Review Article

The Clinical History in Surgical Processes. Bioethical Aspects and Basic Professional Ethics

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Abstract
Surgeons are increasingly facing multiple civil liability claims from their patients. Against this background and taking any eventual liability claims into account, surgeons must be increasingly aware of the importance of maintaining patient medical histories, which raises numerous questions on the length of time and form of keeping them. Ethical and legal obligations need to be taken into account in order to identify the controversial aspects related to patients and their environment, as well as shedding light on the most appropriate behaviour in each case. We must never forget the case history is a clinical document, subjected to the medical art and medical ethics which regulate it.

Key words: Clinical records. Surgery. Bioethics. Professional ethics.

Introduction

Efficacy in surgical care requires that all of the patient's health and disease-related information be collected in a document that can, at any given moment, be consulted by the surgeon or other healthcare personnel. In this way, it guarantees continuity of care, the ability to follow the patient's progress and objectively save the data provided by the patient and their family, as well as the observations, studies and complimentary data.

New forms of medical practice, the changing nature of the physician-patient relationship and changes in the paradigm that governs this relationship require a new model for this document; more formal, more complete, and one in which not only physicians participate, but also other healthcare professionals. The practice of this type of medicine has, to a certain degree, broken this intimate and personal relationship between physicians and patients, in which the private and confidential information contained in the clinical record is shared with other personnel, which are not just healthcare professionals, making it difficult to maintain professional secrecy. However, the fact that records pass through so many hands cannot be at the expense of preserving the confidentiality and secrecy contained within them.

The ethical principle that the clinical record is created and preserved for the purpose of patient care is inviolable and must supersede any other right. Every time a clinical record is reopened, whether it be due to a new disease process,
a review of previous disease processes, for scientific, inspection or legal reasons, it should be done under the same bioethical principles which the document, in the patient's presence, was first initiated.

The patient's clinical record is a continuum, though every medical action recorded in it is an individual action as such, and the surgeon recording it is the responsible of it; however, it is indivisible in regards to the data recorded in it, and we are obliged by legal and moral law to maintain the confidentiality of this data.

The need to preserve and guarantee the rights and obligations of patients, surgeons and eventually of third parties who may use the clinical record as a documentary source for purposes other than delivering care, though equally justifiable and legitimate, has required the drafting of laws that regulate this complex document, not only with regard to its clinical and ethical aspects, but also administrative and legal ones.

Because there are broad legal regulations that must be understood with regard to the requirements for legal protection of the interests involved, some of these are as far reaching as guaranteeing the individual rights protected as Fundamental Rights by Title One of the Spanish Constitution. But one should never lose sight of the fact that the clinical record is, above all else, a clinical document which falls under the standards of medical arts and medical ethics that govern it. In surgical records, it is normal to find entries made in haste that, due to the professional obsession to focus on the act of surgery, may result in bothersome legal consequences in the future.

As stated in Article 7 of the Spanish Medical Code of Ethics (CEDM): “The efficacy of medical treatment requires a completely confidential relationship between the physician and his patient.” Understanding a patient’s problems and suffering is only possible if patients confide in their surgeon without any reservation, knowing full well that these statements, sometimes trivial, sometimes important, will be maintained under strict professional secrecy. The surgeon who is creating or consulting a record can never forget that the information contained in the record is of extreme importance, given that it is directly related to the fundamental rights of the individual: the right to privacy from which other important rights emerge, such as honour, dignity, freedom, physical integrity, and health. If a surgeon is convinced that some specially sensitive information that should never be revealed because of its special relevance and importance would not be kept with the necessary guarantees, he/she should not include it into the clinical record.

The Nature of the Clinical Record

The clinical record is a fundamental document in the physician-patient relationship since it contains a patient's free and voluntary statements and, at times, contains intimate feelings as the patient experiences them. The clinical record should include the case history and examination of the patient, as well as the conscious and voluntary acceptance of the examinations and consultations proposed, the refusal to receive treatment or to undergo certain examinations. It may also record information provided by family members or close friends whenever they are of interest to the diagnosis or treatment. Finally, the surgeon may express opinions in order to justify a decision that is made. It is obligatory, notwithstanding the rights of other professionals, to record the patient's progress and any events and incidents that are relevant to the treatment process. The notes recorded must be relevant to the treatment process, truthful and respectful of the patient and their family. It is not ethical to filter or modify clinical data based on possible future legal requirements.

It is an ethical and legal requirement that all medical acts carried out over the course of the treatment process are faithfully included in the record, and the physician has the irrevocable right and obligation to write it (Art. 13.1, CEDM). The physician is the main responsible for completing and updating the record and he/she should contribute to the record with scientific and personal contributions. In addition, the physician is required to maintain and ensure maintenance of confidential information, whether it is communicated directly by the patient, by other colleagues, or even by consulting the clinical record. Even the death of the patient does not absolve the physician of this obligation (Art. 14 and 15, CEDM and Article 18.4 of Spanish Basic Regulation 41/2002 on patient autonomy and rights and obligations on clinical data and documentation).

The fundamental goal of the clinical record is to facilitate and organize the patient's medical treatment. In order to achieve this, it should contain all of the data and information acquired at each of the medical actions in which the patient has been involved over the course of their lifetime. Also, the record should contain studies and data that have been obtained even when these are normal or have been negative. One should not assume that if data are not available that the findings are normal or negative. It should contain the data that justify the different diagnostic and therapeutic procedures used, as well as supporting documentation of the information received by the patient and of the consent granted by the patient for these procedures.

The surgeon must ensure that the wishes and decisions expressed by the patient are included in the record in a clearly visible location for immediate and/or emergency review. It is an ethical requirement to use the appropriate terms, avoid personal or local terminology and abbreviations, even though they may be widely-used, and write in legible handwriting, though this problem has been resolved with the digital record.

Teamwork allows different surgeons or other healthcare professionals to have access to the clinical record over the course of the same process. The author of each treatment action must be clearly identified in the record, as only this individual would be ethically and legally responsible for that action. Diagnostic and therapeutic discrepancies can and must be included in the record, maintaining the decorum that professional relationships require and without transforming this document into a forum in which differences that are not related to the clinical case are resolved.

Ownership of the Clinical Record and Access to it

The surgeon, due to ethical (Art. 13.2, CEDM) and legal requirements and the institution, where applicable, in which the surgeon works, are required to put practices into place
that: preserve clinical documentation; prevent unauthorized access or use, falsification or elimination of data; prevent theft, malicious changes, loss or accidental destruction of the record during the period of time that it is deemed necessary to store it, which will never be less than 5 years (Spanish Regulation 41/2002, Art.17).

Given that the main purpose of the clinical record is to facilitate care, any use of the record for any other purpose must comply, in principle and with minimal exceptions, with 2 ethical requirements: that confidentiality is not compromised at any time and that consent is granted by the patient and the physician (Art. 13.4, CEDM).

Article 18.1 of the Constitution guarantees the right to personal privacy and the right to one’s own image as fundamental rights. However, as has been established by the Spanish Constitutional Court, these rights are not absolute. On some occasions, excessive protection of these rights may come into conflict with other interests of the society or third parties, which requires this problem to be resolved with the least amount of damage as possible. Spanish constitutional doctrine establishes that, when personal rights are violated in the public interest, it must be ensured that the damage is minimum by following strict proportionality criteria: the damage caused may not be greater than the benefit that is supposed to be obtained by violating that right. Notwithstanding the established in other regulations, Spanish Regulation 41/2002 includes the clinical record issue, stating in Article 7.1 that “all persons are entitled to have the confidential nature of their health data respected, and no person shall gain access to these data without prior legally granted authorisation.”

Only in very specific situations, when the public or common good may override private good, and the principal that justice has been imposed over personal autonomy, can the surgeon reveal the patient’s confidential data without committing an infraction; however, this will always be done in a restricted fashion, with discretion and revealing only that which is necessary and only to those who are authorized by law (Art. 16.2, CEDM). This is one of the situations in which the surgeon acts as the guarantor, especially if the patient could not defend himself.

The general opinion of civil rights experts, with regards to the Spanish General Law on Health, Spanish Royal Decree 63/1995 and some regional decrees, is that the clinical record remains the property of the institution that employs the physician. However, it is clear that there are three actors with well-defined rights and obligations, which leads to a situation of co-ownership:

– The patient is the fundamental element. Without the patient there is no record. The patient actively participates by reporting his symptoms, family and personal history. The patient passively participates by allowing himself to be examined and by undergoing the studies that are ordered. The patient gives legitimacy to the act of providing consent.

– The surgeon directs the case history, examinations and diagnostic tests, while providing the clinical judgement and proposing and carrying out the medical and surgical treatment. The surgeon is the guarantor of confidentiality while the history is in his/her possession. The surgeon gives legitimacy to the medical act while respecting the principle of patient autonomy.

– The institution provides the material and human means to carry out the medical act. It sometimes also provides the therapeutic means. It is legally required to save and store the record.

Given that none of the 3 parties has absolute dominion over the record, there will be rights of some parties that create obligations for others:

– Rights of the patient: the patient has the right to demand that his/her data consist of a record; that this is stored with material and moral guarantees to consult the record or have a copy or part of it; the patient has the right to designate a representative who can speak on his behalf, to authorise non-healthcare personnel to consult it, to prohibit third parties from having access to it, and to decide its destination after his death. The patient is obliged to be truthful in his statements to healthcare personnel.

– The surgeon has the right to write the record of his/her patients and, as the author, no one can modify, amend, substitute or redact it. The surgeon has the right to exclusively reserve a confidential space in order to make subjective remarks (Spanish Regulation 41/2002, Art. 18.3: “[...] respecting the rights of professionals who are participating in its creation, who may refuse the right to access their subjective remarks”); to limit the rights of patients and the administration when, given his/her role as a guarantor, the surgeon has to maintain the right to privacy of certain data belonging to third parties and included in the record in the patient’s clinical interest; and to select information that must be provided to a judge and to the health authorities in order to resolve an issue.

– The centre or the health institution has the property rights over the tests that have been performed at their expense, to determine the way and the type of medium in which the record is to be classified, as well as to establish protocols for storage, use and possession (Art. 13.2, CEDM).

The clinical record contains the relevant explanations given by the patient regarding his personal history and the data provided by third parties known to the patient, generally parents and siblings, but sometimes including interpretations or personal judgements by the surgeon who is responsible for the patient or data and opinions from family members or close friends, sometimes important for the diagnosis, that may also be secret to the patient. Because of this, it may not be convenient for the patient to have total access to the entire clinical record. For example, knowledge of the patient’s alcoholism may be a fundamental datum for the surgeon who is treating the patient, but the way in which this information was obtained may create a conflict between the patient and the informant. The surgeon must include the source of the information in the record, so that it could be consulted at a given time. Any information provided by third parties that the surgeon considers to include in a patient’s clinical record should indicate the source from which the information came and should be recorded with prudence and respect, both for the patient and other persons, including healthcare personnel who may have participated in the treatment.

At times, unlimited access to the patient's clinical record is not advisable, being the reason the patient’s own good. It is not recommended that the patient accesses certain
psychiatric disease or genetic data included in the record, since they may incorrectly interpret the information or it may lead to a situation of anxiety or uncertainty about their future health.

Third-Party Access to the Clinical Record

If, in certain situations, the patient has restricted access to his/her clinical record, this limitation must be also applied to other persons (physicians or other healthcare professionals, administrative and inspection services, etc.). Being a physician does not grant the right to access any clinical record, if said access is not motivated by and based on patient care and is required to carry out patient care. The physician does not have the right either to carry out clinical or epidemiological studies unless he/she has authorisation from the corresponding clinical research ethics committee.

Judges may order confiscation or submission of a clinical record, especially if it is to be used as evidence in a criminal trial. Therefore, it must be surrendered under penalty of disobedience. However, sometimes the judge is not interested in the complete record but rather only a part of it. In this case, the surgeon must inform the judge that the record contains data that, being irrelevant to the investigation, are sensitive and should be separated from the rest of the record. Once the record is in the judge’s possession, he/she shall be the guarantor of its proprietorship and preservation of confidentiality.

In non-penal proceedings (in the area of private law), automatic access for judicial authorities to the complete clinical record is not totally justified. In these cases, the surgeon must request that the portions of the record that are of judicial interest be explained. It must be kept in mind that, in civil proceedings in which private matters are resolved, the clinical record may include data, acquired for certain purposes and in a given context, that may be used to favour one of the parties to the detriment of the other. For example, the case of data in a patient’s clinical record about mental disease or drug addiction that can be used by a spouse in civil proceedings for marriage separation or child custody assignment.

Third-party access to the clinical record, for purposes that are not strictly for treatment, related to supervision and improving the quality and efficiency of care must be accepted, though in a way in which the patient cannot be directly identified, except in those cases in which the patient expressly authorises it (Spanish Regulation 41/2002, Art. 16). Administrative inspection processes are usually for the purpose of obtaining certain data for audits on the quality of care or for the purpose of controlling medical or pharmaceutical costs, as well as to enable statistical studies of undeniable healthcare and social value. However, identification of the patient is not always necessary to carry this out, which is why identifying data should be separated from the other data contained in the record.

The access to the clinical record by the patient’s family members or close friends must be done under certain circumstances:

- In the event that the patient is alive, is of sound mind and gives consent, the family members duly authorised by the patient may access the clinical record with the same limitations as those established for the patient.
- In the event the patient is alive but has been declared incompetent or in the event the patient has died, one must keep in mind that the right to privacy is not lost in either of the situations mentioned. Therefore, the surgeon is ethically obliged to maintain the confidentiality of the clinical record and, in principle, access to the record by third parties should be restricted. In such situations, those making the request must submit their petition and it must be medically and legally evaluated.
- In the event that a person prohibits access to his/her clinical history for anyone after their death, this prohibition must be respected whenever the veracity of this restriction can be confirmed (Spanish Regulation 41/2002, Art. 18.4).

Regardless of age, any person has the right to require the confidentiality of his/her information regarding third parties, including parents (Spanish Organic Law 1/96 of 15 January on the Legal Protection of Minors). The minor may indicate to his/her physician the data that must be maintained confidential. Nevertheless, parents, both legally and morally, are responsible for their children. Civil and criminal law requires parents to care for their children, to educate them and to provide them with nourishment (which includes medical/surgical treatment). Therefore, they have the right to be informed about everything regarding their parental obligations. This implies that they have the right to access their child’s record, but not as if it were their own record. Article 9.3c (Spanish Regulation 41/2002) establishes the age of consent for making medical decisions at 16 years of age. Between 12 and 16 years, the minor may have certain autonomy depending on their intellectual and emotional age, but the parents, as the legitimate representatives and being legally and morally responsible for the actions of the minor, have a right to access the record.

Preservation of the Clinical Record

Surgeons are increasingly facing numerous civil complaints by their patients. Physician obligations in their professional practice are limited to the means; nevertheless, following recent legislation, in some specialties such as ophthalmology and dentistry there has been an evolution into a demand for results. This was already demanded in certain operations of gynaecology, urology and, most of all, plastic surgery. Faced with this prospect, and because of the eventual demands for responsibility, surgeons must be more aware of the importance of maintaining the patients’ clinical records. However, this leaves us with several doubts about the time frame and the manner in which they should be preserved. Spanish Organic Law 15/1999 of 13 December on the Protection of Personal Data (LOPD), in Article 4.5, requires medical professionals to destroy their patient’s personal data when it is no longer necessary for later treatment; however, being conscious of the need to maintain some
information, the requirement to preserve these data for
certain periods has been established, both in the applicable
regulations and in contractual agreements between the
titleholder of the data and the person responsible for
treatment.\(^6\)

With regards to clinical documentation, Article 17.1 of
Spanish Regulation 41/2002 requires data to be preserved
for a minimum of 5 years counted from the discharge date
of each treatment process, though this should not lead us
to believe that once this period has expired, there is no
reason to preserve the patients’ clinical records.

The subject of responsibility should be summed up in one
sentence: how much time has to pass before a patient can
no longer demand civil responsibility as the result of medical
care? In the case of contractual obligations, in which a fixed
criteria is established, the prescribed period for action is 15
years from the date in which it was exercised (Articles 1964
and 1969 of the Spanish Civil Code). Nevertheless, in the
case of extra-contractual obligations, we are faced with a
requirement that may in practice lead to variations with
respect to the time the action can be exercised, beginning
from the date in which the affected party became aware of
the damage (Art. 1968 of the Spanish Civil Code).

With respect to provision in Article 4.5 of the LOPD, once
the period necessary for providing medical care to the patient
has transpired, the data should be preserved in a way that
does not allow identification of the patient.

Matters related to the manner in which clinical records
are stored are no less important or better known. Spanish
Regulation 41/2002, which specifically addresses the subject
of preservation of clinical documents in Article 17.1 cited
above, recognises the option of maintaining the
documentation in a format that is different than the original,
stating in Section 6 of the same regulation, the need to
implement the necessary security measures for personal
data files, falling under the regulations on the protection of
data.

In this regard, very interesting initiatives have been
developed in the area of private practice, both in the Medical
Association of Madrid and the Dentist and Stomatologist
Association of the 1st Region, which offer a service for
digitalizing medical records that were stored on paper, with
the resulting problems of physical space. The objective of
digitalizing is to ease compliance with the obligation to
preserve the information for at least 5 years from discharge
of each treatment process and to carry it out using a system
that is in strict compliance with the LOPD and the security
measures required by the regulations.

When the physician ceases individual private practice,
the clinical records can be transferred to the physician who
assumes responsibility for the patients once both of them
have given consent. The remaining clinical records can be
destroyed in accordance with the provisions established in
the regulations of the Spanish Autonomous Community in
which they practice; otherwise, they can be submitted to the
National Medical Association.

References
1. Serani Merlo A, Burmester Guzmán M. Ética, historia clínica y datos
2. Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía
del paciente y de derechos y obligaciones en materia de información
3. Collazo Chao E. Consentimiento informado en la práctica médica.
2003, Ene; n.° 46.
 Reflexiones sobre la ley básica reguladora de la autonomía de los
6. Medina Castellano C. La protección de datos sanitarios. Recogida,
acceso y comunicación de datos a la luz de la Ley Orgánica 15/1999
y de la Ley 41/2002. Comunicación libre presentada en el IX Congreso
de la Asociación Española de Derecho Sanitario. Madrid, 28-30 de
octubre de 2004.