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Legal Aspects of the patient data cards

by Professor Yves Poulet and Sophie Louveaux

Medical data cards are of interest to a certain number of persons. Each of them has his specific interest : firstly the users of the service, the parties to the basic transaction, healthcare personnel (physicians, nurses,...) and patients; secondly, the providers of the service, those who issue the cards (industrial supplier, hospitals, trust centers, Social Security Administration,...); thirdly, persons peripheral to these relationships (laboratories, pharmacists, government authorities for statistical purposes, employers, ...).

The role of the law is to organize the relationships between all these actors, taking into account their legitimate needs and the risks created by this new instrument.

I. Privacy Regulations

In first place, we have to pinpoint the general principles of the privacy regulations enacted (most of the European countries and Quebec have a Privacy regulation derived from the Convention of the Council of Europe) or proposed (particularly the European directive on the protection of personal data).

In that context, the legal report will also have to take into account different texts, codes of conduct or recommendations issued by the Council of Europe (e.g. the Council of Europe recommendation on automated data banks in the Medical Sector) or by national privacy authorities like the French Commission Nationale Informatique et Libertés or the Quebecian Privacy Commission.

Considering these regulations, the significance of certain concepts and of certain principles has to be highlighted:

- the personal data has to be obtained and processed fairly (art. 5a of Council of Europe Convention n° 108);
- the personal data might be stored for specific and legitimate purposes and not used in a way incompatible with those purposes (art. 5b Council of Europe Convention n° 108);
- the personal data must be adequate, relevant and not excessive in relation to the purposes for which they are stored (art. 5c Council of Europe Convention n° 108);
- adequate security measures must be taken, considering the nature of the data stored and the risks involved (art. 7 Council of Europe Convention, n° 108).

Nevertheless, the consequences of all these regulations are important for the implementation and the use of medical data cards :

- the structure of the cards : the necessity of structuring the card into different zones of access in order to ensure selective or limited degrees of access must be established (e.g. distinction between administrative data, emergency data, other clinical data);
- as regards the delivery of the cards : complete information about the purpose, the nature of data stored, the categories of persons authorized to read the content of the card, the means of access to this content by the bearer is needed;
- the content of the card : does the patient have the right to refuse the inclusion of certain data card or to request the erasure of data ?;
- the use of the card : it must be clear that the physician, with or without the consent of the patient, is not allowed to use the card for purposes other than those in strict relationship with the provision and continuity of health care. However, it should be understood that no individual can be forced to disclose the contents of the card and that no discrimination based on the non presentation of the card can be established.

II. Professional secrecy

Data covered by professional secrecy must remain confidential if recorded by persons bound by it and in conditions in which it is applied.

This rule of secrecy is to be found in all the European legislations. Three questions can be raised thereabout in the context of medical data cards :

- it is generally admitted that the patient has a recognized right to information, although this right may be limited in certain cases, notably where knowledge of diagnosis could have a detrimental effect on the physical and mental health of the patient. Insofar as the patient data cards will provide the patient with an access to the entire data on the card, these exceptions may be ineffective;
- the secret may be shared in the interests of the patient when ensuring the continuity of the treatment. The professional data cards offer a way for sharing data. To specify the people authorized to have access and the legitimate functions for which they are authorized is therefore needed;
- finally, in certain cases, the divulgation of the medical secrecy is authorized by the law (e.g. vis à vis certain administrations or the Courts). So, it may interesting to see how the persons authorized in these cases may request the access to the patient data cards content.

III. Liability

A. The patient data card does not modify the principles of liability, however it complexifies the questions by multiplying the number of actors involved.

- Liability of the healthcare professionals

1. What are the implications of a P.D.C. as related to the keeping of a medical record (exact replica of the medical record, memo of certain items...)?

The answer to this question can influence not only the responsibility of the doctor, but equally of other healthcare professionals.

What is the legal value of the data contained on the card?

To what extent should the healthcare professional who has relied on the information contained on the card be held responsible if the information was incomplete or obsolete? If the physician has a duty, within reasonable limits, to take the necessary steps to verify the information, can the same be said for other healthcare professionals (nurses...)?

2. The setting up of a P.D.C. implies the respect of a certain number of principles by the healthcare professionals.

What is the liability of the health care professionals for not respecting these principles, for example:

- for failing to respect the patients rights;
- for entering false or wrong data, which might provoke damages to the patient;
- for not updating the data on the card;
- for giving access to unauthorized persons.

- Liability of the card holder

If it is widely accepted that the patient has certain rights as to the data contained on the card (for example he may refuse the entry of data on the card, or may ask for the withdrawal of information), does this imply that he could be held responsible in certain cases?

Can one talk of "shared" responsibility between the physician and the patient?

- Liability of the "institutions" involved in the project

Could the PDC system provider or the trust center be held responsible in certain cases? (For example in the event of a technical mishap or for allowing unauthorized access.)

B. The PDC also raises questions of evidence.

It is obvious that the liability of the healthcare professional can be more easily invoked if the information entered on the card is signed by him. However in this context the value of an electronic signature has to be discussed along with the value of the printoff of the content of the record kept by the professional in order to prevent the patients' arguments relating to the presence or absence on the card of certain data.

C. Finally it can be of interest to analyse the different ethical, criminal and civil sanctions available in these cases.

IV. Ownership and Intellectual property

A. Ownership

The suitability of the concept to the P.D.C. must be analyzed. If one can apply the concept certain questions must be resolved:

-Who is the owner of the card itself (the patient, the healthcare professional, the issuer...)?

The answer to this question can help resolve certain questions of liability in the event of the loss or damage of the card.

-Can one speak of the "ownership" of the information on the card?

-Does the PDC modify the ownership of the patient's medical record?

-Does the fact that the patient is the holder of the card imply that he is the owner of the information contained on the card?

The answer to these questions could serve not only to determine liability issues but also the application of legislation (who is the "detainee" of the personal data?)

B. Intellectual Property

The problem of the intellectual property not only of the information written on the card but also of the computer programs and of the chips in the P.D.C. system has to be raised together with its relationship with different actors' rights and duties.

V. Definition and field of practice of the professional associations.

The introduction of a P.D.C. can modify the flow of information in the healthcare system. This could provoke the need for a redefining of the roles and field of practice of the professional

associations and their members (for example between nurses and physicians, between a general practitioner and a specialist...).

The competent authority with regard to the habilitation of a professional and the right of access to certain data contained on the card must be determined (professional association or trust centre?). Who is competent to intervene in the event of an error committed by a professional? Who can disqualify a professional?

These five legal issues must be considered in the light of four variables:

- a) the free and informed consent of the participants,
- b) the function of the P.D.C. (for example, the card can be solely used for administrative purposes or, if it is a medical record it can contain only emergency data or data related to specific diseases),
- c) the generalization of the project not only within a country or within the E.U. but beyond (the transnational characteristic of the use of data cards must be taken into account, implying the problem of the law applicable and beyond that of discrepancies between legislations),
- d) the voluntary or mandatory participation to the project.

An analysis of the legal value of the existing documents should also be undertaken.

In rare cases, there is a contract between the actors, between the physician delivering the card and the patient, between the trust center and the health professional. In other cases, there is a code of conduct regulating the issuing, and the use of the cards. An idea would be to propose model contracts in order to achieve a better protection of the users and to fix the duties and the responsibilities of each actor.