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INFORMED CONSENT IN MEDICAL PRACTICE: A LITERATURE REVIEW

Maria Fernanda Canton Zanatta
Universidade Metropolitana de Santos (UNIMES)
Santos - SP
http://lattes.cnpq.br/3760311689705541

Isadora de Campos Cassemiro
Universidade Metropolitana de Santos (UNIMES)
Santos - SP
http://lattes.cnpq.br/4900500470023046

Juliana Silva dos Santos
Universidade Metropolitana de Santos (UNIMES)
Santos - SP
http://lattes.cnpq.br/0905725697036076

Marcela Alexandra Osorio Franco
Universidade Metropolitana de Santos (UNIMES)
Santos - SP
http://lattes.cnpq.br/8318859811397531

Marcela Lourenço Alves
Universidade Metropolitana de Santos (UNIMES)
Santos - SP
http://lattes.cnpq.br/8303907093586599

Guilherme Zanutto Cardillo
Responsible advisor; medical examiner
Technical Director of Service of the Center for Medical-Legal Expertise of Santos (IML) - SP
http://lattes.cnpq.br/9707681299367051

Abstract: INTRODUCTION: Informed Consent is an ethical legal concept and a daily practice in all health institutions, through which the researcher instructs the patient about the risks, benefits and alternatives of a given procedure or intervention. He must have the ability to understand and evaluate the information provided, communicate his choices and understand the consequences of his decision. OBJECTIVE: The main objective of this work is to reinforce, in medical practice, the relevance of informed consent. METHODOLOGY: The search was performed via MedLine (via PubMed and SciELO). FINAL CONSIDERATIONS: Currently, it is possible to observe a framework of negligence and carelessness of health professionals towards patients, creating a scenario prone to mistakes and violations of an ethical and legal nature. In view of the aforementioned facts, it is necessary to analyze these concepts and principles to remember the value of informed consent in medical practice.
Keywords: Informed consent, ethical-legal, negligence, doctor-patient relationship.

INTRODUCTION

The ethics of research with human beings is necessary from the Nuremberg Code: a response to the atrocities committed by Nazi medical researchers. In view of this, standards are established for carrying out experiments with human beings. Informed consent is consolidated worldwide from the 1970s onwards with the advance of bioethical principles and, thus, becomes the materialization of the principle of autonomy. In the 1980s, with the judicialization of medicine, it advances from an ethical point of view and starts to dialogue with the Law in its different spheres. In Brazil, in the mid-1990s, it was institutionalized and became hospital administrative policy. (MINOSSI JG., 2011)

Informed Consent is an ethical and legal concept, and must be a daily practice in all health institutions, through which the physician instructs the patient about the risks, benefits and alternatives of a given procedure or intervention. He must have the ability to understand and evaluate the information provided, communicate his choices and understand the consequences of his decision. (COCANOUR CS., 2017; MINOSSI JG., 2011) In addition, it is essential in the doctor-patient relationship, since it aims to show that the doctor has fulfilled his role of informing patients about their clinical condition, the risks to to be assumed when performing the procedure against the benefits and, equally, the risks in not performing the procedure.

According to the Federal Council of Medicine, the Informed Consent Term (TCI) must contain: identification of the patient or his/her guardian; procedure name; technical description (in layman's and clear terms) and possible failures and complications. Even more, the document composes the description of anesthetic procedures (if necessary); explanation as to the possibility of modification of conduct; statement that the explanations were effectively understood; confirmation of authorization, with place and date of realization; template for revocation of procedure and signature of witnesses. (MINOSSI JG., 2011)

GOALS AND METHODS

Conduct a literature search by MEDLINE (via PubMed AND SciELO), aiming to reinforce the importance of the theory of informed consent in medical practice.

DEVELOPMENT

The study by Minossi JG. it is proposed to detail the meaning and purpose of informed consent, showing its real role in practice. He explains that although the TCI is a single document, it must be shaped for each patient,

according to their socio-economic-cultural condition, and that the presence of this document goes beyond a judicial consensus, as it encompasses the humanity of the researcher with the researched, in the case of medicine, between the doctor and the patient, where it is understood that the person's wishes (right of self-determination) are above any desire and opinion of the professional. Thus, this document can be revoked at any time and it is vital that the patient is able and not coerced to sign the consent form, in addition to the need to explain the entire process to him, in a language that is understood. Furthermore, this term does not replace any type of oral bond, it must only serve as support for dialogue, it must not be used as a form of Defensive Medicine, but something that helps both the patient and the doctor. It is emphasized that a well-completed medical record with the procedures described has an ethical and legal value similar to the TCI and that every medical act must be governed by ethics, with civil and criminal liability. (MINOSSI JG., 2011). Thus, due to the particularity of each clinical situation, it is not recommended that standardized or printed TCI be adopted as an "adherence contract".

The study by Cocanour CS. aims to review the basic principles of informed consent - when it is necessary, its evolution and how to obtain it. It reinforces the physician's responsibility to adequately convey medical information, always evaluating the patient's ability to understand it and the implications of treatment alternatives. It is understood that it requires a precise communication process to actually provide and obtain informed consent. (COCANOUR CS., 2017)

The review by Shlobin NA. et al. aims to assess the ability of neurosurgeons to provide informed consent to patients, with 21 articles included in the study. To the results, the execution of this theme by the physician, when against the patient, is fundamental, as well as the lack of it proved to be a common factor for medical malpractice litigation. It is inferred that physicians have a duty to provide patients with all relevant information, so that decisions can be made. Thus, it is concluded that it is the physician's responsibility to pass the information to the patient in an appropriate way in order to maintain communication to provide and obtain informed consent. (SHLOBIN NA et al. 2022)

The review by TDD Santos aims to show that the informed clarification process must be marked by a dialogue with language accessible to the patient and never be replaced by the signature of a document. Such conduct can generate distrust in the doctor-patient relationship, which can lead to future conflicts. It also refers to how much the informed clarification must only be obtained by the doctor, without transferring such responsibility. Therefore, it is noted that it guarantees a good relationship between the doctor and the patient, in addition to being on par with the principles of bioethics of respect and promotion of autonomy, beneficence and maleficence. (SANTOS TDD., 2016)

The 2016 recommendation of the Federal Council of Medicine (CFM) deals with how the patient must be able to confront the information and clarifications received with their values, beliefs and experiences in order to be able to decide and communicate this decision, in a coherent and justified way. Thus, it is extremely important that the writing of the document is carried out with clear language, aiming at a better understanding of the patient. Furthermore, informed consent is not only a pro-forma role, but an ethical duty of the physician, supported by the Code of Medical Ethics and non-compliance may be considered an ethical-professional violation. (FEDERAL COUNCIL OF MEDICINE, 2016).

CONCLUSION

Knowledge of informed consent - with its principles and purposes - is essential for medical practice and must be known and practiced by physicians in care practice, by health institutions and in research, since it is not only a moral duty of the physician, but a ethical obligation. Low adherence to the use of informed consent in the recommended manner is observed in medical practice, which can generate a scenario of insecurity for the patient in the face of possible even predictable intercurrences, which may characterize an ethical-legal violation. Therefore, it is necessary to analyze these concepts and principles in order to remember the value of informed consent in medical practice.

REFERENCES

1. Cocanour CS. **Informed consent-It's more than a signature on a piece of paper.** American Journal of Surgery. 2017 Dec;214(6):993-997. DOI: 10.1016/j.amjsurg.2017.09.015. PMID: 28974311.

2. Conselho Federal de Medicina. Resolução CFM nº 1/2016. **Dispõe sobre o processo de obtenção de consentimento livre e esclarecido na assistência médica**. 2016. Diário Oficial da União.

3. MINOSSI, JG. **O consentimento informado: Qual o seu real valor na prática médica?.** Rev. Col. Bras. Cir., Rio de Janeiro , v. 38, n. 3, p. 198-201, June 2011 . Available from <http://old.scielo.br/scielo.php?script=sci_arttext&pid=S0100-69912011000300011&lng=en&nrm=iso>. access on 19 July 2022. https://doi.org/10.1590/S0100-69912011000300011.

4. Santos T.D.D. O **Consentimento Informado na prática médica: Revisão Sistemática**, Salvador, 2016. Disponível em: https://repositorio.ufba.br/ri/handle/ri/20855.

5. Shlobin NA, Sheldon M, Lam S. **Informed consent in neurosurgery: a systematic review**. Neurosurgical Focus FOC, 49(5), E6. Retrieved Jul 19, 2022, from https://thejns.org/focus/view/journals/neurosurg-focus/49/5/article-pE6.xml