DOI: 10.1051/odfen/2016037
Original Article

J Dentofacial Anom Orthod 2016;50:xx-xx

The medical record

Y. Soyer

Qualified specialist in ODF [Dentofacial orthopedics], Assistant University Hospitalist Paris 7 –, Hospital practitioner Hôpital Pitié-Salpêtrière

ABSTRACT

A patient medical record in dentistry has several important functions. It is a documentation of the patient's condition and treatment provided, forecasts and controls, it contains all patient identifiers.

The information contained in the medical record form a working basis for the practitioner and enable to help all healthcare professionals involved in the treatment.

The treating practitioner must be able to produce that documentation to the patient and official bodies who would be entitled to ask as part of a research responsibility in litigation.

KEY WORDS

Medical record, documentation, obligations (ethical, legal, HAS [Haute Autorité de Santé] recommendations), liability, loss of opportunity

INTRODUCTION

At first, physicians could just memorize patient data. Since then, progression from simple note-taking to extensive medical records took place in hospitals to meet the requirements of medicine in terms of quality, safety, continuity of care and also to meet the requirements of research, education, and public health.

The law on March 4, 2002 related to "*the rights and patients and the quality of the health care system*" has modified conditions governing the practice of healthcare professionals in particular with regard to the maintenance of health records[6].

As early as 1936, in its judgment on March 20, the Court of Cassation [U.S.A. equivalent: Superior Court of Appeals] issued the following:

"A true contract is formed between the physician and their client, in which the practitioner has the commitment to cure the patient or at least give him or her care which is not of any kind but conscientious and attentive and exceptional in accordance with the acquired science data."

The concept of best efforts obligation was introduced.

Mailing address:
Yves Soyer
170, avenue de la République – 91230 Montgeron
E-mail: yves.soyer@orange.fr

Article received: 01-04-2016.
Accepted for publication: 20-07-2016.

OBLIGATIONS

After centuries of medical paternalism, advances in medical research and therapeutic advances in the second half of the 20th century has made patients "passive" rather than active participants in the management of their health.

The professional civil liability of practitioners is a contractual responsibility; it results from the contract of care created between patients and their practitioners. This contract is free, and this responsibility implies reciprocal obligation.

Some examples of patient obligations include
- informing oral surgeons of their medical background
- following prescriptions
- respecting and following hygiene advice
- not unilaterally terminating the contract of care except in cases of *force majeure*.

Increasingly more obligations lie with practitioners:
- the best efforts obligation for all care
- the obligation to produce results in the design and supply of prosthetic elements
- the obligation of security
- the obligation of care and due diligence
- the obligation to keep medical records as well as the obligation to give information

Thus, by virtue of the Public Health Code, health practitioners are subject to the obligation to provide conscientious care that is attentive and consistent with acquired science data (articles L.1110-5 and R.4127-233).

If no law required oral surgeons to keep medical records, the law on March 4, 2002 introduced the concept of direct patient access to data concerning their health under conditions that presuppose the existence of records.

Maintaining complete and updated records allows for a comprehensive approach to patient care. Establishing good patient records promotes the practice of a more rational quality.

The objectives of good record keeping are as follows:
- At the clinical level:
  - to allow for global support of patients
  - to improve practitioners' approach to optimize their practice
  - to optimally use various data gathered in records to recall the following:
    - ◊ the medical history and particularly medical alerts and treatments performed
    - ◊ the treatment plan
  - to plan treatments and act in a logical and timely manner
  - to explain and discuss treatments with patients from the items in records.
  - to have a record of treatments performed and the reason for performing
  - to have a reference element for identifications
- At the management level:
  - to facilitate administrative management
  - to find records of patients quickly and without any risk of error
  - to facilitate the transmission of information from the record to another health professional

It is therefore recommended that a record must be prepared for each new consultation at the first appointment, in addition to the medical questionnaire.

In case of computer record usage, a declaration of patient file management must be made to the *Commission nationale de l'informatique et des libertés* (CNIL). The CNIL adopted the simplified declaration standard NS 50 for the management of records held by practitioners who practice independently.

It is recommended that the medical history should not be limited to simple written questionnaires. This questionnaire must be completed by an oral interview conducted by practitioners. This examination makes it possible to verify the potential existence of a general pathology that patients would consider unrelated to odontology[12].

The recommendations of the Haute autorité de santé (HAS, formerly ANAES, in May 2000) specified that medical records should include the following: diagnosis and treatment plan; evidence of information and consent; treatment provided; operational reports; traceability of materials, materials, and sterilization [decree of April 20, 2006, article R.5211-7 of the *Code de la santé publique* (Public Health Code)]; therapeutic follow-up performed; and the management of complications.

The use of dental diagrams in the context of the collection of ante mortem data useful for the possible identification of victims is particularly important[10].

It should be remembered that everyone has the right to be informed about their state of health [Article L.1111-2 of the *Code de la santé publique* (Public Health Code)].

"Everyone has the right to be informed about his or her state of health. This information relates to the various investigations, treatments, or preventive actions that are proposed; their usefulness; their possible urgency; their consequences; the normally predictable, frequent, or serious risks that they entail; as well as other possible solutions and the foreseeable consequences in case of refusal. Where, after the execution of the investigations, treatments or preventive actions, new risks are identified, the person concerned must be informed, unless it is impossible to find them."

This information, which is issued over the course of an interview, is the responsibility of healthcare professionals within the scope of their competence and in accordance with the professional rules applicable to them. Only the urgency or the impossibility of informing can exempt health professionals from this responsibility.

Since January 26, 2016 (law 2016-41 of the modernization of the health system), dental assistants are health professionals. Although the National Council of the Order of Oral Surgeons is working to become the enrollment gatekeeper for these new health professionals[11], the fact remains that within the frame of their skills, dental assistants can only relay information previously given by practitioners.

The maintenance of medical records for each patient is important because it is the legal record of the duty of information that documents its purpose on the usefulness, possible urgency, and consequences of the treatment or interventions proposed by practitioners as well as alternatives to treatment and the consequences of a possible refusal of the proposed treatment.

Information reported in medical records should not be mixed with advertising documents and notices of manufacturers or laboratories.

CONTENTS OF RECORDS

Medical records have two distinct parts of equal importance: administrative and clinical.

From an administrative point of view, it is important to include required and/or desirable information (Table I), as well

Table I: Table of information to collect.

Identification	
Full name (1)	Required
First name	Required
Sex (2)	Required
Date and place of birth	Required
Record number	Desirable
Symbol to report homonyms (3)	Desirable
Administrative Information	
Address	Required
Telephone numbers: home, work, mobile	Required
Profession	Desirable
Social Security number (4)	Required
Chief complaint or long-standing illness	Desirable
Legal guardian, third-party payer	Required
Mutual insurance	Required
Health Alert Data	Required
Appointment	
Name of attending practitioner (5)	Required
Name of referring doctor (5)	Required
Appointment date	Required
Contact type	Desirable
Significant data from the appointment	Desirable
Conclusion/summary of the appointment	Required
Resolution	Required
Updated Medical History and Health Factors	
Date of first care or appointment	Required
Date of last care or appointment	Desirable
Personal medical history	Required
Family medical history	Required
Allergies and intolerance to medication	Required
Risk factors	Required
Vaccinations and other prevention and screening activities	Required
Significant biographical events	Desirable

(1) According to family history

(2) Unisex names and foreign first names

(3) We advise the addition of patients' second given name; the risk of confusion is low, but the consequences can be serious.

(4) The CNIL forbids the indexing of the SS number; therefore, it cannot be used to classify records.

(5) In case of shared records

as the medical history and health factors of patients.

Clinically, in the context of orthodontic records, in addition to the physical or digitized basic documents (radiographs with their respective reports, photographs, and dental arch impressions) (Table II), a true journal must be kept, mentioning each event related to treatment progress (appointments honored with the session of care, appointments canceled, postponed or not honored, reports on various interviews with patients or their guardians, copy all correspondence exchanged concerning patients).

It is essential to relate a true biography of treatment that allows retracing *a posteriori* the history of medical treatment. The fact of simply mentioning in clinical records the acts by their key letters (NGAP or CCAM), apart from all the other indications we have just mentioned, does not meet professional requirements.

Medical records are the support of the obligations that therapists must fulfill (Table III)[1].

They are tools that facilitates the safety of care and, where appropriate, the traceability of certain materials.

In order to identify medical devices (Article R.5212-41 of the PHC), the certificate of conformity and the documentation for medical devices made for patients should be kept. The batch from which the medical device used for patients must be identified[9,8].

Proper record keeping requires practitioners to work away from the presence of patients to incorporate data from different sources into a summary. The question of the quality of the record is directly related to the time devoted to its maintenance.

While it is very useful to keep source documents containing potentially useful information or because they have a medico-legal value, digitized records avoid the major disadvantage of paper record by facilitating the recording and storing of data by direct transmission (Table IV).

Table II

Basic documentation
Models of occlusal studies
Orthopantomogram and/or status of apical radiographs
Profile teleradiography and analysis
Supplementary non-comprehensive documentation
Photos of the face: profile and intraoral
Articulator-mounted models
Radiography of the face
Cone-beam computed tomography (CBCT) review

Table III:

Obligations	
Medical Questionnaire (obligation of diligence)	*Completed, signed, and updated*
Clinical Diagnosis (obligation of diligence)	*Recorded in the dossier*
Additional Tests (obligation of diligence)	*Recorded in the dossier*
Summarized Prognosis (obligation of diligence)	*Recorded in the dossier*
Information (public health code L.1111-2) (obligation to give information)	*Recorded in the dossier; it is an item of proof*
Therapeutic Options (obligation of diligence)	*Recorded in the dossier*
Information and Joint Decision (public health code L.1111-4)	*Found in the Contract of Care*
Quotation and Care Information by Social Agencies (public health code L.1111-3)	*It is desirable that this document be signed*
Consent and Contract of Care (public health code L.1111-4)	*Recorded in the dossier; it is desirable that this document be signed*
Information on Treatment Progress (public health code L.1111-2)	*Recorded in the dossier*
End-of-Treatment and Follow-up Information (public health code L.1111-2)	*Recorded in the dossier*
Preservation of Medical Records (therapeutic risks) (public health code L.1111-2)	*Recorded in the dossier*

Table IV:

Documents to save
Biology test results
Informed consent to care dated and signed by the practitioner and the patient
Informed consent to the care of parents or the legal guardian, in case of a minor or a person under guardianship
Estimate established in accordance with usage and/or regulations
Radiographies and reports with identification number or signed receipt from the patient attesting to their return
Duplicate initial medical certificates drawn up at the patients' request or on the proposal of the practitioner
Moldings and study models with their identification and identification number
Photographs identified and numbered
Traceability of medical devices
Traceability of the sterilization procedure

(1) The preservation of moldings should be done at the same time as that of the medical record. The digitization of three-dimensional models is perfectly acceptable as their reconstruction is easy.

ACCESS TO MEDICAL RECORDS

Any request for the consultation of health professionals or transmission of information from health professionals as well as from patients (or their dependents, as we shall see) must be satisfied.

This right of access is provided for by Article L.1111-7 of the Public Health Code, which states

"Everyone has access to all health information held by professionals and healthcare institutions, which are formalized or have been the subject of written exchanges between health professionals (...) with the exception of information that states that they have been collected from third parties who do not intervene in therapeutic management or concerning such a third party. They may access this information (...) at the earliest after a reflection period of forty-eight hours has been observed. This period shall be extended to two months if the medical information is more than five years old or when the departmental commission for hospitalized psychiatric care is seized... "

The communication of information in medical records is therefore a right for patients and an obligation for health professionals.

Information in medical records may be communicated directly to patients or to any person designated by patients: people they trust (health professionals or others)[4], their legal representatives (in case of minors or adults under guardianship), or their beneficiaries in the event of their death. The Court of Cassation [U.S.A. equivalent- Superior Court of Appeals] admits that in the absence of evidence to the contrary, deceased patients do not intend to deprive their heirs of the means of using their rights.

In addition, holders of parental authority may exercise the right of access to the entire record of minors. However, this right is exercised subject to the objection of minors or their request that the holders of parental authority only access information about their health through health professionasl[5,2].

It should be pointed out that minors' rights to object to the disclosure of medical information concerning them are confined to information related to a single treatment or intervention. They must reiterate their objection to each new medical procedure to deprive the holder (s) of parental authority of their right of access to the medical information of their child (article R.1111-6 of the PHC).

The Public Health Code (article R.1111-1) provides for the access to records and the time constraints imposed (article L.1111-7), that is, patients can access information directly or through doctors they designate, and to obtain the communication within 8 days of their request and at the earliest after a reflection period of 48 h has been observed if the medical information is less than 5 years from the date the medical information was compiled.

This period is extended by 2 months if the medical information is more than 5 years old from the date on which the medical information was compiled (Law 2002-303 on March 4, 2002).

Consultation of medical records on the website is free of charge, but for requests of copies, only the costs of reproduction and sending are invoiced, regardless of the medium.

SECURITY AND PRESERVATION OF MEDICAL RECORDS

Under the terms of the Public Health Code (L.1111-2), *"if new risks are identified, the practitioner must warn the patient".*

Health practitioners must ensure that medical records are confidential, regardless of the medium (paper or computer), and that paper records must be kept in furniture or a room not accessible to the public[7].

For computer records, it is recommended to set up a high-performance security device directly installed with the computer system in accordance with Law No. 78-17 on January 6, 1978. In addition, article R.4127-45 of the Public Health Code specifies the following:

"The physician must keep a personal observation record for each patient; this form is confidential and contains the updated information necessary for diagnostic and therapeutic decisions. In all cases, these documents are kept under the responsibility of the physician. Any physician must, at the request of the patient or with their consent, send to the doctors participating in the treatment or to those whom he or she intends to consult, information and documents useful for continuity of care. The same applies when the patient chooses another physician."

The preservation of patients' medical records is therefore compulsory and has a three-fold objective: the continuity of patient care, the response to a request for communication of information in the record made by patients or their beneficiaries, and the means of proof in case of the pursuit of civil liability.

In a dispute with patients, it is clear that the loss of medical records is always appraised in a pejorative manner, with the suspicion that practitioners seek to conceal information that could be unfavorable to them.

In the event of loss of medical records, the responsibility of practitioners may be retained, resulting in a loss of opportunity granted to patients, depending on the degree of importance of the lost documents [Toulouse Court of Appeal, April 17, 2001, *Tribunal de Grande Instance* (TGI) (Court of First Instance) of Marseille, April 7, 2011].

When attending practitioners cease their activity, it is usually done in a planned fashion. They have the time and the duty to inform their patients (in the waiting room, by oral conversation, eventual announcement in the local press). If they have a successor and subject to free choice of patients, records will be forwarded to their successor. If they do not have a successor, it is up to them, at the request of patients, to transmit their record to practitioners whom they designate to ensure the continuity of care. At the end of this process, which can last for a few months and after sorting the oldest records, they will have records that must be archived. Irrespective of whether they have a successor, it is imperative that attending practitioners inform the Departmental Council of the place where the medical records are kept to be able to guide the access requests of patients if necessary.

In the event of a sudden interruption of medical practice, the Departmental Council assists the practitioner' family in organizing the delivery of records to

medical colleagues designated by patients. An announcement in the local press informs patients of the closure of the practice, inviting patients to send their requests to the Departmental Council. However, the archiving of the remaining files remains the responsibility of the family[9].

A limitation period of 10–30 years is limited to independent doctors only in respect of acts or prejudices caused by the publication of the law in *Journal Officiel*, that is to say, March 5, 2002 in such circumstances the possibility for an independent practitioner to face prosecution within 30 years is not unheard of today, and it is therefore still useful to keep medical records for 30 years or even longer if patients are minors.

This is all the more applicable, if in theory, the period during which practitioners can be prosecuted has been reduced and the legislature has set as the starting point of this new 10-year period the **consolidation of the victim** and not the first medical finding of injury. This starting point enables liability actions to be carried out well beyond the 10-year period when the injury has not been consolidated[3].

CONCLUSION

An implementing decree published in *Journal Officiel* on July 5, 2016 (decree 2016-914) defines "the conditions and modalities for the creation and implementation of the shared medical record." Rules concerning data and access to the *Dossier Médical Partagé* (DMP) (shared medical record) are published on the *Caisse nationale de l'assurance maladie des travailleurs salariés* (The National Health Insurance Fund) website. While the DMP, which brings together all health data, aims to promote prevention, quality, continuity, and the coordinated care of patients, it is not intended to replace records held by each health professional[11].

Medical records are essential elements of treatment. If there is no strict rule for the development of patient records, practitioners must provide medical records of each patient they are treating.

Medical records must be clear, legible, and up-to-date and must contain information on patients' health statuses, lifestyles, and orofacial structures. Their presentation must be evolutionary and people who complete them must be identified.

The traceability elements and the documentation of medical devices used must be contained in medical records.

Paper records must be indelibly written, and corrections must be identifiable. Personal comments must be recorded on a separate form, and accounting data must be separated from medical data.

Medical records should be preserved and safeguarded according to standards described; this is essential in preventing patients from losing the opportunity to access to their medical records.

Conflict of interest: The author declares that there is no conflict of interest.

BIBLIOGRAPHY

1. Bery A. La notion de risque. Rev Orthop Dento Faciale 2004;38:245-252.
2. Bery A, Delprat L. Droits et obligations du chirur-gien-dentiste. Editions du Puits Fleuri 2006;202-203.
3. Bery A, Delprat L. Les nouveaux délais de conservation des dossiers médicaux. Rev Orthop Dento Faciale 2008;42:225-229.
4. Bery A, Moussa-Bradan S. Les incidences pratiques de la réforme des tutelles de 2007 sur la prise en charge des soins de la personne en situation de handicap. Rev Orthop Dento Faciale 2011;45:223-229.
5. Levigne P. Responsabilité professionnelle dans le cadre de soins dispensés aux mineurs. Rev Orthop Dento Faciale 2009;43:449-457.
6. Lievre A, Moutel G. Le dossier médical : Concepts et évolutions, www.ethique.inserm.fr, mai 2010.
7. Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés. Article 29.
8. Missika JM, Bery A. Réactions allergiques et principe de précaution. Rev Orthop Dento Faciale 2002;36:169185.
9. ONCD. La Lettre n° 98, juin 2011 24-26.
10. ONCD. La Lettre n° 145, février mars 2016, 13-15.
11. ONCD. La Lettre n° 150, septembre 2016, 14-19.
12. Soyer Y. Maladies rares : mode d'emploi. Rev Orthop Dento Faciale 2014;48:65-68.