Free and clarified consent in anesthesiology

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.
Abstract

Informed consent in anesthesiology

This article aims at describing the Free and clarified Consent understood as a tacit agreement or a clearly expressed approval when participating either in a diagnostic or therapeutic procedure. However, such term is not an mandatory document for anesthesia procedures. This discussion is based on a statistical research carried out by the '*Conselho Regional de Medicina do Estado de São Paulo – Cremesp'* (São Paulo Regional Council of Medicine), which shows 100 registered denounces in the Anesthesiology area from January 1999 to January 2004. Conclusions show that anesthesiologists should adopt the Free and clarified 1Consent in their daily professional practice aiming at protecting the professional as well as patient's autonomy who, thus, may exercise his/her right of choice.

Key words: Informed consent. Anesthesiology. Ethics, Medical.

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Informed consent, or as it is designated in Brazil, free and clarified consent, comprises patient's expressed or tacit approval regarding allowing or participating in determined diagnostic or therapeutical procedures. This bioethics area topic has caused intense ethical and legal discussions in past years. In Brazil, the issue is relatively new.

The term consent consists in an instrument that originally has been used in researches involving humans, which proposes to assure, above all, the respect for the well being and research subject's autonomy. CNS Resolution no. 196/96, from the National Health Council, *Guidelines and Standards for Research Involving Humans, defines it as research subject's agreement and/or his legal representative, free of vices (simulation, fraud or error), dependence, subordination, or intimidation, after full and detailed explanation on the nature of*

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the research, its objectives, methods, foreseen benefits, potential risks, and discomfort that it may bring on, formulated in a consent term, authorizing his voluntary participation in the experiment[1]. Therefore, in addition to the document itself, consent characterizes as well for being a process that implies correctly informing and accessible to research subject's understanding the procedures that one intends to carry out, its benefits and risks.

In view of the importance of consent for ethical practice in health sector, and of free and clarified consent term (TCLE) as its regulator instrument, the objective of this article is to guide Anesthesiology professional so they adopt its use also in anesthetic procedures practice. Even if patient has agreed and formally consented with undertaking of procedure that implies anesthesia, it is not too much, for the anesthesiologist to count on a specific document. It would confirm if patient (or its legal representative) was informed about anesthetic techniques to which will be subject, and its probable eventual risks, as well as been clarified on any issue related to the process that may be considered doubtful.

Term of consent

In clinical area, that is, in physician's professional practice, normally known under the denomination of informed consent, represents a break in the traditional physician-patient relationship, in which physician's decision power was considered absolute. As consequence, the Hippocratic tradition that for millennia guided physician-patient relationship is undergoing changes throughout the last decades. With valuation of the respect for sick's autonomy, physician began to share information and discuss, with patients diagnosis and treatment alternatives.

This mode of companionship, in clinical practice, did not arise spontaneously in medical area, having its origin in the United States courts, from the beginning of the 20th Century. The precursor ruling recognizing patient's self-determination, understood as his right to autonomy, was given in 1914, in the United States by the New York Court. It dealt on Schloendorff *versus* The Society of the New York Hospital lawsuit. Mrs. Schloendorff filed a lawsuit against the hospital because she was submitted to a surgical procedure to withdraw without her consent of fibrous tumor. The judge in charge of the case stated that: *every human being in adult age, and mentally capable has the right to determine what will be done to his own body*[2].

A few decades later, already in the 1950s, the United States courts started to face questionings related to procedures and therapeutics. They focused the notion, increasingly consubstantiated, of patient's autonomy: *patients have the right not just to know which procedure is proposed by physician but to decide if intervention is acceptable as well, taking into account its risks, benefits and available alternatives – including not undertaking proposed treatment* [3]. Regarding this change in clinical practice guiding principles, Guz state: *thus, in order to patient could make such decision, it was necessary recognizing of a physician's affirmative duty, in the sense of not just communicating proposed treatment, but to inform patient about risks and benefits of such treatment, as well as possible alternatives* [4].

Therefore, one may define that getting patient's consent to carry out a certain medical act implies in its agreement, even if revocable, which should be preceded by clear and sufficient information and clarifications about the procedure that one intends to undertake, as well as its possible implications. Thus, free and clarified consent does not restrict itself just to be a ethical-legal instrument, since it represents, mostly, a patient's right, through which he expresses his autonomy. Contrarily to what happens in relationships based in heteronomy, in which physician's will prevails in relation to patient's physical and psychological integrity, the later, by manifesting his autonomy, may decide on his participation in scientific studies, and as well in accepting proposed medical diagnosis and treatment.

The expression informed consent arose in 1957, in the United States legal area, in the case Salgo versus Leland Stanford Jr. University Broad of Trustees., Martin Salgo, who suffered permanent paralysis in consequence of a translumbar aortography, claimed in the lawsuit not have been warned about the risk of this procedure. The Court accepted his claim sustaining that the patient should have been informed about all possible sequels [3]. Informed consent, since this ruling, was linked closely to autonomy concept.

Patient's right to informed consent protects and promotes his autonomy.

Thus, the act of consent should be genuinely voluntary and based in exact revelation of information. Faden and Beauchamp establish that in order to action be considered as autonomous, they must fulfill three conditions: intentionality, suitable knowledge, and lack of external control. Considering the difficulty for the three conditions be achieved ideally, one seeks to establish autonomy in face of certain topic or condition [2].

Consent in medical ethical code

Ethical regulation of professional exercise is stated in ethical codes, and it is its enforcement that defines professionals' duties and rights, mandatory to every physician. By setting standards for professional exercise, ethical codes seek to promote the best for patient, society, and for physicians. The code reflects physician's thought and stands at the time of its designing and approval, as well as it mirrors the yearnings of society at the time. It is what one observes, not by chance, in the Medical Ethical Code (MEC) [5], which went in force in the same year of the new Constitution of the Federative Republic of Brazil, establishing citizenship and human being's dignity as fundamental principles, as well as right to health ensured by the State [6].

However, despite reflecting social conjuncture of the historical and cultural instance in which they were developed, codes do not translate always integrally prevalent and consensus positions, while there is, inclusively, doubts that they have eminently practical sense, given its philosophical weight. It is in consequence of this feature that concepts like *autonomy and consent*, for example, have revealed, increasingly, to be prevalent topics in current medical ethical codes.

In designing MEC [5], in 1988, for the Brazilian physicians, two formulations were under discussion. The first was the proposal of a code structured under generic statements, such as, for example: *physician should do always what is best for his patient*, which summarized, suitably, what society at the time expected from physicians' work [7]. The second proposal, being doctrinarian and practical document, characterized as a mix of moral code that, in some way, expanded and redefined principles of the Hippocratic doctrine, and it targeted to regulate precisely many practical features of the profession without, nevertheless, prevent discussion of controversial points of medical work, particularly considering sciences scientific and technological progress, as well as the social conquests of the period [7]. The *Fundamental Principles,* the rights and duties of physicians stated in this code were considered as deontological, and its articles susceptible to penalties.

However, physicians' overwhelming majority opinion was that the growing complexity of professional exercise, from technological sophistication of new diagnosis and treatment methods to the difficulties of the delicate priority

problems of resources allocation, made recommendable existence of a set of guidelines that would lead professionals in their relationship with patients and society [6]. Of course, the document formulated in 1988 fulfilled, any way, its fundamental function as medical ethical code, which is to set moral limits for physician's behavior and attitudes in many situations of his professional practice.

In consonance to these yearnings of the medical class, the 2009 Medical Ethical Code [8] changes the perspective of previous document, emphasizing patient's autonomy, as when it assures, for example, that *physician should do what he considers best for his patient, as long as there is clarification and his consent.* As exemplified in other countries codes, current MEC contemplates fundamental ethical principles, like absolute respect for human life, obligation to enhance continuously knowledge, and maintenance of professional secrecy. It reaffirms incorporation of relevant features in the realm of medicine, such as: physicians and patients rights, human rights, organs and tissues donation and transplant, and medical research.

In this new code, the chapter dedicated to physicians' fundamental ethical and rights principles are just guidance of conduct, while physicians' duties are considered as deontological and their article susceptible to penalties. With scientific and technological progress in medical area as well as in consequence of new duties and rights in physician-patient relationship, professionals have faced ethical conflict situations in many instances, such as in cases of assisted reproduction, definitions about beginning of life terminality, resource allocation, among many others – which were incorporated into the new code.

The councils of medicine, agencies responsible for supervision of professional ethic and, at same time, judging and regulators of physicians in Brazil, seek to establish guidelines to lead professionals in these situations of difficulty or conflict in daily practice, through ancillary documents to the ethical code: the resolutions. Therefore, conflicts may arise regarding attitude that physician should assume in view of situation not clearly defined in medical ethical code – which have been discussed not only in the medical ambiance but, as well, involved participation of other professionals from the health sector and from outside the sector, inclusively in communication media with expressive participle of people and social groups. The outcome of discussions points to the need of periodic review of the medical ethical codes, such as occurred in Brazil in 2009.

In the clinical practice, considering physician-patient relationship, free and clarified consent becomes necessary for the definition and/or undertaking of a diagnostic or therapeutical procedure. OFree and clarified consent, in physician's professional practice, is stated in Article 22 og Chapter V about Human Rights, of the Medical Ethical Code, which prohibits physician to *let go*

without obtaining patient's or his legal representative's consent after clarifying him about procedure to be undertaken, except in case of eminent risk of death [8] – which is reinforced also in Article 24 that prohibits equally physician *to not ensure patient the exercise of his right to freely decide about himself or about his well being, as well as to exercise his authority to limit him* [8]. Still, it is stated in Article 31 of Chapter V, about Relationship with Patients and Family members, *when it sets forth that it is prohibited to physician to disrespect patient's right or of his legal representative to freely decide about execution of diagnostic or therapeutical practices, except in case of eminent risk of death* [8].

Anesthesiology and medical ethics: data from a case study

According to the State of Sao Paulo Regional Council of Medicine (Cremesp), about 20% of denounces related to anesthesiologists turn into disciplinary processes. Statistical assessment referring to 100 denounces registered in the Anesthesiology area, between January 1999 and January 2004, shows that 20 of them, that is, 20%, turned into disciplinary processes, which differs from the general statistics of the institution for all other areas, which is approximately 13% [9].

Many factors compete for this difference in relation to other specializations. One of them is that Anesthesiology presents high risk of eventual complications to become sequels, often irreversible or evolving to death . Another, are anesthesiologist work conditions, not always the best ones, concurring to expand risks exposition.

Major complaints related to Anesthesiology during surveyed period are, in decreasing order of complications (sequels and death), 39%; abandonment of on-duty period, 15%; physician-physician relationship, 9%; probable anaphylactic chocks, 6%; absence at surgery room, 4%; physician-patient relationship, 4%; problems with honoraries, 3%; refusing to undertake anesthesia, 3%; chemical dependence, 3%; working conditions, 2%; sexual harassment, 1%; incapacity disease, 1%. The percentage related to *other general causes* corresponded to 10%.

Concerning complications variables (sequels and death), 39%; work conditions, 2%; and probable anaphylactic shock, 6%, adding to 47% of recorded problems, CFM Resolution no. 1,802, of October 4, 2006, in its Article 2 set the minimum safety conditions for anesthesia practice. Anesthesiologist must require from the clinic management in his working place the fulfillment of this standard [10]. Another major point of this resolution – in Article 1, third paragraph – deals with record, in anesthesia sheet, of patient's vital signs, added to completely filling up of inter-occurrences and measures taken, both in the anesthesia sheet and in the medical evolution sheet. Equally, MEC Article 87 prohibits the physician *to let go without preparing legible record sheet for each patient* [8]. These measures are essential, as these data will be analyzed when

there is need to assess information about any inter-occurrence attributed to anesthesiologist's ethical-professional performance.

Still on these variables, regarding undertaking simultaneous anesthesia, the above mentioned resolution, in its Article 1, fourth paragraph, is very emphatic: *it is attempting act to Medical Ethics undertaking simultaneous anesthesia in different patients by the same professional, even if it is in the same surgical ambiance*.

Concerning physician-physician relationship, which corresponds to 9% of complaints, and issues regarding honoraries (3%), data analysis related to anesthesiologists is similar to other specializations. The professional must be accurate, clear with patient, and family. The Medical Ethical Codes, in that sense, in its Chapter V, related to patients and family members, and Chapter VIII – Professional remuneration – regulated directly this relationship.

Abandonment of on-duty period is well typified in Articles 7, 8, and 9 of the Medical Ethical Code [8], as well as in the later single paragraph, which defines scheduled physicians' responsibility to perform on-duty periods in urgency and emergency services, as well as of the institution in which they render service. Cremesp Resolution no. 74/96 defines Distance on-duty or availability on-duty periods. These two types of complaints were identified in the survey with percentage of 15% for abandonment of on-duty period, and 4% for absence of surgery room.

The *chemical dependent* medical professional, whose percentage of complaints in Cremesp assessed material corresponded to 3%, was evaluated in a work carried out by the Alcohol and Drugs Survey Unit of the Paulista Medical School of the Federal University of Sao Paulo (Unifesp/EPM), in partnership with Cremesp. The outcomes of this analysis, which was published in September 2001, showed, in percentage, the most susceptible specializations. Medical Clinic (24.76%) was in first place, and in second, tied, Surgery (12.13%), and Anesthesiology (12.13%) [10].

Discussion of judged processes

Out of the completed and judged processes involving Anesthesiology specialization, between January 1999 and January 2004, 36% were condemned and 64% acquitted. Regarding applied penalties, 36% received penalty A (confidential warning in reserved notice); 18%, penalty B (confidential censorship in reserved notice); 18%, penalty C (public censorship in official publication); 28% got penalty D (suspension of professional service for up to 30 days, and official publication). None got penalty E (abrogation of professional exercise *ad referendum* of CFM). There was not, in the statistics of the period, referenda abrogation process, since it, with appeal level at CFM or at judicial realm, is computed only after ruling in these instances.

Among major medical specializations related to denounces during this survey period, out of a total of 12,830 received, Anesthesiology is in 14th position. In the first ranking position are Gynecology, Obstetrics, and Ophthalmology, respectively.

In previous periods, the specialization ranked 7th and 12th positions. This decrease of infractions is due to enhancement of the Brazilian Anesthesiology Society Teaching and Training Centers, to improvement in working conditions, influenced by ethical councils resolutions, and enforcement undertaken by the Cremesp Investigation Department, and of the Sanitary Surveillance, to prevention, through didactic classes and simulated judgments, and, still, to increase in the amount of legal actions.

Final considerations

It is evident that, in face of the exposed in this brief analysis of installed and judged processes within the scope of Cremesp, the term free and clarified consent for anesthetic procedure should become a mandatory document, and convenient that professionals from this specialization to adopt it. Even if patient agreed and formally consented with the undertaken of a procedure that implies anesthesia, it is not too much for the anesthesiologist to count with specific document as well. In fact, the trend among professionals of the area is toward its use, since it may help in future processes. It should be highlighted that medical insurance firms have made already requirements regarding the filling up of a document in the model of a consent.

The term to be completed and signed would confirm that patient (or the legal representative) was informed about the anesthetic procedure and its eventual risks, as well as been clarified on doubtful issues related to procedure. Just like the other documents attesting consent, it should be signed by patient or his legal representative, the anesthesiologist doctor, and by one witness. One suggests that the document states: 1. Patient's identification; 2. Explanation about the anesthetic procedure (type of anesthesia) or proposed treatment; 3. Possible alternatives to proposed procedure; 4. Foreseeable risks and benefits; 5. Necessity and alternatives to blood transfusion and/or of its components, when indicated; 6. Patient's signature or his legal representative, accepting procedure undertaking; 7. Witness' signature; 8. Anesthesiologist's signature.

The issue is not a consensus, and it lacks broadened and deepened discussion. It is fit still to record that such discussion will be as fruitful in as much as one considers that consent is not just a response to professionals' legitimate interest in the area of anesthesiology, but, particularly, as an instrument targeted to promote patient's autonomy.

Resumen

Consentimiento libre y esclarecido en la anestesiología

El artículo tiene por objetivo discurrir sobre el Consentimiento informado, comprendido como la aprobación expresa o tácita del paciente en lo que se refiere a participar un procedimiento diagnóstico o terapéutico, que, no obstante, no es obligatorio para el procedimiento anestésico. Basa la discusión en levantamiento estadístico realizado por el Conselho Regional de Medicina do Estado de São Paulo - Cremesp (Consejo Regional de Medicina del Estado de São Paulo), que apunta la existencia de 100 denuncias registradas en el área de Anestesiología, en el período comprendido entre Enero de 1999 y Enero de 2004. Concluye presentando la sugestión de que los médicos anestesiólogos adoptasen el Consentimiento Informado en su práctica laboral, visando tanto respaldar al profesional como proteger la autonomía del paciente, que, de esta forma, puede ejercer su derecho de elección.

Palabras-clave: Consentimiento informado. Anestesiología. Ética médica.

Resumo

Consentimento livre e esclarecido em anestesiologia

O artigo tem por objetivo discorrer sobre o termo de consentimento livre e esclarecido (TCLE), compreendido como a aprovação expressa ou tácita do paciente quanto a participar de um procedimento diagnóstico ou terapêutico, que, no entanto, não é obrigatório para o procedimento anestésico. Baseia a discussão em levantamento estatístico realizado pelo Conselho Regional de Medicina do Estado de São Paulo (Cremesp), que aponta a existência de 100 denúncias registradas na área de Anestesiologia, no período compreendido entre janeiro de 1999 a janeiro de 2004. Conclui apresentando a sugestão de os médicos anestesiologistas adotarem o TCLE em sua prática laboral, visando tanto a respaldar o profissional quanto a proteger a autonomia do paciente, que desta forma pode exercer seu direito de escolha.

Palavras-chave: Consentimento livre e esclarecido. Anestesiologia. Ética médica

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