

Legal considerations about informed consent inside health field

Reflexiones jurídicas del consentimiento informado en el ámbito sanitario

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Abstract:

Informed consent is a process by which people are previously informed in a clear, complete, truthful and timely manner about the disposition of their human body, in life or post-mortem, whether for therapeutic, teaching or research purposes. Is a legitimating principle of the biomedical act as guarantees respect for the autonomy of the patient and justifies the intervention of health personnel. There are various forms of externalization of informed consent, according to the stipulations of the regulatory framework. It is considered as an inherent obligation to the actions of the health care professional, so it is understood as an integral part of the *lex artis*. A brief review of its legal regulation and of the doctrinal elements is made in order to identify its mandatory and legal significance.

Keywords:

Informed consent. Biomedical Act. Autonomy. Medical care.

Resumen:

El consentimiento informado es un proceso por el cual la persona es informada previamente de forma clara, completa, veraz y oportuna sobre la disposición de su cuerpo humano, en vida o post-mortem, ya sea con fines terapéuticos, de docencia o de investigación. Constituye un principio legitimador del acto biomédico, pues garantiza el respeto a la autonomía del paciente y justifica la intervención del personal de salud. Existen diversas formas de exteriorización del consentimiento informado, de acuerdo a lo que establezca el marco normativo. Se considera como una obligación inherente al actuar del profesional de la salud, por lo que se entiende como parte integrante de la *lex artis*. Se hace una breve revisión de su regulación jurídica y de los elementos doctrinales con el propósito de identificar su obligatoriedad y trascendencia jurídica.

Palabras Clave:

Consentimiento informado. Acto Biomédico. Autonomía. Atención médica.

INTRODUCCIÓN

Interventionist nature of healthcare activity has legal involvement, this it goes beyond to the patrimony of the person because of right-dignity, life and personal integrity, why is necessary to identify the legitimizing criteria.

Formerly, the patient was limited to follow the indications from the health personnel, without having the right to participate in decision making. This relation has been determinated as paternalistic model, mainly based on the healthcare action which is looking for the person's well-being emerged from hippocratic tradition.

However, inherent dignity of a person was imperative to recognize autonomy as an attribute that let him decide freely and conscientious about aspects of his/her life. Henceforth model of deliberate emerges, whereby the patient has the opportunity not only to comment on but also to authorize any intervention that is practiced about corporeality.

Due to this, informed consent came up, which is in health sector is really important because it constitutes the respect of patient's autonomy, allowing him/her to decide about intervention of healthcare personnel, having as a reference the previous information about its scope and content.

In the consensual legal act, the consent is an element of existence that is to say that a contract should have legal effects, it requires the willingness of the people involved on that.

The National Commission of Medical Arbitration (2016) has defined informed consent as:

The free and voluntary act done by a competent person, for this reason the patient accepts the diagnosed or therapeutic actions suggested by his/her doctor. It is relevant to comprehend the information given about the risk and the benefits that it can cause him/her.

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In some cases, this legal process is only viewed as a document that denies all responsibility to the healthcare personnel. Nevertheless, it is a legitimizing act (Pacheco, 2011) that guarantees respect in terms of autonomy of the patient and also as a health professional exercise. It is about a process in which is given clear, complete, truthful and appropriate information in order to affect his/her decision making of accepting or refusing about the proposed procedures within full freedom and awareness of the same. Therefore, it is not only focus on the document, because it will be showed during the process of information given.

First of all, information must be obtained from the patient and in case that he/she can give it because of a temporary or permanent disability, it could be consider the nearest relative that accompany him/her. As will be demonstrated later on, if there is an impossibility to take this information from them, in case of emergency, authorized assistance staff of the setting would accept to safeguard the patient's health and life because they have the possibility to apply the necessary procedures. In the case of implementation of palliative care, including the Hospital Committee of Bioethics can decide based on the same terms.

In the health sector, the consent is an essential requirement to the disposition of the human body in acts such as medical attention and health research in human beings, as well as a corpse for the purpose of transplanted, teaching or research. In respect of medical attention, collecting of informed consent is not limited to the therapeutic measures, but also to those diagnosed or prevented, or paraclinic studies that carry an invasive procedure, for instance, vaccines, imaging studies with contrast dye, in other words, implementing all that related to the person's integrity.

In this respect, medical attention is given in a multidisciplinary way by personnel of different health professions such as medicine, odontology, nursing, nutrition, psychology, gerontology to name a few. Because of that the obligation to obtain informed consent not only applies for the medical personnel, but also to any professional that provides medical attention. The articles 32 and 33 of the General Health Law define it as the set of services that are given to the person to protect, to encourage and to restore the health through preventive, healing, rehabilitation activities and palliative care without limiting the professionals of medicine.

In this sense, when giving medical care or developing investigation procedure to human beings, it is established a juridical relation between the service provider and the userⁱ which lead to the consequence of imposition of obligations and in the mutual acknowledgement of the right between the

parties. Consequently, if the user's right is included to give informed consent, its collecting is viewed as an obligation to the service provider without restricting any profession and being suitable to all health personnel that provide medical care.

The consent is an important part of the *lex artis*ⁱⁱ, thus within the inherent duties to the health professionals, we can find respect to the dignity of a person. This is an imperative that results in obtaining authorization prior to any intervention. In addition, it relates to the principles of the mainly Bioethics such as autonomy, beneficence, non-maleficence and justice.

In terms of autonomy, opportunity is guaranteed to the patient to decide on his or her care once he or she has been informed. With respect to the principle of beneficence, its authentic exercise by the health personnel is accredited, by relying on the permission granted by the patient, because otherwise one could not speak of a benefit if one acts violating his will.

Observance of the principle of non-maleficence translates into giving truthful, complete, clear and timely information, in order to warn the patient of potential risks and, with knowledge of this, they are able to decide whether to accept or reject the proposed procedure.

The principle of justice implies that consent would be obtained from any patient who is able to express it, avoiding any type of discrimination on grounds such as age, state of health, religious ideas, ethnic origin or sexual preferences.

DIFFERENT WAYS OF ASSURING INFORMED CONSENT.

On the basis of its form of expression, this consent may be classified as follows:

a) Tacit consent:

This form of consent refers to the presence of unequivocal signs of acceptance in medical care, the most frequent case of that is consultation, in which the patient without expressing verbally or written consent, he/she accepts the indications expressed in the prescription or receive the meal plan in nutritional care.

It is valid as long as the legal rule does not require another way. It also applies to the disposition of post-mortem organs and tissues, since numeral 324 of the General Health Law determines that if there is no express refusal of the person. It is understood that there will be tacit consent of the disposer, even when the authorization of the spouse, concubine, descendants, ascendants, siblings, adoptee or adopter is required. According to that order, in their capacity as secondary disposers.

b) Verbal consent:

As long as the legal norm does not oblige the written expression of informed consent, it can be given verbally, which happens in cases such as paraclinic studies, the application of questionnaires or interviews, the elaboration of clinical history, wound healing, among others.

This way of expression is applicable to procedures with less invasive degree and low risk.

c) Written consent:

As mentioned above, the legal norm establishes the cases in which consent has to be expressed in writing, which is embodied in the so-called informed consent letters. Official Mexican Norm NOM-004-SSA3-2012, of the clinical file, in its numeral 4.2 defines them as the written documents, signed by the patient or his/her closest legal representative or family member in bond, by means of which a medical or surgical procedure with diagnostic, therapeutic, rehabilitative, palliative or research purposes is accepted, once information has been received on the risks and benefits expected for the patient.

The minimum requirements that these letters must contain are:

- Name of the institution to which the establishment belongs, if it is applicable.
- Name, reason or social denomination of the establishment.
- Title of the document.
- Place and date of issue.
- Authorized act.
- Indication of the risks and benefits expected from the authorized medical act.
- Authorization to the health personnel for the attention of contingencies and urgencies derived from the authorized act, attending to the principle of prescriptive freedom.
- Full name and signature of the patient, if the patient's state, allow it. In the case that the patient's state of health does not allow him/her to sign an issue consent, the full name and signature of the closest family member present, guardian or legal representative.
- Full name and signature of the doctor that providing the information and obtaining consent for the specific act that was granted.
- Full name and signature of two witnesses.

In relation to this, several normative precepts establish the obligatory nature of obtaining authorization by means of informed consent letters. Some cases are hospital admission, major surgery procedures and general or regional anesthesia, salpingoclasia and vasectomy, disposition of organs, tissues and cells for transplantation purposes, clinical research on human beings, hospital necropsy, diagnostic or therapeutic

procedures that in the opinion of the doctor are high risk and those involving mutilation.

It is also required in the application of blood transfusions, temporary methods of family planning, dialysis and hemodialysis procedures, virus detection studies, among others.

Since the exigibility of this way of consent is based on the greater risk represented by the procedure and its invasive degree, it is left to the judgement of the health personnel to obtain it when they consider that the act warrants it.

However, it is essential that all the information provided to the patient or in the case the representative. Since if they are only abstract and generic documents, they will not have the legal effectiveness to accredit the fulfillment of such obligation. In this regard, the Second Chamber of the Supreme Court of Justice determined that the existence of generic and abstract documents signed by patients that do not meet the minimum requirements of the corresponding Official Mexican Standard is insufficient for this purpose, and that the preparation of these letters should not be considered by health personnel as an excessive burden, but as a means to provide them with the legal certainty of adequate professional practice.

It is evident that the letters must be prepared for each patient, taking into account their idiosyncrasy, state of health, cultural context, etc.

These documents are integrated into the clinical file. If their accreditation is required before a claim or act of vigilance of the authority and it is not exhibited, it could generate the presumption of malpractice without causal link to the patient's state of health. Since being part of the *lex artis*, it would lead to the breach of an obligation.

On the other hand, as mentioned above, when the patient's state of health does not permit consent to be obtained from the patient, he or she will seek it from the next of kin in attendance or by the legal representative or guardian. This form of consent is called proxy consent. It is highly recommended that if it is possible, the patient will be asked, in the case that he or she is unable to grant it, he/she must designate the person who will do it in his or her place.

However, in the event that it is not possible to obtain it from the patient or his representative and it is a medical emergency, ⁱⁱⁱ two authorized doctors by the hospital will record this circumstance in the clinical file and start the required care ⁱⁱⁱⁱ. In this case, the so-called presumed consent is updated, since it generates the presumption that the person would seek to safeguard health and life, in addition to being legal assets protected by public law.

As far as the information to be provided is concerned, its relevance must be taken into account, since excessive provision of such information would weaken confidence in the doctor-patient relationship, since a possible exercise of defensive medicine would be appreciated and could lead to greater concern or distress for the patient.

It is also important to warn that, in the exercise of the patient's autonomy, he can decide whether or not to share his health information, a right that will have to be respected. Unless it is necessary for his/her care, a situation that would expose him to authorize whoever can also be granted. In the event that the person does not wish to share the information, it is advisable that the family members be informed of the patient's decision, so that they are aware of why they are not being informed 4.

Agustín Viguri, mentioned the criterion of the Spanish Supreme Court, points out that considering whether it is curative medicine which could be added or necessary or satisfactory or voluntary medicine, is the information that must be provided. For the first case the typical and general risks that may arise, while for the second case, information would be provided on all even if they are remote, unlikely or exceptional. In relation to this, it is estimated that effectively in the satisfactory procedures, it is offered in a complete way, since it is an elective act of the patient, so he/she must be aware in the most complete way to take a free decision 4.

Similarly, it is recommended that the resolution capacity of the medical unit would be known in order to avoid false expectations and that the patient is aware of the means at his/her disposal.

REGULATORY ASPECTS

Article 51 Bis 1 of the General Health Law states that information must be sufficient, clear, timely and truthful about diagnosis, prognosis, treatment and evolution. According to this precept, information is not only for obtaining informed consent, but also during the entire medical care process.

On the other hand, article 9 of the Regulations of the General Health Law regarding the provision of medical care services, which provides for the observance of the scientific and ethical principles of medical practice, imposes as an obligation the obtaining of consent, since failure to do so would violate the autonomy of the patient.

Both in the General Health Law and in its regulations on the different subjects, as well as in the Mexican Official Norms, there are precepts that require the patient's authorization to be obtained.

An important aspect to mention is the case of involuntary income in mental health care. As it is a restricting measure the freedom of the person and acting beyond their autonomy, it is essential to justify such a measure requiring a psychological diagnosis, neurological, psychiatric and those medical specialties necessary, depending on the clinical condition of the user. The diagnosis must be accompanied by a report of the area of social work, which must be supported by analysis and studies according to their symptoms and the request of a responsible relative, guardian or legal representative, all in writing. Based upon the foregoing, in accordance with numeral 5.6.2 of the Official Mexican Standard NOM-025-SSA2-2014 for the provision of health services in units of comprehensive hospital medical-psychiatric care. The same precept regulates that in case of emergency and it is not possible to obtain the authorization, once the conditions allow it, it will be provided with the necessary information so that the person can give consent and his/her internment becomes voluntary.

Mental health users are in a situation of vulnerability, since there is a prima facie appreciation that they cannot exercise their autonomy because the suffering completely cancels it out. However, the affectation in the mental sphere does not mean that the autonomy is absolutely lost, because there will be the possibility that the user himself/herself can decide, or he/she needs the support of a family member or personnel of his/her confidence and only in extreme cases, the consent will be granted by a legitimate third party.

Given its legal significance, informed consent has been addressed in judicial activity, so two criteria of the Judicial Branch of the Federation are presented as an example through the Supreme Court of Justice of the Nation and the Collegiate Circuit Courts:

In thesis 1a. XLIII/2012 (10a.) the First Chamber of the Supreme Court of Justice of the Nation, determines that it is the patient's right to give or not give validly informed consent in the performance of medical treatments or procedures, so that the characteristics of the procedure must be made known, as well as the risks involved in such intervention.

Another criterion is supported in thesis 1a. CXCVII/2016 (10a.), in the sense that informed consent has two purposes. On one hand, is the authorization of a person to undergo medical procedures that affect his/her physical integrity, health, life or freedom of conscience. On the other hand, is the fulfillment of an obligation of health personnel to inform the patient about the diagnosis, treatment and/or medical procedure, as well as the implications, effects or consequences that could bring to his/her health, physical integrity or life.

In this regard, it is considered appropriate to clarify that in addition to the information provided to the patient upon obtaining his or her consent, throughout the process of providing medical care, the patient has the right to be informed of his or her diagnosis, evolution, prognosis and treatment. In the same jurisdictional pronouncement, the First Chamber of the Supreme Court of Justice of the Nation, without expressly recognizing the so-called presumed consent, refers to emergency cases in which it is not possible to obtain the authorization of the legitimate person, the procedure may be initiated with the agreement of at least two doctors authorized by the hospital, establishing such circumstance in the clinical file.

CONCLUSIONS

On the basis of the foregoing, it can be seen that informed consent is a point of connection between law and medicine, or the various health disciplines by virtue of the fact that being considered part of the *lex artis* is assumed as an obligation in the provision of the health care service.

It is necessary to insist on not conceiving informed consent only as a document, but as the process of complete, truthful, timely and clear information for the patient and, where appropriate, for the family member or legal representative.

There is a normative framework, particularly in the rules of health law, that regulates the assumptions and ways in which informed consent is obtained and expressed, provisions that are applicable to acts of medical care or health research, including the use of the corpse. Given the multidisciplinary nature of medical care, the obligation lies not only with the physician, but with all health personnel involved in the integrity of the patient.

Likewise, it is not a defensive act for the health personnel, but in the instrument to guarantee respect for the autonomy of the patient and as the legitimator of the biomedical act.

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i Generally known as the doctor-patient relationship.

ii The *lex artis* is a set of rules universally accepted by medical science for the correct execution of the biomedical act. It is recognized, for example, in article 9 of the Regulations of the General Health Law regarding the provision of medical care services and in article 2 fraction XV of the Regulations of Procedures for the Attention of Complaints and Expert Management of the National Commission of Medical Arbitration.

iii Article 81 of the same Regulation provides for this.