subject's decision-making power. Such a limitation should not occur, since the same CEM, in its article 31, prohibits the health professional from *disrespecting the patient's right* (…) *to freely decide on the execution of diagnostic or therapeutic practices, except in case of imminent risk of death* [4], before which the decision falls to the attending team.

But the proper use of the ICF imposes some difficulties, such as the fragility of the patient-doctor bond, especially regarding communication, whose deficiency impairs the patients' understanding of their clinical condition, reducing their ability to give their opinion on the treatment. This situation can be aggravated by the emotional burden of hospitalization, which increases uncertainties and fears and intensifies vulnerability, compromising care.

The bibliographical analysis also showed that the ICF has been used to protect not only the patient, but also the healthcare provider. Nevertheless, the knowledge of doctors and patients about the real function of the document

and the ethical consequences of its use in the health environment is still poor.

Self-determination or autonomy is only exercised when no therapeutic procedure is performed without verbal or written consent from the patient or legal representative. For this, it is necessary to consider the particularities involved and be careful with communication, which must be established in clear and understandable language, free of technical terms, allowing the patient to grasp all the important aspects for decision-making. Finally, this topic calls for further discussion, as patients must understand their rights and doctors must value the consent process, being trained to properly use instruments such as the ICF.

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