

Legal considerations about clinical records

Consideraciones jurídicas del expediente clínico

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Abstract:

The clinical record is a set of documents in which the care provided to the patient is accredited. It is the ideal mean by which the interventions of the health personnel, the patient's authorizations and, in general, someone's health condition gets established. On the one hand, it guarantees an information bank so patients may know the data related to their health, and on the other hand, it allows health personnel to accredit the service provided to the patient.

Keywords:

Medical records, Medical care, Health obligations.

Resumen:

El expediente clínico es un conjunto de documentos en el que se acredita la atención brindada al paciente. Es el medio idóneo para que las intervenciones del personal de salud, las autorizaciones del paciente y en general el estado de salud queden asentadas. Por una parte, garantizan un banco de información para que el paciente pueda conocer los datos relativos a su salud y por otra, permite que el personal de salud acredite el servicio otorgado al paciente.

Palabras Clave:

Expediente clínico, Atención médica, Obligaciones sanitarias.

INTRODUCTION

Medical attention is one of the actions to guarantee the right to health protection. Therefore, it is important to comply with its laws and regulations. From the relation between the health care provider and the user, several mutual obligations and rights emerge.

One of those inherent obligations is to make and integrate a clinical record, defined as the only set of personal information and data of a patient which is created within an establishment of medical attention, whether it is public or private, where they have written, graphic, imaging, electronic, magnetic, electromagnetic, optical, magnetic-optical, and any other type of files in which the health care personell register every intervention and health care attention provided to the patient, according to the applicable legal provisions¹.

LEGAL FRAMEWORK

This set of documents has a legal framework in several laws. For example, some provisions are the following: in the

General Health Law, the article 77 bis 37 section VII states that the beneficiaries of free health care services for people with no health insurance, have the right to a clinical record; the regulations to this law regarding medical care benefits state that the medical record should be preserved 5 years since the last medical intervention. On the other hand, the specific standard for its regulation is the Mexican Official Standard NOM-004-SSA3-2012, regarding the clinical file, besides other similar ones like those about the disposal of human blood, anesthesiology service, family planning, psychiatric attention, among others.

LEGAL RELEVANCE

The clinical record is not made by medical staff, it is made by several health care professions like dentistry, nursing, psychology, nutrition, gerontology, pharmacy, physical rehabilitation, to mention a few. The owners of the clinical records are the health care provider or the establishment, depending on the case.

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The doctrine mentions the following principles of the medical record (Cantoral, 2012):

1. Principle of confidentiality;
2. Principle of clarity and intelligibility;
3. Principle of protection of the patient's rights;
4. Principle of veracity;
5. Principle of de completeness;
6. Principle of content of authenticity;
7. Principle of unit and integration.

It can be affirmed that it is part of the *lex artis*, as it is an inherent obligation when providing health care because of the following reasons.

First, the activity of each health care professional will be accredited, leaving proof of their authorship and work. It is important not to consider it only as proof in case of a claim on behalf of the user, because it will only limit its usefulness in a legal process. In contrast, it is the mean to have a record of the attention provided and therefore have a bank of information about the condition of the patient's health which can be consulted at any moment by both the health care professional and the user.

That way, the patient will have the certainty that there is a record of all the medical interventions he or she has been through as the owner of the information, and on the other hand, the health care staff will also have the certainty to know the diagnostic and therapeutic background by looking to that source of information. That is its legal relevance.

Although it is a source of information so people can have access to their health information, it must be considered that it is a confidential source, meaning that only authorized people can have access, like the patient (who owns the information) or the health care staff who are providing the attention.

In fact, the law that protects personal data includes health information within sensitive personal data, which refers to data of the intimate sphere of the owner or data that might lead to discrimination or to a serious risk to the present or future health of the owner, as well as the genetic informationⁱⁱ. Therefore, the secrecy of the content must be guaranteed, avoiding any unlawful intrusion.

According to the Official Mexican Standard NOM-004-SSA3-2012, about the clinical record, section 5.6, the minimal period to preserve this bank of information is five years from the last medical intervention. It is important to mention that, in other cases, like human blood disposal, the Official Mexican Standard NOM-253-SSA1-2012, mandates that the clinical records are preserved for the same period in an active file and for the same period remain archived. That way, to analyze particular cases, the information will be available for a longer period of time.

There are several ways the owner of the personal data can have access to the clinical record content. In case of continuous treatments, the patient can constantly ask for information to the health care staff in charge of his/her attention –who will give it according to their professional competence – and it is

enough to ask for it verballyⁱⁱⁱ. It can also be requested in written if needed; there are some necessary precisions about this. The purpose of doing the request in written is to justify the delivery of information to the authorized person, releasing the health care staff from preserving it. According to the General Health Law Regulations regarding the provision of health care services and the Official Mexican Standard regarding the clinical record, it will be given to the patient a clinical overview. This has led to several disagreements for considering it an unjustified limitation to their right to access to their personal data, giving them only an overview and not a copy of the whole document. However, it must be considered that the clinical record has a technical character, making it easier for the patient to understand an overview –which in many cases does not have health information -. It must also be noticed that the health care staff believe that for the patient having full access to his/her clinical record might generate a defensive when using it in a possible trial. Nevertheless, they must not believe that because if the provider of the service has made and integrated properly the clinical record according to the *lex artis*, they will prove their fulfillment to their obligations. According to the previously mentioned, the patient can get a copy of his/her clinical record through administrative and judicial procedures to claim his/her human right of having access to their personal data.

It was mentioned that the patient (as owner of the information) is the authorized person to request the information. However, if he or she cannot claim his/her right because of a health disability or age, the closest relative, a legal representative or the person who has his/her custody, can request it. It is natural that they request it, but we must always protect the decision of the ill about sharing the information or not, except when the information is disclosed to a relative to benefit the ill. In such case, having access to the information does not allow them to improperly share it, thus they are obliged to keep confidentiality.

INTEGRATION OF THE CLINICAL RECORD. GENERAL ASPECTS.

Regarding the integration of a clinical record, the already mentioned standard NOM-004-SSA3-2012 establishes the minimal criteria, letting each health profession decide the elements to form it. In this regard, the Official Standard makes available the sections 5.15 and 5.16 which, in the cases of dentistry, psychology, nutrition and other similar ones with outpatient attention, the clinical record and the evolution notes will be adjusted to the nature of the services and will respect the scientific and ethical principles of the medical praxis.

Thus, the general requirements for its integration are the following:

1. General data of the establishment or service provider and the patient.
2. Every medical note and report must include at least:
 - a. Full name of the patient, age, gender, and number of bed and file if applicable.

- b. Date, time, full name and signature of the person who makes it.
3. The different notes will be written in technical language, readable letter with no alterations nor erasures. In this regard, it is worth mentioning that such requirements guarantee the intelligibility and legibility that characterize the clinical record, also allowing to identify who was the author of the notes.
4. It will be integrated taking into account the generic services of a general consultation, hospitalization and emergencies. If the attention of any of those takes place in one establishment, only one record will be integrated.

Based on the way the Official Mexican Standard mandates its integration, comments about the legal transcendence of each not will be made.

In the first place, in the informed consent letters it is stated the previous information given to the patient (or a representative) to express his or her will to accept or reject the diagnostic or treatment procedures indicated by the health care staff. The legal provisions establish the cases in which these letters must be made, as in the rest of the cases it can be a verbal consent.

If a medical emergency cannot wait and if it is not possible for the patient or his/her representative to decide, then we are before a presumed consent, which refers to the presumption that the patient would accept the measures to save his/her life. Therefore, two authorized physicians will state such situation in the record to legalize their action. These documents will also be useful to accredit that the patient was informed about the risks and benefits of the procedures.

INTEGRATION OF THE CLINICAL RECORD. EXTERNAL CONSULTATION.

Now, as for the external consultation service, number 6 and subsequent of the multicited Mexican Official Standard state that it will be integrated by:

- a) Clinical record.

In this document it is stated the interrogation and physical exploration that allows making a biography of the patient and identifying his/her idiology. It is wellknown that each person responds differently to therapeutic measures, therefore it is crucial to obtain precise data to have an approximation of the effects of each procedure, allowing to evaluate the risk-benefit of the measures to be indicated, trying to avoid or decrease the risks, or to take the provisions to tackle them. This document accredits the duty of the health care staff to interrogate the patient (Pacheco, 2011). It will be made depending on the discipline, taking into consideration relevant data for a proper attention.

- b) Evolution note.

This note will be elaborated in each revision of the patient. This will allow to have an updated record of the patient's interventions and the evolution of his/her health condition. It is made by health care staff who provide external consultation,

like dentistry, psychology, nutrition, gerontology, etc. If paraclinical studies are indicated, they must be justified and the interpretation of the results must be written down. Its legal relevance resides in being the ideal document to accredit a continuous attention provided to the patient.

- c) Interconsultation note.

When the clinical problema of a patient requires the intervention of other professional, his/her clinical evaluation and the result of it must be registered. It is a note where the participants are the professional who is requesting and the one who provides the interconsultation. The health care staff, according to their obligations, have the duty to ask for the opinion of other professional in case of an associated condition or a complication, because when the case is beyond their professional competence, their actions will not only lack of scientific support, but the patients would not be treated with dignity, violating the ethical principles of the medical practice^{iv}.

- d) Reference/transfer note.

If the response capacity of the establishment is not enough, the patient will be sent to another unit. Against the risks that the transfer implies, it is necessary to justify such decision so the risks can be validly asumed. This note will be useful to proof that every possibility for a better attention was sought, even another unit.

INTEGRATION OF THE CLINICAL RECORD. EMERGENCY SERVICE.

- a) Initial note.

Given the haste that the attention of a medical emergency represents, it is demanded an initial note that contains a summary of the anamnesis and the physical exploration. It is useful to proof the moment of the patient's admission to the service and which were the diagnostic and therapeutic indications. It is important to always write the date and hour of the attention, since one of the most frequent claims is the delay of the emergency attention.

That is why it has been necessary to establish a *triage* to evaluate if it is a real emergency or if it is perceived as an emergency by the patient.

- b) Evolution note.

The characteristics and importance of this note have already been mentioned; however, it must be highlighted that it is necessary to make it (if only briefly) each revision to the patient, because if it is necessary to accredit a strict surveillance to the patient in such emergency, this note⁴ will be the ideal document. If there is no note, the contrary can be presumed.

- c) Reference/transfer note.

It has been mentioned in the section of external consultation. When elaborated correctly, it allows to accredit the timely transfer to a unit with a better response capacity.

INTEGRATION OF THE CLINICAL RECORD. HOSPITALIZATION SERVICE.

In the service of hospitalization, several disciplines participate, so there are more notes to write on behalf of different professionals.

a) Admission note.

This note states a summary of the clinical record, as well as laboratory and image analysis, as well as the treatment and prognosis. The hospital admission is one of the actions that requires an informed consent letter, since it is necessary to have the patient's authorization, because being hospitalized, besides limiting personal freedom, it must be considered the risk of infections associated to the health attention. Therefore, once the patient has been informed about all that, he/she, together with the health care staff assume the inherent risks. Precise time and date must not be forgotten, because based on them the corresponding staff is in charge of the medical attention.

b) Clinical record.

As it has been mentioned in regard to external consultation, the clinical record represents the document where it is stated the information requested to the patient to know him and identify his ideology to be able to point out the risks and benefits of the procedures and their possible effectiveness for the patient. It can also be useful to interpret the patient's preferences related to certain measures in case of a disability to grant his/her consent; for example, if an unconscious patient requires a transfusion and the family do not accept it for religious motives, the data content in the clinical record can prove in the patient shared the same religious believe.

c) Evolution note.

Besides the already mentioned about the external consultation service, it must be highlighted the registration of any change in the health condition of the patient, as well as in the therapeutic indications. The existence of notes with common phrases with the same indications, without any change for several days, indicate an inadequate revision of the patient. The note elaborated by the physician is related to the nursing sheets because they include a registration of the general condition of the patient with the continuous take of vital signs.

d) Reference/transfer note.

The information of the previous sections will be retaken. It must be mentioned the importance of justifying the risks that the transfer implies. To validly assume the risks, the need of the patient is a condition.

e) Preoperative note.

Data previous the surgery like diagnostic, planned surgery, surgery risk, and prognosis, will be written. The surgical safety checklist is very important and it is responsibility of one of the members of the surgical team. The purpose of the checklist is to take the essential safety measures and foresee frequent risks that can compromise the health and life of the patient. With such data, it can be accredited that the actions of the health care staff were prudent and diligent.

f) Preanesthetic note, surveillance and anesthetic record.

Made by the person in charge of applying the anesthetic during the surgery. The importance of this note is having with a document that states the risk-benefit evaluation of the anesthetic procedure, the intravenous fluid administration – including blood and its derivatives-, as well as the general condition of the patient during the surgery, whose surveillance is in charge of the person who applies the anesthetic. With this document Con este documento se podrá tener constancia del cumplimiento de las obligaciones inherentes a este profesional de la salud.

g) Post operative note.

This note will state everything that happens during the surgery. Among the relevant data is the type of surgery that was planned and the one that was performed, the surgical findings, the number of gauzes and compresses, and the names of the surgical team. It is a mean to identify the participation of each one of its members. It should also include the sending of the surgical pieces for a histopathological study, crucial to get to a diagnosis in which a macroscopic test is not enough. Frequently, this is the only note that is elaborated, trying to substitute the preoperative note. This is not convenient because if the note is elaborated subsequently, it is presumed that it does not include true data.

h) Discharge note.

It will include the motive of discharge, whether it is an improvement, a greater hospital benefit or death. In the case of a voluntary discharge, another note is elaborated. Besides the registration to hospital attention, the recommendations for outpatient attention, unresolved clinical problems, the attention of risk factors, and prognosis, will be stated; information that will be given by the patient in writing and in an understandable way. In case of death, the causes of death will be stated in relation to the death certificate. In the legal evaluation, the death note and the death certificate are correlated, mainly to clarify the chronology; that is why the must be elaborated correctly and consistently. This note will allow to explain the discharge in case of a claim arguing a lack of attention.

i) Reports of professional and technical staff.

They contain the activities carried out by the nursing staff and the diagnostic and treatment assistants. When the assessment of biomedical actions is carried out, the whole process of medical attention is covered, thus it is of great importance to have the information generated in these notes. This will allow to identify the participation and obligations of those who were involved in the service, contrasting the information with the rest of the notes of the clinical record.

j) Other documents.

a. Informed consent forms.

When the legal provisions demand the informed consent in writing, the notes must be elaborated and integrated in the clinical record. The accreditation of the acceptance or rejection of the patient, or his/her legal representative, to the suggested measures with

the knowledge of the risks and benefits they comply, as well as the consequences of his/her decision.

b. Voluntary discharge note.

This note is of a great importance since it states the will of the patient or legal representative when the patient cannot express it himself, of leaving the hospital. The complete information given to the patient about the consequences of doing so should be written down. It will also include a clinical summary and the suggested measures for the health care of the patient, who will receive a copy. This way, the hospital staff will proof having given the patient the measures to follow from the moment of discharge. This note releases from all liability the institution from the momento of discharge of the patient.

c. Notifce to the Public Prosecutor.

If the patient has injuries probably linked to the comission of a crime, it is a duty to inform the corresponding authority in charge of criminal prosecution. This is not an accusation of someone in particular, it is just providing information so the corresponding investigation is carried out.

k) Report of cause of death under epidemiological surveillance.

This report shares information to protect the public health, since it is an inherent obligation of the health care staff. To do so, several Mexican official standards (particularly those of epidemiological surveillance) establish the minimal data they must include.

l) Death and stillbirth notes.

It is evident the legal transcendence of these notes, since they determine the momento of death of a patient. It is important that the data for the death certificate is obtained from this note, because it is elaborated by the person who declared the death, achieving consistency between the two documents.

Once the different notes that integrate the clinical record have been disclosed, it is necessary to make some clarifications about their legal evaluation.

To do that, the Mexican Official Standard about the clinical record compels to take into consideration the scientific and ethical principles that guide the medical practice, the respect to freedom –faculty of the health care staff to act according to their professional criteria based on the *lex artis*-, and the conditions of circumstances, time and place. These aspects will allow to evaluate more fairly the overall aspects of medical attention.

Also, it must be realized that the investigation of a posible bad praxis, is not limited only to the revisión of the clinical record, but it must also cover everything that the medical attention implies, this is, a set of resources that sistematically intervencen for prevention, healing and palliative care of diseases affecting the users, as well as their rehabilitation^v.

In this regard, the Mexican Supreme Court (2016) has determined that, even when one of the obligations assumed by the health care staff is to properly elaborate and integrate the clinical record, the noncompliance of this obligation is not always translated in an element to determine the liability of the health care staff, since the damage, the guilt and the causal connection between them must be proven.

Such criteria will guide the authorities so in a fair context, the cases in which a bad praxis is alleged, are evaluated; meaning that if the noncompliance of the provisions about the clinical record is not the reason for the patient's damage, the legal consequence will be translated in an administrative penalty; on the other hand, if the failure is related to the fateful result, the corresponding liability will be confronted.

CONCLUSIONS.

The clinical record is the set of technical and legal documents where all the medical attention provided to a patient is registered. Besides being a bank of information of a health condition, it will accredit the health care staff compliance to their obligations, since they must be included in the record itself.

The information is confidential, therefore, it can only be shared with the staff in charge of the medical attention, with the patient, with authorized third parties and those linked to him/her, and the authorities empowered to that end.

Its elaboration and integration are parte of the *lex artis*, so it noncompliance could be a legal accusation.

In the analysis of probable bad praxis cases, the evaluation of the clinical record will be done like one more element part of the medical attention, without considering that a bad integration of the record could be a reason of a harmful result for the patient.

A proper compliance to the laws about the medical record will provide certainty to both the patient and the health care staff, about the information being true and therefore prove a proper service.

REFERENCES

- Cantoral, K. (2017). *Derecho de Protección de Datos Personales en Salud*. México: Editorial Novum. ISBN-10: 6077986364.
- Pacheco, A. (2011). *Legitimación del acto biomédico*. México: Editorial Alfíl. ISBN: 978-8045-49.5.
- Suprema Corte de Justicia de la Nación (2016). *Responsabilidad civil extracontractual por negligencia médica. Estándar para valorar si el incumplimiento de la normativa que regula un expediente clínico actualiza o no una conducta negligente*. México: Tesis 1a. CXCVIII/2016 (10a.). Disponible en https://sjf.scjn.gob.mx/SJFSist/Paginas/DetalleGeneralV2.aspx?Epoca=1e3e10000000000&Apendice=1000000000000&Expresion=expediente%2520c1%25C3%25ADnico&Dominio=Rubro,Texto&TA_TJ=2&Orden=1&Clase=DetalleTesisBL&NumTE=25&Epp=20&Desde=100&Hasta=100&Index=0&InstanciasSeleccionadas=6,1,2,50,7&ID=2012113&Hit=8&IDs=201523,2021448,2018488,2013945,2012887,2012869,2012512,2012113,2012107,2012106,2006298,2002615,2002614,2001385,2001384,2001233,162418,163637,164822,164752&tipoTesis=&Semario=0&tabla=&Referencia=&Tema=

ⁱ En términos del numeral 4.4 de la Norma Oficial Mexicana NOM-004-SSA3-2012, Del expediente clínico.

ⁱⁱ Artículo 3, fracción X, de la Ley General para la Protección de Datos Personales en Posesión de Sujetos Obligados.

ⁱⁱⁱ De acuerdo a lo dispuesto por los artículos 51 Bis 1 de la Ley General de Salud y 29 de su Reglamento en materia de prestación de servicios de atención médica.

^{iv} Hay que recordar que el artículo 9° del Reglamento de la Ley General de Salud en materia de prestación de servicios de atención médica ordena la observancia de los principios científicos y éticos que orientan la práctica médica.

^v En términos de la fracción V del artículo 7° del Reglamento de la Ley General de Salud en materia de prestación de servicios de atención médica.