

CONCLUSIONS*

Javier Carnicero, Carlos Amézqueta y Ana Granada

Health and Medical Record. Electronic Health Record.

Communication and Information Technologies (CIT) have permitted the evolution of the traditional paper-format concept of medical record as an exclusively medical document, limited to collect information about the episodes of the doctor-patient relationship at a certain time and place, towards a new medical record, the Health Record, which is able to integrate all the information related to a person's health:

- Accumulated along the patient's life and not limited to certain interventions.
- Related to health and illness data.
- Generated by all the people responsible for the health care in the different care service times and levels.

The Electronic Health Record (EHR), or Health Electronic Record, is the appropriate format to store and integrate all the information related to health, and it allows to improve or even solve traditional record common problems, such as legibility, format, fragmentation, lack of order, access, availability, confidentiality and deterioration.

The terms Electronic Health Record or Health Electronic Record seem to be more appropriate than Computer or Computerised Medical Record (CMH), due to the current or future use of several technologies as a whole: computing, communications, sound and image among others. Those present at the meeting did not reach an agreement about which of the names is the most accurate: Electronic Health Record or Health Electronic Record. That is the reason why both terms are indistinctly used in these conclusions.

The EHR, which must be only, and whose information must be relevant, appropriate, non-redundant, heterogeneous and enduring, possesses as a distinctive characteristic its accessibility anytime and anyplace.

The EHR then means to apply the CIT to health care and thus change the concept of Medical Record, which becomes part of a medical information comprehensive system, instead of simply being a record with the information related to the doctor-patient relationship.

Individual person identification

The need of a univocal way to identify the health service users has been made clear in several countries and more so when the medical record is computerised.

The different identification systems existing in our country (Registry Office, Identity Card, Social Security) do not guarantee this univocal identification. The identification promoted by the health services, based on the health card, has made confusing the terms identification and Social Security benefits accreditation.

* The conclusions in V SEIS Report were agreed by all the participants in the meeting of the 18th December 2003 in Pamplona

Furthermore, there are no identification code standards, nor standards for the information printed on the health card, the magnetic strip or the databases. This situation can be defined as a regrettable lack in our National Health System.

The incorporation of the CIT to the health service activity and the creation of integral information systems, demand not only the accurate identification of patients but also the establishment of information exchange standards, as well as the compliance with the confidentiality and safety regulations. It is equally necessary the identification of the professional and the health care providing institution, as well as knowing the care the patient has received.

Electronic Health Record Models

Computerising a health record implies to overcome the concept of medical record model and replace it with the concept of data collection and presentation. The model ceases to be something static and becomes dynamic and adaptable to different contexts, in constant evolution.

The data collection can basically be “personal” or “non-personal”, and it is conditioned by the information origin, type of record and analysis. Data presentation in reports is conditioned by the environment in which it is disposed of: public information, primary care, specialised care, social services, public health service, research, teaching, administrative services and health managers.

Introducing the EHR and overcoming the classic medical record model can meet different types of difficulties, depending, for example, on the data collection system adaptability to each professional working habits, on the “agents” participation in the system design, on the functional format support, and on the available resources, among other factors.

The professionals’ decision-making independence will need to be considered in the EHR design and evolution.

The Internet expansion, mobile devices, and voice-writing recognition programs, interface “humanisation”, condition the future of the EHR

The genetic information development may also be an influence in the future EHR family “model”, or at least in an appropriate integration system of this information in the individual EHR.

Communication and Information Technologies committed to Electronic Health Record.

CIT support, make possible and encourage the dynamic evolution of the EHR.

The current technological context enables the use of multi-tiered distributed application models, J2EE and .NET and web Services. Grid technology is a new proposal which interest researchers as well as industry.

Data must be integrated to be shared in an appropriate way. In order to do so we must consider the situation of the classical technology based systems as well as the new web-based work solutions, based on web services and potentially in the GRID technology.

The need of data migration must arise when it is not possible to keep a system. We must assess the risks and benefits of the data migration in advance. Before it actually takes place, it might be preferable to try to communicate different systems by exchanging documents. XML seems to be the ideal tool for these processes.

The system analysts must take into account the ergonomic and perception principles which affect the human being. Designs must be simple, clear and adjusted to the user knowledge and skills.

Standards

Users are the ones who, in the first place, must clearly define their needs and fix the standards, because the industrial product development will come after. Anyway, a convergence of the standardisation processes is needed.

The most important regulations, which are nowadays the axis for standard construction, are PreEnv 13606-1, HL7, DICOM and OPEN EHR.

Regulation development is usually slow because the users' participation is voluntary, there is a lack of resources to reassure their participation and consensus is required as well.

Besides, some of the technology suppliers opt for a property system, which enables them to keep their market share. On the other hand, medical computer systems usually have a very good theoretical base and a very poor experimental one.

Reference sources for the convergence of a common health record model would include:

- CEN ENV 13606 and its implementations in Europe.
- OPEN EHR, GOM, UCL SynOM (shortly united as an object reference model openEHR)
- DICOM Models
- HL7 v3 Reference information model

Legal aspects of the Electronic Health Record

The EHR is a consolidated reality from the legal point of view, and it is accepted as people's health information format.

It is mandatory to inform the patient of the existence of the computerised record, of the identity and address of the person in charge of it, but their consent for the computerised data processing is not required.

The patient has the right to access the data recorded in the record, except for those confidential data which affect other people, subjective notes taken by the professionals, and those data which access must be limited for the patient because of therapeutic reasons.

The legal procedure for the clinical information preservation and closure does not seem to be solved in a clear and satisfactory way yet. This situation is due to the application of both the health regulation, especially Law 41/2002, from 14th November, basic regulatory of the patient's autonomy and the rights and duties related to clinical record and information, as well as data protection.

The professionals involved in the patient's diagnosis and treatment may access the record by confirming their identity, the access being recorded, and every other security requirement being fulfilled.

There are several cases in which medical record data might be transferred even without the consent of the person concerned:

- Judges, Courts, Ombudsman, Public Prosecutor and National Audit Office.
- Emergency situations.
- Epidemiological studies, public health actions, research and teaching, once the information is depersonalised.
- Health inspection, assessment, accreditation and planning.

There is a usual delay between the legal regulation definition and the technological evolution. But we must as well assume the difficulty of legislating before the clear and well-defined EHR format is known.

There is a certain lack of concordance between autonomic and state laws.

The legal responsibilities about the confidentiality guarantee of the clinical information are penal, civil and administrative, according to the case.

Security, confidentiality and availability

In order to guarantee the security, confidentiality and availability we must adopt a security plan related to people, machines, programs, data and communication infrastructures.

We must reach a balance between availability and security, so that the latter does not collapse the systems making the information unavailable.

The targets that must be accomplished in order to guarantee security, confidentiality and availability are those of authentication, confidentiality, integrity, no rejection, authorisation, auditory and availability. In order to achieve this, the following measures must be implemented:

- Digital certificates
- Information coding
- Digital signature

- Authorisation and privileges management
- Access records
- Appropriate service level management

A very important availability method is the service level agreement, which must be reached by managers, final users and CIT responsible. This agreement makes compulsory the supply of a certain quality and amounts of service, and limits certain expectations and requirements about the system.

Security, confidentiality and availability require prior organisation. The first organisation measure is to achieve that every member of the institution is conscious of the problem and sensitive to its importance.

Auditory, authentication and no rejection are considered security guarantees.

Some of the present at the meeting also considered a security guarantee the patient's control of the professional's access to their clinical information, or at least, the patient's authorisation to access that information considered as "sensitive".

However, no agreement about this patient's control and authorisation in the medical information access was reached in the meeting, or about whom, how and in base of which criteria we can or must define the information considered as "sensitive".

Information system inference

We can consider the following as the basic functions of the traditional as well as the electronic medical record: helping tool for the attention and care given, legal document and information source. The use of CIT in a health information system produces a series of inferences related to those functions. Those inferences offer new prospects and possibilities for the scientific research and health professional development. These inferences can be:

- Vegetative. They are produced just by the fact of the use of CIT itself: better file management, availability, plasticity and security improvement. At the same time it is made clear a certain technology dependence and vulnerability different to the one in the traditional model.
- Operative, directed to a particular purpose and needing certain specific development: Integration of heterogeneous and varied origin information, which gives a global and updated vision of the facts related to a person's health. We could take as examples the repetitive tasks and procedures automation, and the improvement in the professionals communication, whose leading exponent would be Telemedicine.
- Epistemological: They try to contribute material to the knowledge. They are based in a better use of the great calculation capacity computers have. They will include, among others:
 - Management assistance tools, such as the balance scorecard.

- Care assistance systems which diminish the clinical variability and improve the health results and the decision taking process.
- Artificial intelligence, such as expert systems, which allow predictions, suggestions and alternatives in the decision taking process.
- Teaching and research

Electronic Health Record impact in research and teaching

The benefits of the EHR for research cover every aspect from basic to clinical and public health research.

- Allows the collection of better quality, more precise and larger number of data.
- Improves the access to proof-based medicine, care quality research and results assessment.
- Enhances the development of disease, tumour and transplant records, genetic databases and research centres and virtual nets.

The EHR advantages related to teaching are, among others, a better access and availability of the histories, the disposition of assistance tools for the decision taking and the use of web technology for distance training.

For all this, the record must meet certain prior technological requirements, such as the improvement of structured data entry, the creation of depersonalised data replace systems, and the adjustment of standards for metadata, image and biomedical signal.

A change is also needed in relation to organisation, training and attitudes, incorporating medical computer training to the health professional studies and to the patient's education.

In practical research ethical and data intellectual property problems arise, and there should be a clear regulation to solve them. We must also remember to protect as far as possible the patient's anonymity.

Electronic Health Record. International perspective. Present and future.

Up to now we can say the definite change from paper record to "something else" is yet to come.

The concept of Health Record is not uniform, homogeneous or only. There is a necessity for a concept definition of Health Record. There are many terms with a particular meaning or context: Clinical information, Medical record, Patient's information and Database.

Health Record tends to be considered as a reflection of the change in health care. The target must be the construction of continuous systems for the information flow, which make it easier the improvement of the professionals' performance and which allow at the same time a more efficient and transparent interaction with people and patients. The key word is flexibility. Most of the applications and projects tend to show similar functions, such as making the access to the information available anyplace and anytime during the health care process, and the existence of integrated systems for the

information management. The trend is, in short, towards more multidisciplinary, distributed and virtual electronic health records.

There are a variety of different electronic health record supports in our environment, which are not compatible. However, in Europe, a safe and interoperable electronic record for everybody to use is in project.

In this forward-looking project we can think about the patients as the responsible of their own EHR maintenance.

In the international context, EHR projects we can identify nowadays as the most interesting are:

- ERDIP in the UK
- OPEN EHR in Australia.
- EHR in Canada.

Final conclusions

The EHR as a record integrating all the personal lifelong health information, referred to the different health and illness states, and generated by every health professional linked to this person at any care level, presents undoubted advantages regarding personal attention, teaching and research, but also health service and public health management and planning.

The EHR would not be possible without the application of the CIT to health care. However, to make this existence possible, we need univocal personal identification methods and the strict compliance with the security requirements, confidentiality and availability, which, on the other hand, are required by the current legal regulations. These legal regulations admit the existence of the electronic health record and legally validate it completely.

In the nowadays technological context, the EHR will be constructed on multi-tiered distributed application models. Web services and XML seem to be appropriated technologies for the communication between different systems.

The EHR needs standards that make possible the interoperability of different health information systems. The most important regulations, which are nowadays the axis for standard construction, are PreEnv 13606-1, HL7, DICOM and OPEN EHR.