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Legal aspects of the medical data card - Part I

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LEGAL ASPECTS OF THE MEDICAL DATA CARD

The purpose of this article is to present a description of the legal conditions and demands relevant to the use of electronic memory health cards. More precisely our concern is to determine the minimum conditions necessary to ensure the confidentiality of medical information or, in other words, respect for the privacy of patients issued with the card. Personal medical history has traditionally been regarded as concerning to the most intimate sphere of the individual and must therefore benefit from a specific protection. We shall first examine, from that point of view, the challenges raised by the introduction of a medical data card. In Part II we shall look at the existing applicable regulations and, finally, in Part III we shall try to outline a new normative framework. But before starting this analysis, we shall first of all, define the card itself and present its advantages and handicaps.

INTRODUCTION

The Medical Data Card (MDC) can be considered as a kind of personal medical identity card. It may be described more technically as a plastic card incorporating either a microchip or laser technology capable of recording medical information without recourse to a network. The principle of the card is as follows: each patient carries his own medical data accessible in all or in certain medical centers. The patient is thereby, and this is the point at which the card is fundamentally innovative, the owner, in a material sense, of medical and administrative data concerning him, even though he may not necessarily know the precise contents.

Other cards may come into existence; we talk about a card for medical professionals which will enable the same, under certain preconditions, to have access to the medical content

of the MDC. We are analyzing only the patient's card. The advantages of the patient's MDC are primarily in the area of logic: the rapidity of treatment can be noticeably increased, particularly in cases of emergency. Furthermore, the patient benefits from a greater freedom in the choice of his physician without the latter, as was formerly the case, having to open a new file. Finally, confidentiality of the data, if well organized, can be better assured, while errors of transcription can be markedly reduced.

The principal difficulties raised by the introduction of such a card can be summarized by the dilemma represented by the necessity of rapid access to medical information and the virtue of respecting the confidential nature of the same.

The difficulties concern essentially the following areas:

- the violation of medical secrecy;
- medical responsibility: regarding the card may, according to certain authorities lead the physician to dispense with a conscientious examination of the patient;
- misguided purpose: the medical information could be put to unethical uses;
- discriminatory practices: such as a closed network of health care where only those in possession of a card are eligible for treatment;
- safeguarding the free choice of physician by the patient;
- the liberty of the patient to communicate his card or not to different physicians participating in his treatment (guaranteeing his right of informational self-determination);
- the security, reliability and technical limits of the system and consequently the liability of his creators;
- the risk of destruction or modification of the medical information, whether intended or not.

Finally, we want to give our discussion a European dimension even though we worked essentially with Belgian sources.

I. THE MEDICAL DATA CARD AND THE QUESTIONS AT STAKE

The questions at stake with the introduction of MDC are twofold: what are the contents of the card? Whose interests are involved? These are the two questions that we propose to study in this first part.

1.1 CONTENTS

1.1.1 THE DISTINCTION BETWEEN INTERNAL AND EXTERNAL CONTENTS

A. External contents

'External contents' include all information contained on the card in a legible fashion without recourse to any technical procedure. This information has the function of identifying the bearer of the card.

Name and first name are not seen as sufficient to guarantee the material identity of the bearer, that is to say, that the person presenting himself as the bearer is in fact the card's rightful owner. The enclosure of a photograph or the requirement of simultaneously being requested to present an

identity card offers a better guarantee in this respect.

In case of loss or theft, such as information permits the retrieval by the person concerned without recourse to technical means, thereby avoiding the reading of the internal contents. But one may ask whether, in order to exclude all risk, it might not be preferable to indicate on the card only the institution responsible for its issue. In this manner, the card would be protected "from the curious."

B. Internal contents

"Internal contents" includes such data as can only be read by the appropriate technical procedure (reading device) and having the goal of identifying the bearer and furnishing his medical history (infra).

It is at this level that the most acute problem presents itself, namely the necessity of finding a balance between a respect for individual liberties and the requirements of accurate medical data.

1.1.2. DISTINCTION IN FUNCTION OF THE RECORDS CONTAINED

The card permits the regrouping in a single source of such heterogeneous elements which were formally dispersed and includes the following:

- hospital records, or all information pertaining to the specific function of a hospital that provides health services (this data being under the responsibility of the hospital director)
- family physician's and specialist's records;
- medical pass book;
- administrative records.

Note that only the medical pass book is currently accessible to the patient. This pass book is rare and does not exist in all countries. In Belgium, for example, young children have a vaccination book.

The revolution in record keeping takes place at the following level: we are moving from the storage of a record localized in one place and held by one person to a mixture of records. The principle innovation of the MDC resides in the assembling of an individual dossier where can be found all medical and administrative records formerly kept by autonomous instances.

1.1.3. DISTINCTION BETWEEN ADMINISTRATIVE AND MEDICAL CONTENTS

One can distinguish between the primary data created by the granting of the card and the subsequent data arising from the use of the card. First the administrative data, are inscribed on the card at the moment of issue and are usually not subject to modification. Second the medical data, are inscribed on the card at intervals as treatment progresses.

A. Administrative data

This category regroups information relative to identification, social insurance and eventual complementary cover. Thus appears a minimum of information necessary to identification, name and first name of patient, sex and birth date.

A difficulty arises at the mention of the insurance number. Certain national legislations could consider this information as sensitive and as a result forbid its mention because it refers indirectly to the philosophical or political opinions of the bearer¹. Administrative data are used when admitting a patient to hospital or consultation.

It should be noted that the possibility of administrative data such as health care insurance, places of hospitalization, former admissions to a determinate service or that hospital, influences the quality of care provided.

The nature of information collected depends after all on the nature of the user.

B. Medical data

Medical information is recorded on the card as an assistance to treatment.

By nature, the content is very varied. A first attempt at classification establishes a distinction of the medical data into two separate lists, distinguishing between objective and subjective data. For example, weight, age, sex, height may be considered as objective data. The results of physical examinations, soundings, data generated by machine (electrocardiographic, scanner, x-rays), data from interpreting commentary (radio diagnostic, diagnosis of ECG) and data from hypotheses advanced by one or more physicians using their personal capacity for analysis may be considered as subjective data. Such data may all be considered subjective to the extent that they require an interpretation on the part of the physician.

It is nonetheless difficult to trace a clear line between these

two categories.

A second possible distinction founded equally on notions of objectivity and subjectivity develops the idea in a different manner. It ranges on the side of subjective data as all information pertaining to the patient's medical history. This classification is also not totally satisfactory. Information bearing on the history of a patient is of such importance as to be classified as objective.

Let us take as an example of data connected to inherited genetic characteristics termination of pregnancy (excluded by the french CNIL except with written permission of the card bearer), alcoholism, drug addiction, mental illnesses, seropositively in AIDS trace tests, etc.

Furthermore, it can be asked whether the criterion of free and informed consent suffices to justify the mention of such data on the card.

Whichever one chooses, no distinction will ever be entirely satisfactory inasmuch as some information is more sensitive than other, as is the case, for example, with psychopathic conditions.

This problem serves to illustrate the difficulty in determining the pertinent criteria for categorizing the information to be recorded on the card.

1.1.4. DISTINCTION RELATIVE TO TARGET GROUPS

One might think that an MDC system will rapidly embrace the entire population. Such a general diffusion will be conducive to increasing the efficiency of the system. Indeed, the smooth functioning of the system depends upon a sufficient number of scanning devices, and only a massive issue of cards would justify a sufficient diffusion of scanners. However, that may mean, limiting the target groups is currently the most practical approach (the aged, pregnant women, diabetics,...). From this point of view the desired goal is more effective surveillance of a particular risk group.

1.2 THOSE INVOLVED AND THEIR SPECIFIC INTERESTS

Medical data cards are of interest to a certain number of categories of persons. Each category has his specific preoccupations, first the users of the service (health care professionals-patients), then the providers of the service and then the people who gravitate around any of these.

1.2.1 PARTIES TO THE BASIC TRANSACTION: HEALTH CARE PROVIDER-PATIENTS

A. Card users

Card users are extremely varied. One may, however, distinguish between physicians, health professionals who are not physicians, and those whose work revolves around health professionals.

The members of the medical body would include the physician directly associated with the treatment or his replacement, general practitioner or specialist, the physician working in a hospital – more and more frequently part of a team – physicians working at home – individually or in association – medical biologists, insurance company physicians, company physicians, and the physician called upon as an expert witness...

Health professionals other than physicians such as chemists, physiotherapists and dentists would also be included.

¹The new draft Bill in Belgium for the protection of privacy in matters of personal data forbids the processing of data of a personal nature relating to opinions pertaining to the choice of such insurance.

Finally other personnel in the health care institution whose work revolves around health professionals are among other hospital personnel, medical and paramedical personnel (whether in clinical or domestic services) and administrative personnel,...

The interests of health care workers are directly connected with the services rendered whether in treatment or on an emergency basis. In any case, this adaptation can be more particular as, for example, a medical biologist for whom the medical data on the card may be of use in determining what sort of analyses it would be appropriate to make.

For health care workers, the card raises a double difficulty. Firstly, the patient is always in possession of his entire medical record whereas under the former system, physicians could limit the information until they know exactly to whom they are divulging the information recorded on the card. Thus the physician loses a part of his control over the information.

B. Beneficiaries

Beneficiaries are those carrying the card, whether they are representative of the entire population or only a particular sub-group of the same.

Their main interest as health care consumers is the quality and rapidity of the medical care they receive.

In this respect, the data card avoids both the necessity of opening a new medical file and the transfer of the same by each consultation with another physician. This facilitates the continuity of treatment and allows a patient to change physicians without difficulty.

Nevertheless, the use of the card is no neutral matter for the patient and leads to certain difficulties.

First and foremost, the patient may not necessarily wish the physician he consults to be aware of his whole medical history. In reply to this preoccupation: the patient chooses to give or not to give his card and thus decides the degree to which the physician may receive information concerning himself. In this way, the patient can be sure of his right to informational self-determination, or, in other words the right to control the flow of information relating to himself.

Nonetheless, this assumption is relative when one places the relationship physician-patient in its context. Such a relationship is of the type "specialist-uninitiated" and may in reality illustrate a certain lack of equality. In practice, it would appear rather difficult for a patient to refuse his card to the physician who asks for it, inasmuch as such a demand serves a medical purpose and not malicious curiosity.

1.2.2. THOSE WHO ISSUE THE CARD

The host could be an industrial supplier, an administrative office, physicians, or a research center. It could even be a combination of any or all of these. The actual makers of the card occupy a privileged position both as material suppliers and as those responsible for the logic system's base.

This can justify the will to reserve the management and the supervision of the MDC's for institutions controlled by the State or to public bodies responsible for the public health. It would seem essential, whatever the composition of the host, that the latter contracts within the framework of its functions, to guarantee respect for the principles of medical ethics and to ensure the global security of the system.

Indeed, the principal functions of such hosts, consist, on the one hand, in the allocation of the cards and the means of access both in reading and recording, and on the other, in the development of a system enabling those authorized to connect with one another by means of telecommunications

network.

Those issuing the card must, within the framework of these functions, be held responsible for the performance of the system, its eventual malfunction, the unethical uses to which it could lead, and, in a more general way, for its security and reliability. Furthermore, it is indispensable to achieving standards of hardware and software, necessary to free both physicians and patients from being bound, for better or worse, to one particular host.

1.2.3. PERSONS IN PERIPHERY OF THIS RELATIONSHIP

A. Government authorities

The Government authorities are preoccupied with the politics of public health and the reduction of health costs. Do these preoccupations justify even the most limited access to the MDC and the keeping of a summary file of card holders?

B. Health insurance institutions

More precisely, the health care insurance department of the Social Security, the Mutual Insurance Funds, and the private insurance companies.

The aim of these organizations is principally the reduction of costs. The data card could be notably useful as a basis for the reimbursement of health care charges.

Does this goal justify the fusion of the current social security card with the MDC? Wouldn't a reference to the paying institution sometimes present a danger with regard to the law of the protection of personal data?

C. Ethical institutions and/or medical unions

These are concerned for the respect of professional ethics and more particularly in protecting the interests of health care professionals. They will be very attentive to the impact of the system of MDC's on the medical practice. Let us mention, for example, the risk of discrimination between physicians owning a reading device and those who do not.

They may play an important function in the matter of controlling the smooth functioning of the system and in the one that pertains to the distribution of cards controlling access entitlement and authorization for health care professionals.

D. Employers

Employers are interested in the contents of a medical dossier for two reasons. Firstly, when they select a candidate for a job in order to know the state of health of the candidate employment and secondly, when they arrange the conditions of work with regard or in response to the health of the employee.

E. Judicial authorities¹

The data card can serve as evidence in private litigation or criminal prosecution. One can also imagine that some would wish to use it in establishing questions of paternity. One may envisage, insofar as the card contains inputs that are signed and dated, that it would help to determine the physical presence of a physician at a certain time and place. Finally, it seems likely to us that certain person could use it to determine the responsibility of a physician, that is in relation with professional misconduct or with prove negligence or fault connected to the use of the MDC system itself.

¹current or future

F. Institutions for medical research

Research institutions play a key function in improving the quality of health care, although they are not participating directly in treatment.

The information contained on the card may serve on one side for the purpose of medical research and on the other side for the control of populations considered at risk, or for disease prevention. The MDC system creates a double advantage. Firstly, inasmuch as the totality of medical data is conserved on the card, it retraces the patient's complete medical history, or at least its salient points, enabling the evolution of the patient's health to be surveyed. Secondly, it represents treatment of data already processed and partially centralized by the host in respect of an entire population or a large sample of right. The partial centralization realized by each

host must remain partial to avoid too great a centralization in the research laboratory.

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¹civil and penal suits

INFORMATION

SURVEY PREDICTS 33% GROWTH IN COMPUTER-RELATED LITIGATION

The first annual Survey of Computer-related Litigation in the UK by computer consultants Mathiason Turner Associates Ltd (MTA) predicts an annual total rate of growth of 33% in that area. Above-average growth is predicted for cases involving Employment (42% growth), Data Protection (42%), Intra Computer Industry disputes (40%) and Intellectual Property (40%).

A 61% increase in litigation involving Finance Houses is forecast for the next 12 months and despite its newsworthiness, there were only two cases of computer crime reported by participating firms (although the *Computer Misuse Act* was not in force at the time).

The most significant trend in the settlement of computer disputes is the forecast of growth of Mediation or Conciliation (60%). The very small number of references to Arbitration is forecast to fall.

The 1990 UK Computer-related Litigation Survey was conducted among the Top 200 firms of Solicitors. The sample included 35% of the Top 100 firms of solicitors and over 500 instructions in 1989.

MTA estimate the total number of disputes involving the supply of systems to End-users as 900 and the total number of Software copyright disputes as 400. Their estimates are substantially lower than all previously-published "guesstimates" of the number of computer-related disputes in the UK. The five firms with the heaviest total case-load are all located in the Provinces. Size of firm is not correlated with Computer-litigation case-load; some of the very largest firms have relatively small case-loads. Only 34% of firms have a current claim in excess of £1 Million but 70% reported that their lowest claim is less than £10,000.

Respondents agreed about the issues most frequently found in End-user disputes – 66% cited Bespoke Software faults, 64% Pre-Contract Representations, 62% Lack of or Inadequate Specification, and 60% cited Non-compliance with Specification.

CASE-LOAD SAMPLE

The sample covered a total case-load of 523 matters in 1989, including 193 matters concerning disputes about the supply of systems to End-users and 131 matters concerned with Software Copyright. There were only 2 Criminal matters reported in 1989 (Section 4.7.2).

Of the 1989 total case-load, 253 matters were resolved by Litigation, 210 by Negotiation and 45 by Mediation or Conciliation and only 3 matters were resolved by reference to Arbitration (Section 4.7.3).

GROWTH

The 1990 forecast of growth of total case-load is 33%. The most substantial forecasts of growth are for matters involving Employment (42%), Data Protection (42%), Intra Computer Industry disputes (40%) and Other Intellectual Property (40%) (Section 4.7.2).

The most substantial 1990 forecasts of growth by type of Client are Finance Companies (61%), End-user Suppliers/Dealers (37%) and Professional Advisers (30%) (Section 4.7.1).

The most significant trend in settlement is the forecast of growth of Mediation or Conciliation (60%). The number of matters forecast to be

resolved by reference to Arbitration was 2, representing a substantial decline (Section 4.7.3).

COMPARATIVE CASE-LOADS

Two of the Top Three firms in terms of total case-load are Medium-size firms. Some of the largest firms have relatively small computer-related case-loads (Section 5.1). The five firms with the heaviest total case-load are all located in the Provinces (Section 5.2).

SIZE OF CLAIMS

70% of firms have a smallest claim of less than £10,000. Only 34% of firms have a current claim in excess of £1,000,000 (Section 4.3).

TYPES OF WORK

100% of firms are currently instructed in End-user supply disputes and 72% in Software copyright disputes (Section 4.7.2).

DISTINCTIVE FEATURES OF COMPUTER LITIGATION

The most common difficulty solicitors find with computer disputes is their Technical Complexity (62%). The cost of resolving computer disputes was also cited by 51% of respondents (Section 4.4).

Respondents agreed about the issues most frequently found in End-user disputes – 66% cited Bespoke Software faults, 64% Pre-Contract Representations, 62% Lack of or Inadequate Specification, and 60% cited Non-compliance with Specification (Section 4.5).

However there was little agreement about the issues most frequently found in Software Copyright disputes. 46% of firms cited Breach of Contract of Employment, and 38% cited Breach of Confidence (Section 4.6).

STAFFING

72% of firms have no staff in the department dealing with computer litigation with any experience of working in the computer industry (Section 4).

EXPERT WITNESSES

There was agreement about the most useful sources in identifying potential expert witnesses. 72% of firms cited Personal Knowledge and 65% cited Professional Recommendation. None of the nominating bodies or published sources were cited by more than 13% of respondents (Section 4.8).

There was virtually no agreement among the respondents on the importance of the attributes normally sought in choosing an expert witness (Section 4.9).

A copy of the 60 page Survey report is available from Mathiason Turner Associates Ltd., 25 Kingshill Drive, Harrow, Middlesex HA3 8TD. (Tel. 081 907 0200 or 0432 275727), price £250.