



HEALTH DATA PROCESSING IN RELATION TO MEDICAL RECORDS

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I. INTRODUCTION.

The Mexico Declaration, adopted on the occasion of the 4th Latin American Conference on Data Protection, from 2 to 4 November 2005, included a section specifically with regard to processing health data in which, to sum up, the following matters were raised:

- Consideration of health data as specially protected data requiring specific guarantees.
- The need to reflect on the definition of the concept of health data.
- The motives that legitimate their processing.



- The search for balance between personal rights with regard to clinical information and its processing linked to reasons of general interest.

Formulation of this catalogue of reflections led to the Latin American Data Protection Network¹ resolving to establish a specific working group on processing of health data in relation to medical records, to prepare a document to be presented to the 5th Latin American Conference.

Under that mandate, the Working Group met to prepare this document in Santa Cruz de la Sierra, Bolivia, on 3 to 5 May 2006.

II. THE CONCEPT OF HEALTH DATA .

The reference to health as a right of citizens is a constant factor that is recorded in constitutional texts that declare the fundamental rights linked to it, and even detailed sectorial regulations in the field of health.

However, it is difficult to find a concept to facilitate definition of what health data is within such an ample range of regulations.

This definition considers at least two questions that are interrelated. On one hand, establishing what information may be considered related to a person's health – e.g. information on good or bad health, situations of incapacity or

¹ The Latin American Data Protection Network, open to all the countries of the Latin American Community and specifically recognised by the 13th Latin American Summit Meeting of Heads of State and Government, held in Santa Cruz de la Sierra, Bolivia, in November 2003, was created by the Declaration of La Antigua, Guatemala, in June 2003.



handicap, obesity, dwarfism, consumption of alcohol or drugs, genetic information – and, on the other hand, whether the interpretation criteria to determine, in the event of doubt as to whether or not we are dealing with health data, must be restrictive or expansive.

The answer to both questions has a great practical transcendence in that, based on the principle that health data must be subject to specific guarantees, the replies given will determine a more open, or more restricted, regime of protection.

In relation to the first matter, the Constitution of the World Health Organisation (1946) (WHO) – a specialised body recognised by the United Nations under article 57 of its Charter – declares it a basic consideration for health to be considered thus: *“health is state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”*

In regional terms, the Pan-American Health Organisation signed the Agreement with that Organisation (1949) by which it joined it under the terms of the Charter stated.

On the other hand Council of Europe Convention 108 (1981) for protection of individuals with regard to automatic processing of personal data, in section 45 of its Explanatory Report, defines the concept of health data, considering its scope to cover “.. information concerning the past, present and future, physical or mental health of an individual. The information may refer to a person who is sick, healthy or deceased ...” and adds that it “also covers those relating to abuse of alcohol or the taking of drugs”. In turn, the Addendum to Recommendation No. R (97) 5 of the Committee of Ministers of the Council of Europe (1997) states that the expression “medical data” refers



to all personal data concerning the health of a person and also affects data manifestly and strictly related to health, as well as to genetic information.

Directive 95/46/EC defines personal data as “all information on an identified or identifiable person”, considering an identifiable person as anyone whose identity might be determined, directly or indirectly, in particular by means of an identification number or one or several specific elements, characteristics of his physical, physiological, mental, economic, cultural or social identity and attributes special protection to health data.

In relation to this, the sentence by the Court of Justice of the European Communities, on 6 November 2003, Lindqvist, Case C–101/01, the Court, after considering the information on a foot injury and circumstance of leave from work as data concerning personal health, adds that “it is necessary to provide an ample interpretation to the expression “health data” used in article 8, section 1 (of Directive 95/46/EC), so as to cover the information on all the aspects, both physical and mental, of a person’s health”.

According to the foregoing, one may appreciate that the concept of health related data is not limited to the person’s specific state, but also affects past, present and future situations, and permanent lack of a fully healthy state, so it covers information on situations concerning incapacity or handicap.

One may thus conclude that the concept of health data covers a wide range of items and that its interpretation must be performed with an expansive, not a restrictive criterion, in order to grant it the maximum level of protection.

III. PROCESSING HEALTH DATA AND MEDICAL RECORDS



As aforementioned, in the Mexico Declaration, the Latin American Data Protection Network undoubtedly recognised that health data must be included within the category of especially protected data that requires additional guarantee instruments (legitimation for processing may only be based on legal authorisation or the specific consent of the data subject, obtained previously, subject to precise information on the processing that is to be performed and, most especially, concerning the purpose or purposes determined and specified for which the data will be used. That processing must be carried out implementing security measures at the highest level that may be required and guaranteeing confidentiality of the information on the basis of an obligation to professional secrecy upon those who might access it).

These guarantees must be operational within a wide degree of sectors, as processing of health information arises in the most varied settings and activities such as, for example, health assistance, insurance, labour activity, teaching, research, biomedicine, clinical trials, pharmaceutical attention, social services, court cases or processing genetic data.

However, the specific analyses of these matters must be the subject of other documents, so we will stick strictly to processing health data related to medical records in this one.

1. Concept of the medical record.

A medical record may be conceptualised as a set of documents, whether on hard copy, audiovisual, computer or other kinds of media, that contain data, evaluations and information of any nature on the situation and clinical



evolution of a patient throughout a care process, identifying the doctors and other health professionals involved in it.

Obtention, use, filing, custody and transmission of the information the medical record contains must comply with such basic principles as respect for personal dignity, the autonomy of the patient's will and privacy and protection of personal data.

According to these principles, the individual appears as the receiver, *par excellence* of the health related information. However, that personal right must be made compatible with other juridical rights so the basic principle of consent may be limited according to the actual mechanisms of a democratic society, that is, when such a limitation is a necessary measure due to reasons of public interest recognised under a regulation with the rank of Law.

There may also be cases in which a patient's right must be made compatible with the rights of third parties who require an equivalent level of protection.

2. Purpose of the medical record.

One of the essential principles guaranteed by the fundamental right to personal data protection is that of purpose. This principle, by defining the specific purposes for which personal data may be processed, makes it possible to specify the licit uses of information, to analyse the grounds that make its processing legitimate and to determine the possible limitations on the rights of the data subjects.



Due to this, to respond to the preceding considerations, it is necessary to analyse what the purposes of the medical record are.

In this regard, one must affirm that the main purpose of a medical record must be to provide health care, so it contains all the data that, according to medical criteria, allows true, updated knowledge of the state of health.

This basic purpose of the medical record inherently gives rise to some necessary requisites for it to be achieved, such as the patients being bound to provide data in their health in a loyal, truthful manner, and to collaborate in gathering this, and for the professionals to record their intervention and include all the information obtained in the care processes, and that which is transcendental for true, updated knowledge of the patient's state of health.

On the other hand, the competent public powers should contribute to the information on the medical record allowing one to achieve that purpose by regulation establishing at least its minimum content.

Finally, the competent authorities in health matters and public and private health centres must fulfil a key role to ensure the medical record is kept with criteria of unity and integration, at each care institution, so it may provide professionals the best, most adequate knowledge of the patient's data in each care process.

3. Access to the medical record.

Definition of the purpose of the medical record, under the terms already stated, provides criteria to initially define access to the data it contains.



Thus, the patient has to be entitled to know, with regard to any health related intervention, what information is available in the medical record.

That right constitutes a specific manifestation of the right to health established in the international instruments and Constitutions of democratic countries. This also includes the right of access to the personal information forming part of the essential content of the fundamental right to data protection.

The patient's right of access must include that to obtain a copy of the data included in the medical record, without that necessarily amounting to a power order disposal over the original documentation.

However, that right to access may not be absolute in nature, but rather, it is necessary to take into account conditioning factors that might limit it, to guarantee other third party rights worthy of equivalent protection.

Thus, one might consider that a patient's right to access might be limited to guarantee the right of third persons to the confidentiality of data included on the medical record in the therapeutic interest of the patient himself.

Moreover, one might consider the possibility of opposing the right to access, when this is recognised by law, the right to professionals who participate in preparation of the medical record to reserve their subjective annotations. To the extent that this amounts to limitation of a fundamental right, the rules recognised under that possibility must be interpreted restrictively and their exercise be attributed strictly to the professionals who participated in their preparation, without being able to replace these in practice by the centres or institutions where their services are provided.



In this regard, one must insist on the need for the regulations to define the minimum content of the medical record and the convenience of developing the necessary protocols or standards of action to prevent reservation on access to subjective annotations from illegitimately limiting the patient's right to access.

4. Uses of the medical record.

Having defined the main purpose of the medical record, its inherent obligations with regard to the information it must contain and stated the basic rights of access to that data, one may not forget the need to consider additional uses and access legally covered according to reasons and legal requirements of general interest, related or linked to protection of public health.

Identification of these purposes is the remit of the competent Public Powers and, most uniquely, due to the intrinsic requisites of democratic rule, the Legislative Power.

However, one may consider that those demands arose in the case of data processing related to epidemiology, inspection, evaluation of quality and planning provision of the health service and research or teaching - although the latter two cases must be compatible with the patients' right to consent to access and use of the information -.

There are also reasons of general interest in access and use of clinical information for judicial purposes, although in these cases, the public interest may not only be related to public health, but rather to guarantee the fundamental right to effective judicial protection, or that of public security.



According to the diverse nature of the public interests concerned, access to the data on the medical record may be subject to diverse levels.

In all cases in which access and use of the clinical information may satisfy the general interests that make it justified, without the need to know the identifying particulars of the patient, the general rule, imposed by law, must consist of access being performed so the identifying data are kept apart from those of a clinical or care related nature, so the dissociation assures the anonymity; as far as possible, such dissociation must be irreversible.

However, in other cases, among which one must consider investigation by the judicial authorities to be included, or others that necessarily require identification of the patients, the rule of anonymity must be waived. Due to this, it is necessary for the competent authorities to be legally empowered to decide on the need to link data on the patients' medical record, in a regulation with the rank of Law, through reasoned decisions.

In all the cases described, processing data from the medical record, whether dissociated or not, must be strictly limited to the specific ends that justified their access and use.

Special mention is to be made of access and processing of clinical information by the staff in charge of clerical duties, management or billing at health centres and, thus, those performed by the companies that provide health assistance coverage, such as insurance companies and provision institutions, which must know that information in order to bill the cost of those services and/or determined the scope of the coverage. In these cases, access to the data on the medical record will be limited strictly to what is required to



perform those duties. In that regard, the need to access the medical record will also be limited in cases in which there are scales or parameters that allow the cost of the different modes of health care or guaranteed coverage to be evaluated on the basis of reference modules, that may make it unnecessary to access the specific information on each patient.

Access to medical records raises a last question to which reference is made, concerning authorisation of third parties other than the patient, who may be allowed to access the data they contain. This possibility of access may arise while the patient is subject to health care, as well as following decease.

In all cases, one must act on the basis of the principle that such access to the medical record must be authorised under a legal provision that might recognise, or if appropriate, establish limitations on access by third parties other than the professionals who participate in providing the patient health care, to the medical record.

In any of the cases described, one must bear in mind, as a general rule, the will previously expressed by the patient with regard to authorising access. Or in cases in which the law allows direct access to health data by such third parties, but recognises the patient has the power to prevent this, one must attend to the will he or she has expressed in that sense.

Access must be considered admissible when, according to the criteria of the doctor attending, the patient lacks capacity to understand the information, in which case the professional may inform close relatives, or when in fact the information is relevant to actions related to adequate health care.



Limitations on the right to the patient's information based on the powers of the doctor to limit that information due to severe reasons of therapeutic need must also be disclosed to third parties related to the patient by bloodline or fact. Such reasons are understood as the power of that professional to act when, due to objective reasons, the patient's knowledge of his own situation might be severely damaging to his health. However, the doctor must leave an explanatory record of such circumstances on the medical record. That circumstance would not amount to a limitation of the right of access that the patient himself might voluntarily exercise.

As to deceased patients, one may admit the right of access to medical records by persons related to the patient, as long as this is legally allowed on the basis of general interest. In particular, one must consider the possibility of allowing access when this is due to health risk to third parties, as long as that access is limited to the relevant data and the privacy of the data subject, and the rights of other persons or the right of professionals to reserve their subjective annotations, under the terms aforementioned, is not affected.

5.- Conservation, security and confidentiality of medical records

To fulfil the inherent purposes of the medical record and allow exercise of the rights on same, it is necessary for health centres to establish diligent active custody mechanisms that guarantee the authenticity and integrity of their content, the possibility of their future reproduction and protection against non authorised access. As to authorised access, one must strictly evaluate the purposes that justify it.



Thus, adequate conservation terms must be provided for the purposes of the medical record and safety measures must be established, of a technical as well as organisational nature, to enable effective fulfilment of those requisites.

These obligations of management and custody of the medical record must also be considered the responsibility of health professionals who perform their activity individually, with regard to the documentary assistance they generate.

In any case, the guarantee of confidentiality of the medical record requires both health professionals as well as persons other than those who are authorised to have full or partial access to the medical record, to be subject to the obligation to keep professional secrecy with regard to knowledge of that information.

On the other hand, the competent public powers must provide measures that guarantee conservation, integrity and confidentiality of the medical record in the event of the professional or health centre ceasing activity.

IV. INTEGRATION AND CO-ORDINATION OF MEDICAL RECORDS.

As aforementioned, the basic purpose of the medical record is to provide the patients health care.

That means medical records must be kept with criteria of unity and integration, at least at each healthcare institution, in order to provide the best, most appropriate knowledge for medical staff of the data on a specific patient, in each care process.



On the other hand, access to the health services covered by the health systems for which the public authorities are responsible must foresee guarantees of mobility, in order to allow healthcare regardless of wherever they are in the country at the moment of entitlement.

The Public Authorities must also encourage implementation of compatibility systems that, taking into account the evolution and availability of technical and financial resources, and the diversity of systems and types of medical records, enables their use by any healthcare centre nationwide that attend the same patient, to prevent them being subjected to unnecessary repetitive examinations and procedures, which will additionally cause cost saving and lower risks to privacy.

The unity and integration of the medical record, the guarantees of mobility in access to healthcare and co-ordination of medical records may be considered purposes of general interest that justify establishment of health information exchange systems between different bodies, centres and services in the health system, to allow citizens and healthcare professionals access to medical records under terms that allow one to guarantee the quality of that care, confidentiality and integrity of the information.

This conclusion is particularly relevant in Federal or decentralised States where diverse public powers are responsible for the health services.

In cases in which access or information exchanges take place through electronic communications networks, it will be necessary to provide a safe network to ensure adequate protection guarantees. Among them, one must consider establishing electronic certification requisites, electronic signature and encryption, pursuant to the laws in force.



V. THE INDIVIDUAL HEALTH CARD

Citizen's access to the care provided by the health services may be provided through an individual health card, as is the case in some countries.

If issue of such a document is decided on, it would be configured as an administrative document that records, in standard form, the basic identifying data of its holder, the rights to which he is entitled with regard to the health services and the Authority issuing the card. It may also contain a unique personal identification code for each person, when this is necessary to facilitate the search for health information on a patient, that might be held by diverse, widespread bodies, centres or health services.

Thus, the individual health card will enable medical information to be located and consulted by the health professionals in cases when this is strictly necessary to guarantee healthcare, as described under the preceding headings. The individual health card issued may have computer media embedded.

In any case, both exchanges of health information, under the terms stated, as well as issue, the content and purpose of the individual health card – especially if computer media is embedded – must have an appropriate standard authorisation. Likewise, inclusion of information other than that stated, or data on its holders' health, will require specific legal authorisation that establishes the purpose of the data processing with regard to reasons of public interest.