Legal aspects of the medical data card - Part II - Existing regulations

Boulanger, Marie-Helene; Poullet, Yves

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PART II – EXISTING REGULATIONS APPLICABLE TO MEDICAL DATA CARDS

The first part of our study attempted to define the principal areas of risk connected with the introduction of a MDC system. In this second part, we wish first to pinpoint the applicable regulation taking into account the general principles of the privacy laws and the professional secrecy and, secondly, taking into account the principles specifically applicable to medical data cards.

2.1 GENERAL PRINCIPLES

2.1.1. GENERAL PRINCIPLES DERIVED FROM THE LAWS OF PRIVACY

The Convention of the Council of Europe of 28th January 1981 for the protection of individuals with regard to automatic processing of personal data states some general principles (accepted by the majority States of the Community) which seek to assure the protection of confidential data and thereby respect of privacy. We propose to analyze the different principles of this convention with regard to the MDCs.

A. The collection of data by fair and legal means is covered by article 5a. This latter article is based on the idea that the patient must be fully cognizant of the individual information gathered concerning himself, and secondly of the purpose it is intended to serve. As a result, a card that contains information of a secret or coded nature without the bearer's knowledge would not be permissible.
This is a matter of informing the bearer of all those who have access to his card whether reading or recording.

B. Articles 5b and c require respect for the principle of finality in the storage and use of data.
On the one hand, data should only be stored in proportion to the needs it serves. The only purposes permitted to justify the recording of data are relative to the admission or treatment of the patient. The storage of socio-economic datum (salary, profession,...) is, to the degree that it does not fulfil these requirements, ruled out.
Furthermore, as the data may not be used to serve a purpose other than the one for which they were recorded, it is necessary to clearly delineate the finalities.
We can assume that the data is stored and transmitted in order to assure effective health care. More precisely, the data must facilitate the treatment of the patient – also in the case of emergency – and the continuity of the same, while the administrative data must serve for the admission of the patient to a hospital or consultation.
The question of whether the informed consent of the patient should be regarded as sufficient to permit the data to be used for some purpose other than these just mentioned (e.g. scientific research, supervision of the physicians) will be examined later.
Finally one must observe, that the data should be structured in such a way as to serve these different purposes (administrative, emergency and treatment).

C. Article 5d is concerned with the quality of data. These must be exact and kept up to date. This relies on the responsibility of the physician with respect to the conservation of data. A patient who chooses not to present his card accepts as a consequence that it cannot be entirely up to date. Finally, the programmer is responsible for the conception and functioning of programs.

D. In conformity with Article 5e, data may not be kept for longer than the period necessary to serve the legitimate goals of treatment. The question can be raised as to whether it is necessary to conserve medical data for a sufficiently long period.

E. Article 6 forbids the processing of various 'sensitive' data unless domestic law provides appropriate safeguards. Medical data fall into this category, provided the diversity of MDC applications, statute law might not be the best solution.
Their collection and processing must be made in accordance with the principle of finality (see point A).

F. The principle of data security enunciated in article 7 is intended to protect data from accidental or unauthorized destruction or accidental loss, unauthorized access, alteration or dissemination, (either to the card or by the intermediate of the host).

G. Article 8 grants every individual the right of access and correction of all personal data recorded relating to him. Taken from there, this right is applicable to medical information. Certain limits however may restrain the exercise of that right.[1]
Firstly, it is not always desirable that the patient has direct access to the medical dossier on his MDC[2]. Secondly, should it be possible for someone to access his personal data contained in someone else's MDC, for example a father in his children's MDC if a hereditary disease requires him to be mentioned on the MDC. Even though the right of the patient be limited, he still retains the right to receive an intelligible summary of the same from his physician. This mediation offers certain advantages:

- the accessing of data takes place within the framework of a confidential relationship between physician and patient;
- the communication of data is to a certain degree adapted to the patient inasmuch as diagnoses of a grave or fatal nature are only communicated with reference to the mental state of the patient;
- medical secrecy is safeguarded inasmuch as access, even indirect, by unauthorized persons cannot occur.

Finally, such limitations may bear upon the patient's right of rectification. Such is notably the case if the rectification demanded is contrary to the observed medical situation.

2.1.2. PROFESSIONAL SECRECY

A. Principle

Data covered by professional secrecy must remain confidential if recorded by persons bound by that secrecy and in conditions in which the latter is applied. The fact that the patient is the bearer of this data need make no difference to the application of this principle.

[1] In Belgium, article 323 of the code of medical ethics requires the physician to reveal his prognosis to the patient. A grave prognosis may however be legitimately concealed from the patient, and a fatal one may only be revealed to him under exceptional circumstances.
In France, according to article 6 of the law of January, 6, 1978, a doctor may choose that which he reveals to his patient, and according to article 42 of the code of medical ethics he is authorized not to say everything.
[2] In the same manner it is sufficient that the card be incomplete. The doctor simply does not record on the card those pathologies that he does not wish the patient to know.

The obligation of secrecy reposes upon the privileged relationship established between physician and patient. It extends over all that the patient reveals within the framework of the relationship and, more widely, over everything observed or confirmed by the practitioner.
Such an obligation of secrecy is founded both on the interests of the patient, and on the collective interests of general health relative to good medical practice. Basically, the patient must be able to confide unreservedly in those who care for him, speak freely of his history and of the symptoms he has felt. The rule of secrecy if to be found in all European legislation. By way of example, we shall present in some detail the regulations current in Belgium and France.
In Belgium, Article 458 of the penal code requires that a physician or any person holding secrets of state or secrets of profession that have been confided to him is liable to penal sanction in the event of his revealing the above, except when called upon to testify in court or when the law otherwise obliges him to reveal the same.
Article 55 of the Belgian code of medical ethics obliges a physician to observe professional secrecy in all circumstances. The legal exceptions are delineated by the same code under article 58.
In France, professional secrecy is imposed on all physicians in the interest of the patient within the conditions established by law. Article 378 of the penal code prescribes sanctions against physicians or other health care professionals who have revealed secrets confided to them in their professional capacity. Article 89 of the code of medical ethics is similarly phrased.

B. Trustees of the secret
In order to be in conformity with this principle, the reading of medical information, must be confined solely to persons bound to silence. These are generally physicians and those involved directly with treatment. In this latter group, there is a certain gradation of the obligation to secrecy under various national studies.
For certain professions such as psychologists or social workers, professions engaged more indirectly with treatment, a certain ambiguity persists.
Those not normally engaged in treatment (ancillary and administrative staff, insurance personnel) are not traditionally bound by the obligation of secrecy.

C. Persons with regard to whom exists an obligation of secrecy

1. With regard to the patient
It is generally admitted there exists no obligation to keep information from the patient, on the contrary, the latter has a recognized right, to information although this right may be limited in certain cases, notably where knowledge of the diagnosis could have a detrimental effect on the physical or mental health of the patients (see above 2.1.1. G).

2. With regard to the third parties

a) In general
It is clear and evident that an obligation of secrecy towards a third party exists. Nevertheless, the revealing of secrets may be condoned in certain cases if it is made in the best interests of the patient or if a legal obligation exists. But this divulgence even in the interest of the patient or if prescribed by the law must limit itself to that which it is indispensable to reveal. Even the tacit authorization of the patient does not remove the obligation to secrecy. Indeed, according to certain sources, even an explicit authorization does not suffice to allow the revealing of medical information.
Note that the obligation of secrecy persists even after the death of the patient.

b) Particular cases
- ***The public administration:*** the law enumerates and limits the cases where a secret can be divulged;
- ***the courts:*** professional secrecy is not at the patient's disposal. The fact that the patient may have delivered his physician of the burden of secrecy does not oblige the latter to divulge, even in court, facts covered by medical secrecy.
- ***the medical research institutes:*** medical secrecy is not violated if the patient is not identified, the principle of secrecy does not apply to the illness per se, but rather to its relation with a distinct individual.

3. Sharing the secret

The secret may be shared in the interests of the patient when ensuring the continuity of the treatment.
Sharing is generally admitted inside the health care team. It is also allowed between the hospital physician and the family physician.
Beyond this, the sharing of data is often a simple matter of fact resulting from teamwork situations common in clinics and large practices.

2.2 PRINCIPLES APPLICABLE TO THE MEDICAL DATA CARDS

Before responding to the challenges posed by the card, we propose to review the norms specifically applicable in this domain. We shall open with the recommendations elaborated by the Council of Ministers of the European Council, n°R (81) 1 of 23rd January 1981 on the regulation for automated medical data banks and n°R (83° 10 of 23rd September 1963, on the protection of personal data used for scientific research and statistics. Afterwards we shall look at the essential principles delineated by the Commission Nationale Informatique et Linertés (C.N.I.L.) resulting from the experience gathered in France since the introduction of the MDC and at the Belgian experience in this matter.

2.2.1. RECOMMENDATION NO. R.(81) 1 ADOPTED BY THE COMMITTEE OF MINISTERS OF THE COUNCIL OF EUROPE ON 23RD JANUARY 1981, ON REGULATIONS FOR AUTOMATED MEDICAL DATA BANKS

These regulations, although they are not constituting a normative statute in law, state important principles that the Member States must respect when framing their national legislation.
The applicability of this Convention rests on two points:

1. the card represents a miniature automated data bank and
2. its purpose is clearly that a medical care.

We shall only deal here with the principles relating to the intrusion of MDCs.
The Recommendation delineates above the necessity of subjecting any medical data bank to its own specific regulations, whose parameters are defined in the appendix to the Recommendation (A). It also aims to promote awareness and information about the protection of medical data and the principles relative to both recording and accessing data (B and C). Finally, the explanatory report mentions the necessity of a major campaign of public information which would seem particularly desirable before introducing a system of Medical Data Card (D).

A. Regulation of data banks (point 'a' of the Recommendation)

Specific regulations, established in conformity with the laws of the State concerned must comprise among other things, precise provisions as regards the following (article 3 of the appendix to the Recommendation):

- the specific purpose(s) of the data bank, categories of information recorded, the body or person for whom the data bank is operated and who is competent to decide which categories of data should be processed;
- categories of person who are entitled to record, modify or erase data;
- the parameters of access to the data bank and of the communication of information to third parties or individuals concerned and also the procedure relative to demands for the use of data for purposes other than those for which it was collected;
- the security of data and installations;
- the conditions under which, should the need arise, the data bank may be permitted to link with other data banks

Let us mention that separate supplementary regulations must be adapted to cases where the data bank contains several sets of medical records or sub-systems of medical data.

B. Recording of data

The text takes up in detail the principles of the European Council such as (article 4.1 of the appendix to the Recommendation):

- collection by fair and legal means;
- the collection only of data adequate and appropriate to the declared purposes;
- the accuracy (verification within the limits of the possible) of the data and its actuality as appropriate.

The inexactitude of data can indeed cause considerable damage. But, on the one side, the technique of cross-checking may be used in order to minimize the risk of error, and on the other, the data recorded on the card is always subject to review by a physician. Keeping a medical record up to date is justified in the light of the necessity of continuity of treatment.

The text adds a principle specific to medical records, which the necessity of structuring the files in such a way as to guarantee the possibility of selective access and the security of information. (article 4.2 of the appendix to the Recommendation). This obligation must be imposed on the designers and producers of cards. The files must also as a general rule be so designed as to enable the separation of identification data, administrative data, medical and social data. A distinction between subjective and objective data should also be affected in the last two categories.

We must recall at this point the difficulty of determining what is subjective and what is objective in the classification of medical data.

C. Access to data (article 5 of the appendix to the Recommendation)

Primarily, access should be reserved, as a general rule, to medical staff. However, in conformity with national legislation, this access could be extended to other health care staff. In any case, no one should have access except to that information pertinent to the exercising of his specific duty, neither may he make use of that access for a purpose other than that for which he originally had access to those data. Exceptions are made to this principle inasmuch as the information is rendered in a form which makes the person concerned unidentifiable or when the different usage results from a legal obligation (contagious diseases ...)...

Finally, neither the existence nor the contents of a medical record may be communicated to third parties other than persons or bodies occupied in the fields of medical care, public health or medical research except in cases where the laws of professional secrecy permit it.

D. Public information campaign (article 2 of the appendix to the Recommendation)

The appendix to this Recommendation also underscores the necessity of a campaign to inform the public of the existence or development of a medical data bank. This knowledge should make it possible for those whose interests are affected to make their point of view known and, particularly in the case of a data bank in the process of development, to do so before the sums invested have become too important.

2.2.2. RECOMMENDATION No (83) 10 ADOPTED BY THE COMMITTEE OF MINISTERS OF THE COUNCIL OF EUROPE ON 23 SEPTEMBER 1983, ON PROTECTION OF PERSONAL DATA USED FOR SCIENTIFIC RESEARCH AND STATISTICS

Let us note that the study of the Recommendation is relevant as the personal data recorded on the MDC can, and probably will, be used for scientific research.

It recommends that the governments of Member States take as their basis, in their domestic law and practice concerning the use of personal data for scientific and statistical purposes, the principles and guidelines set out in the appendix to the appendix to the Recommendation.

The use of personal data for research purposes requires special protection measures in order to assure a complete respect for the privacy.

Whenever possible, research should be undertaken with anonymous data (article 2.2. of the appendix to the Recommendation). Furthermore, the person furnishing data concerning himself should be adequately informed about:

- the nature of the project;
- the objectives of the project;
- the name of the person or body for whom the research is carried out.

(article 3.1. of the appendix to the Recommendation).

Further, if the required information, given the purpose pursued, cannot be disclosed before the data are collected, the person should first be fully informed after the collection is completed and should be free to continue his co-operation or withdraw it and, therefore, be entitled to ask for the erasure of the data connected (article 3.3. of the appendix to the Recommendation).

On the other hand, the person from whom data are sought benefits from the freedom to provide the requested data or to withhold his co-operation; anyway he is under no obligation to disclose any reason for his refusal to co-operate (article 3.2. of the appendix to the Recommendation).

The personal data obtained for research should be used for no purpose but research. In addition they should not be used to make any decision directly affecting the person concerned nor, as collected for the purpose of a given research project, they should not be used in connection with another project substantially different from the first one, except within the context of the research (in the first case) or with the consent of the person concerned (in both cases) (article 4 of the appendix to the Recommendation).

2.2.3. GENERAL PRINCIPLES OF THE COMMISSION NATIONALE INFORMATIQUES ET LIBERTÉS

At the time when opinions were given concerning experiments with cards, the French Commission Nationale Informatique et Libertés (C.N.I.L.) placed the accent more particularly on the following recommendations resulting from the lack of transparency of electronic memory cards. The following recommendations are particularly relevant as the issue has long been largely discussed in France:

- Respect necessity for the rights of the persons involved in the experiment;
- Security devices to guarantee, in full confidentiality, access to the data only by medical personnel specifically authorized to that effect;
- Study the effect of the use of MDCs on the practice of medicine, on the relationship physician/patient, on the application of medical secrecy and ethics.

Taking into account the respect necessity for the rights of the persons involved in the experiment delineated above:

1. ***Voluntary nature:*** the users – professionals and patients – must be allowed the freedom to participate or not in the setting up and functioning of the system. No penalization may be consequent upon a refusal to participate.

2. ***Free and informed consent***[1] to the use of the card. Patients and physicians must be clearly informed of the purposes and parameters of the system, the method for inscription and erasure of data, the persons authorized to read the information and the rights and means at their disposal. The initial consent of both parties as reinforced by the restatement of that consent at each application of the DC system; the freedom of the patient to refuse to present his card or to refuse access to certain types of data (confidential codes for particular kinds of data ...).

3. ***Exclusion of all discrimination*** between bearers and non-bearers of the card, whether physician or patient.
Above all the introduction of a MDC system may not limit or restrain the patient in his choice of a physician.[2]
Finally, a physician who participates in the MDC system may not refuse to a patient who either does not participate in the same or who refuses to produce his card.

4. Necessity of good information in communication between physician and physician or physician and patient.

2.2.4. THE BELGIAN EXPERIENCE

We shall first sketch the experiment of the uniform medical "emergency card" set up by the Flemish Community and, afterwards, the advice formulated by National Council of the Order of the Belgian physicians.

A. The uniform medical "emergency card"

In Belgium a uniform medical "emergency card" has been set up by the Flemish Community[3] with the purpose of standarization. The card consists usually of a in two fold "paper fort" but the use of a magnetic card may be allowed. The following data may be recorded with the acknowledgement of the holder:

- the full identity of the holder;
- the identification number;
- some vital data which are of essential importance for a proper treatment of the holder (i.e. haemophilia)

These last data are covered by the medical secrecy and must therefore by only ready by the treating physician.
And furthermore penally sanctioned:

- the unauthorized delivery of the card;
- the delivery of a different card or its putting into circulation.

B. Advice of the 'Conseil national de l'Ordre des médecins" (National Council of the Order of the Belgian physicians)

The Council of the Order[1] warned the public of the dangers inherent in the use of "Medicard", a Belgian MDC:

- dangers resulting from an abusive use of the card;
- the card may raise a false feeling of security (for the patient); the summary character of the data recorded on the card might lead to serious mistakes in the diagnosis; it is therefore of no great help in the treatment of the patient;
- the card consists of incomplete and out of date data with regard to the new clinical state of the patient.

The "Counseil National" pinpoints furthermore that the use of the "Medicard" may violate the patient's privacy as the thereon recorded data may be diverted from their original medical purpose.
The National Council has constantly reaffirmed its position.

[1]There must be a written consent according to the C.N.I.L.
[2]See article 27 of the Belgian code of medial ethic.
[3]Order of the Flemish Community d.d. 23 December 1986 setting up the uniform emergency medical card, M.B., 19 February 1987, at 2357. Decree of the Flemish Executive d.d. 25 June 1987 for the enforcement of article 4 of the order of 23 December 1986 setting up the uniform card, M.B., 30 September 1987.

[1]Advice of the "Conseil National de l'odre des médecins" about the "Medicard", d.d. 21 May 1980, Bulletin Officiel, No 28, 1979-1980.

Professor Y. Poullet
Professor at the Law Faculty of Namur (Belgium). Director of the Centre de Recherches Informatiques et Droit.

M.H. Boulanger
Assistant at the CRID.
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