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European Health Card
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THE EUROPEAN HEALTH CARD

The idea of creating a European health card dates back to 1978. A project to this end was the object of a European Parliament report which was accepted by the environment, public health and consumer protection committee and adopted in plenary session on 18 April 1996.

This report recommended the adoption and creation of a European health card and fixed a precise legislative timetable which, at the present time, has not been followed in that the European health card should have been the object of a parliamentary bill before 1 January 1997 which would have thus enabled the card to be functional by 1 January 1999.

The legal bases for the creation of this card are:

- the clauses of article 129 of the treaty instituting the European Union which state that the community must play its part in ensuring a high level of protection for people's health;

- the clauses in directive 95/46/CEE of 24 October 1995, relating to the protection of individuals with regard to processing of personal data and on the free movement of such data.

Objectives

In the context of the computerisation of healthcare systems, the European health card must contribute to the fulfilment of certain objectives:

- to cope with the growing mobility of community nationals within the European Union;

- to allow European citizens to enjoy adequate health care when they move from one member state to another;

- to communicate emergency medical data and to access medical files in emergencies;

- to simplify administrative tasks especially for insurers;

- to make budget cuts in health expenditure (?);

- to promote the use of new technologies amongst patients and health professionals.

Health cards and a health information system

Health information is a complex subject which cannot be understood without a so-called "systemic" approach. The very concept of a health information system oversimplifies the problem. It is very dependent on the often highly complex organisation of the health system which it is meant to represent. Like any technological tool, the electronic health card is a response to needs identified through the conceptualisation of the information system. This very difficult conceptual process has been carried out only in a very small way, if at all. In fact, all computerisation goes through a preliminary study which is sometimes reduced to producing terms of reference which state the requirements desired by the users (patients, professionals, insurance companies, the state, etc.) with respect to the information system itself. Within the framework of standardisation work, this approach has resulted in new concepts: the "global domain model" for the CEN at the European level, the "reference model" for HL7 for the North Americans. The technological solutions should, in whatever case, be the final stage and come out of the needs and constraints expressed during the preliminary stage. If this does not occur, there is a risk that technical solutions are proposed which do not respond to the needs of the users and serve, more or less deliberately, as a technological "Trojan horse" and are useful only in showing the amount of effort put in by a country at the industrial level (software, microprocessors, card readers, etc.).

Some of the experiments carried out so far in Europe have suffered from an obvious lack of preliminary thought and most of them have not benefited from a sufficient amount of critical analysis to draw lessons on the expected benefits mentioned above. The description of an information system should end with a description of the different functionality required to resolve the communication problems between the various people who will be using it. The current experiments are limited to developing, testing or deploying existing technologies with a single functionality. We will come back to this subject.

Current situation

On the basis of projects taking place in various community countries, the card should include data relating to the civil status of the bearer, to his entitlements to social security and to reimbursement of medical costs as well as diverse medical data mainly concerning blood group, allergies, medication taken, chronic and occupational illnesses, current treatment, vaccinations, details of medication which the cardholder should be able to obtain freely in pharmacies across the European Union indicating the basic pharmaceutical ingredients (the generic and not the brand name of the medication), indicate if necessary if the cardholder refuses transfusions of blood or derived products for religious reasons, as well as indicate any desire to be an organ donor.

The introduction of this card is often envisaged as happening progressively with priority being given to people suffering from chronic illnesses or serious ailments requiring continuous or urgent care, adapted to specific cases.

In fact, in a very trivial fashion, the projects (38 registered in Europe) are marked by the omnipresent role of the state whose overall vision of the health information system can be

summarised essentially to the relationship between professionals and health insurance companies with respect to the reimbursement of costs. Paradoxically, the people who have been consulted the most (doctors in most cases) are drawing little, if any, advantage from the developing automation of these procedures.

On the other hand, most of the time, the complexity of these projects has been very poorly understood in the preliminary (feasibility) stages. Their implementation then becomes long and costly thus considerably reducing their credibility in the eyes of patients as well as professionals. The software architecture which has been designed has taken very little notice of the need to open up the systems and the constraints that that imposes, and has been developed within proprietary environments which are not very favourable to developing interoperability between applications.

Arguments in favour of and against a medical section on the cards

Firstly, no comparison should be made between the old experiment with children's health records which were created in many countries after the second world war and the current experiments with health records in several European countries.

The former contain only biometric information about growth (weight, height, head circumference), information about vaccinations received and acute ailments of early childhood.

We know that notes about previous obstetric problems, severe infections (HIV) or information of a genetic nature have led to numerous disputes and controversies over the risks of violating confidentiality of sensitive medical data by people not authorised to receive it or incapable of interpreting its significance.

No study has yet been undertaken on the role of these health records in improving continuity of care, on their usefulness in reducing the number of unnecessary paraclinical examinations, the quality of medical follow-up or the co-ordination of care between different health professionals. It is therefore necessary to determine first what the objectives and purpose of the card are, and then its content.

- A medical aide-mémoire for any one

In this case, the doctor's role would be that of a compiler putting declared facts (family and personal past history) into medical form, recording a statement that the patient has fulfilled legal (or voluntary) vaccination requirements, or else copying personal medical details (possibly verified by him) but fully known by the patient. This form corresponds to the European emergency health card established in 1981 in the 9 languages of the European Community and which was recommended to the European Parliament by the Leopardi report at the beginning of 1996.

- A medical record

This could be an improvement to the health card. The difficulties encountered during experiments have led those involved to envisage creating a semi-open multi-purpose record.

The failures that have been recorded have resulted sometimes from the lack of communication between doctors because of the use of very personal abbreviations or terminology, sometimes from insufficient memory space for chronic illnesses, sometimes from an insufficient quantity of card readers available to health professionals and sometimes from the excessive amount of time taken between writing and reading (8 to 12 seconds).

The Santal experiment carried out at Saint-Nazaire (France) since 1988 on the basis of the European “Cardlink” project has been the subject of several reports and evaluations and has led to a product validated by several authorities.

The medical section includes the following administrative information:

- information identifying the cardholder
- a statement of his entitlement to obligatory health insurance
- a statement of his entitlement to complementary private health insurance

… and medical information which is broken down into:

- a European section of emergency data of the Cardlink type
- a specific Santal section (medical and surgical history, history of anaesthetics and transfusions, vaccinations, nature and dates of principal examinations - without results, blood group and agglutination, details of prescriptions and their delivery, summarised accounts of hospital stays, risk factors, specialist follow-up, details of general practitioner).

This medical section therefore includes both essential emergency information and a portable, summarised medical record which has been standardised and coded.

The most interesting part consists of the signature of the medical data recorded therein and the existence of “pointers” leading to other sources of more detailed medical information.

- A specialised medical record

It is certainly easier to build up a medical record for one illness or one specific condition than one which can be used in every situation encountered in general medicine.

In fact, the ordering of items based on a prototype of a clinical examination or of results from stereotyped or standardised examinations makes it easier to organise the actual structure of the record. The standard records drawn up by many medical teams in France dealt with resuscitation, cardiology and perinatal medicine. Because of the success and the durability of such an initiative, it is possible therefore to think that other applications could usefully be researched, in particular all the chronic conditions (asthma, breathing problems, diabetes, high blood pressure, chronic kidney disease, epilepsy, cancer, blood disorders, organ transplants), that is to say in fact, all the so-called long term conditions.

It is therefore necessary to determine, at European level, what function needs to be attributed to the content of the medical section of the smart card:

- a simple card with emergency data (the European emergency health card)
- a card with emergency data plus a simplified multi-purpose medical record
- a specific medical record for chronic illnesses or conditions.

- Security criteria for the health information system

These criteria should be at the basis of the design of any health information system. They rest on different concepts:

- confidentiality, to which we will return;
- authentication of those involved: patients, professionals, structures;
- accessibility: who has access to what, when and how?
- availability: health information has no meaning unless it exists;
- "traceability": which for professionals translates into terms of responsibility for the data supplied and exchanged.

If these criteria are not respected, it seems pointless to define the information system itself.

- Legal and ethical aspects

In all European countries laws exist concerning the transfer of data as well as principles of medical ethics.

It seems that, in principle, unless there is contrary legislation, any person can legally refuse to let health information about himself be collected on a computing medium which might ultimately be used as the basis for constituting a data file, and any doctor asked to read a card with a name on which includes health information must inform the cardholder if he wishes to transfer the content of the card onto his own computer.

The legislative and ethical data are often contradictory since, in principle, the patient should be able to be informed of all information concerning him; this information should be communicated clearly and understandably and should be in accordance with the content recorded on the smart card. As a result, one may not and must not hide anything of the card's content from the cardholder; this can, with certain illnesses, create difficulties.

Furthermore, certain laws allow the patient to demand that information concerning himself be rectified, added to and up-dated, or erased. It is easy then to imagine that a cardholder could ask a doctor, not necessarily the initial compiler, to modify or remove such information which he himself reckons to be incorrect or dangerous, and to imagine the conflict which might result with a practitioner who refused on the grounds that the information is fundamentally important when the patient moves around.

In all these cases, it is possible to have doubts about the value and the completeness of the medical section of a card produced for a doctor seeing a patient for the first time.

- Technical constraints linked to the card: the reliability of available medical information

The possibility of a cardholder carrying his own medical record as he moves around seems to be an attractive solution medically in emergency situations and psychologically beneficial for the majority of European citizens.

At the current time, agreement has been reached to talk of medical "warning signals". This idea allows the relative importance of accessible information to be ascertained in certain

medical care situations. Thus the accessible medical data must “warn” the practitioner in order to help him determine the level of urgency of the situation according to the clinical picture.

However, there are a certain number of disadvantages and constraints liable to counterbalance the possible advantages:

- the card is lost or stolen. This possibility means that the data in the medical section must be duplicated onto another medium. The general practitioner must therefore be in a position not only to read or write on the card, but also to copy the content.

- the card gets full. We know that certain elderly patients suffer from multiple chronic conditions and that their state justifies many examinations, investigations and prescriptions. It is possible therefore to imagine a situation when the card becomes full before its expiry date.

A simple procedure might consist of removing and replacing the oldest data and information with the most recent: this would not work with medical matters. The importance of the information given by the data is not in fact linked to its chronology. Thus, surgery for stomach cancer is a more important piece of information and of more lasting value than data about the last four episodes of flu, a sprain or upper respiratory tract infections.

Transcribing selected data of a card’s content is a medical procedure which consists of evaluating, possibly with the patient, the significance and repercussions of a symptom, of an occurrence of a condition and the existence or not of after-effects of this or these events.

The updating of data is a recurrent problem. In fact, what credit can be given to information integrated into the card if it includes neither dating nor the signature of the person who recorded it? The data organisation must satisfy software architecture which quickly becomes complex to implement in such a small medium.

The design of the medical section must have the ability to evolve (e.g. have the possibility of adding/removing headings). This is perfectly possible (medical information is not carved in stone) but it is likely to be particularly complex to organise and to have heavy financial implications (updating all the cards!).

- Length of life and size of the card

Updating the administrative situation, however old the information is, is easy if there are terminals situated in many places. On the other hand, for the medical section, when a card is being exchanged it is necessary for its content to be transcribed automatically and in full onto the new medium without needing to be read and verified as this would necessitate involving a doctor. The patient must be informed that his card has been exchanged and that an accurate copy of the medical section of the former one has been made.

Other technical constraints have been or will be raised as progress in micro-electronics

occurs: standardisation of readers and software, increases in the card's memory capacity, reduction in the time to access, read and write on the card.

Despite all this progress however, the memory of the part reserved for the medical section is limited in size. Every doctor knows how the medical records of chronically ill patients are forever increasing in volume with the accumulation of numerous results or even of successive treatment plans the details of which are necessary to note. In order to store the maximum information in the minimum space it is necessary to code it, organise it and ensure that it is coherent and that its significance is clear to any doctor asked to provide care to the cardholder.

This remains problematic when the patient crosses borders, even within Europe, unless the same standards are adopted as in the European projects of the Cardlink type.

- Confidentiality of the data and medical section

Medical secrecy is an extremely ancient concept, even older than Hippocrates. A recent survey of all doctors in France (62,000 responses) shows that keeping medical secrecy is, in their opinion, a vital concept for the safeguarding of future medical practice.

The medical section of the health card includes personal, named medical data and no-one therefore must have access to the content of the card without the express agreement of the cardholder. Giving the card to a third party therefore constitutes a voluntary act to the extent that the cardholder is duly informed of the exact content.

In the case of the general practitioner or any health professional giving treatment, knowledge of this medical record is perfectly legitimate. This is not the case for doctors working in health insurance organisation and even less for insurance company doctors or medical experts. What can one say then of an employer or an insurance agent who acquires a card reader?

This is why the health professional's card which allows its cardholder to have access to certain medical services has clearly defined, on the one hand, the profession carried out and, on the other hand, has recognised in each card four classes of different functions (general practitioner, hospital doctor, supervising doctor, preventive medicine doctor). But these activities are sometimes cumulative and carried out simultaneously.

Allowing the cardholder himself to block access to the health record seems to be a safe solution. Knowledge of an access code is a simple method and, of course, the principle used for bank cards. But what happens if the cardholder forgets his number, has a memory loss (frequent amongst the elderly) or is simply in a serious medical condition, unconscious or in a coma? The advantage of a portable emergency data section would then be totally wiped out. Can one then accept that the unconscious person implicitly consents? Is the cardholder its true owner? These important questions raise the problem of what has been agreed to call the Unique Patient Identifier.

Let us recall the fact that to treat a patient, especially one in a serious condition, a doctor is not required to ascertain his identity but it is very much in his interest to ascertain that the accessible data does actually belong to the patient.

Following on from that, there are two possible solutions:

- the first consists of establishing a central index of access codes with which a doctor could communicate by identifying himself using his own professional's card. This is a flexible solution which poses the problem of the professional's own identifier when in a context of international communication;

- the second would provide more security a priori with respect to identification. The patient's card could include some biometric data of the person (fingerprints, anatomic nature of the hand or ear). With respect to fingerprints, 80 points are sufficient to identify someone with a risk lower than 10-4. But it would then be vital for "dataglyph" readers to be available at least in every casualty department. A technical solution like this is becoming cheaper and thus becoming quite plausible. Less elaborate than iris or retina scanners or a speech recognition system, it has the advantage that it is widespread, reasonable in price and practical to use in emergency medicine.

It is always possible to break into a computer data file. It depends on the available means, time and cost and the competence of the hacker. That is why possessing a card with a health section should remain voluntary and only be agreed to if the risks of loss of confidentiality are very low which is the case if security requirements are respected.

Conclusion

The concept of an electronic medical record seems an attractive proposition but the constraints are considerable. We feel that the hesitations about it are due to an incorrect preliminary concept of the health information system at the heart of which is the patient's medical record. The latter is not a simple entity. It evolves, it is shared, and is made up from very diverse information sources: it is the archetypal information "network" which needs the strictest security rules.

Thus the medical section of a European health card should only be filled in after the doctor has given the information and with the agreement of the user. If the latter should refuse, he should not be penalised by being refused benefits from the obligatory health insurance scheme that he is affiliated to. The only justification for having portable medical data is its immediate availability in the case of danger to life. That situation implies that anybody intervening in an emergency situation can have access to it, without delay.

In these conditions, the content of the medical data should be fully known by the patient who should have the right of access to read and, if necessary, correct the information using the services of a doctor. If the medical section includes, in addition to the emergency data, elements of a medical record, access to that part should be limited to health professionals alone. It requires the authorisation of the cardholder in a form to be determined (access code and personal identifier).

Another approach could be to consider the patient's card as a formal electronic authentication system (e.g. a key-card on the principle of the bank card). This is the "network" approach. The only pieces of information available on the card are "pointers" which enable the cardholder to be put in contact with the data making up his medical record. This data is managed by the professional(s) who have treated or are treating the patient. The development of health networks argues for this approach. The use of "open" languages, derived from the need for structured documentation, and developed within the context of the

Internet (XML) then authorises the retrieval of elements of the medical record onto whatever work station connected with a simple browser. Access to the data is conditioned by the exchange of messages authorising, or not, the transactions.

Whichever approach is chosen, however, the communication of medical data between health professionals, in the interest of the people concerned, implies the coexistence of several conditions (we do not consider the list hereunder to be exhaustive):

- a standardisation of reading/writing techniques between health cards, medical records for ambulatory care and medical records within health establishments in order to guarantee interoperability at national as well as international level;

- a standardisation of the semantics and the structure of medical records according to European standards (CEN TC 251) and/or international ones (ISO TC 215) as well as a standardisation of the messages exchanged;

- a minimum level of coherence concerning the structure of identifiers and identification procedures for patients and for professionals;

- shared rules on the exchange of information favouring the respect of confidentiality, which should include a concerted development of the regulatory frameworks in each Community country and even at international level;

- the adoption of encoding standards.