Good Characteristics for describing Electronic Healthcare Records and Systems

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Abstract. Electronic Healthcare Record Systems are on the market since the beginning of the eighties. In many Member States, candidate users can choose amongst a great number of them while only in a few Member States guidelines or criteria on functional or technical issues are available. In this paper, we propose a set of characteristics that can become the basis for a European agreement on minimal criteria for electronic healthcare records and systems. These criteria can become a guide for users on how to identify systems that meet their needs, while developers can use them to improve their products.

1. Introduction

As a result of the MEDIREC project [1] and the activities of CEN/TC251, there is now more or less an agreement that a comprehensive, communicable and secure electronic healthcare record (EHCR) in each Member State should be installed. This EHCR should respond to the needs of all involved parties, while it should allow interconnection with other health telematics applications. This can only be realised when electronic healthcare record systems (EHCRS) are built that can adequately operate on the data of the EHCR without barriers being put up as a consequence of improper implementations.

Though non-academics very often have difficulties in seeing an EHCR separate from an EHCRS, the distinction is however very important. Water does not stop to be water when the tube through which it flows, is broken. It might perhaps not reach its destination anymore. When the tubes are too small, pressure might be too low as well such that the water cannot be used to take a shower. Or more dramatically, when the tubes are made of lead, people drinking the water may get sick.

The opposite is true as well. The most sophisticated water supply system becomes useless, not to say a real danger, when anything else than water flows through the tubes.

As such, this allegory should make clear that systems at the one hand should be seen as independent from the subject matter they work upon, while at the other hand misconceptions at one side, will affect the proper functioning of the other side.

2. The Holy Trinity

With respect to healthcare records, not two, but three separate entities should be considered. First, there is the *healthcare record proper* (HCR): the total amount of data pertaining to one single patient. These data can be everywhere, and most often are shattered over various places: the

memories of the patient, his relatives and the physicians that have been or still are caring for him. Part will be on paper in different files at various locations.

Some data will be stored electronically, what brings us to the second entity: the *electronic healthcare record*. The EHCR can be defined as the amount of data pertaining to one single patient stored in digital format on electronic media. Ideally, the EHCR should be a copy of the HCR (hence being comprehensive) with additional requirements on top of it such as those related to data-organisation. These additional *record-requirements* are discussed in this paper.

Finally, there are the systems that operate on the EHCR. Their task is double: first to manage the data of the EHCR in such a way that the record-requirements are fulfilled. Second, they also should serve as interface between data and user in such a way that they interfere as little as possible with the normal practice of medicine. A "good" EHCRS should be perceived by the physician as a normal tool of his routine equipment, giving not more burdens than a stethoscope or a needle (though, with respect to the needle, we agree that a patient will see other burdens than the physician). The requirements that make systems behave in the way indicated above, are further called *system-requirements*, and will also be discussed in this paper.

3. The four Archangels

Many actors in the field of healthcare and healthcare informatics have more or less precise record- and system-requirements in mind. If in individual Member States, or at European level, good characteristics for the EHCR and EHCRSs are to be defined, four of the actors should be involved in that endeavour.

First there is the *patient*. It is after all his health status that is described in the HCR. He will have specific concerns on confidentiality. By law, he has now also the right to be informed on what kind of data are gathered, even to ask for modification or removal of specific pieces of information when they are erroneous or not pertinent.

The second major player is the *government*. Whereas the data specific to one patient is not of interest to the government, statistical studies performed on cohorts of data over all patients within a country or region, are extremely valuable for defining or changing health policies, or for cost containment. Such studies only can be performed when the required information can indeed be deduced from the data in the HCR. If that is possible, then it certainly will be much more convenient to use EHCRs then traditional, paper-based records.

The third actor is the *user*, being GP, nurse, medical specialist or whatever healthcare worker. He is not only interested in what data the EHCR should contain, but also in how he can use the EHCR in routine practice. He must be able to enter or retrieve data quickly and accurately. Flexibility of hard- and software is one of his additional concerns.

And finally, there is the *developer* of EHCRSs. He is the poor guy that has to take all the constraints and demands put forward by the other parties into account in order to build an adequate system. His role is not just passive though. Specifically in the stage when criteria and requirements are defined, he must use his technical know-how to inform the other parties on the feasibility of their requests. It is indeed useless to define criteria that cannot be fulfilled. This attitude, how justified it might be, is often not appreciated by users, hence leading to a situation where the developer becomes the "Fallen Archangel". Indeed, discussions on standards and criteria for the EHCR tend to be conducted in an atmosphere of religion and inquisition, a situation that PROREC successfully is trying to overcome [2, 3].

4. Good characteristics of EHCR and EHCRS

In this section, we will describe the issues that need to be taken into account when developing criteria for the EHCR and EHCRSs. Though a strict separation between record- and system-requirements can be maintained, we opt for a transsectional approach in which the issues are discussed - where applicable - from both viewpoints.

4.1 Architecture

Both the architecture of the EHCR and EHCRSs are heavily debated on. Regarding the EHCR, the notion of architecture refers to the principles according to which the logical (i.e. conceptual) structure of the healthcare record is organised. According to CEN ENV 12265, data in the EHCR should respect a context-content distinction where context must be preserved when moving data around between applications [4]. Though users can differ in meaning where exactly the boundaries are, it has been shown that from a formal mathematical point of view, this little matters, provided that the architecture of the system operating on the EHCR, is built using formal terminological systems [5]. Whereas the architecture of the EHCR fixes the upper bound potential for future exploitation of data, the system architecture fixes actual performance by constraining the exploitation potential.

Two essential requirements for EHCRSs with respect to the architecture, can be put forward. First, that the systems follow the architectural design of the EHCR proposed in a specific country (including the provisions dictated by Europe), and second, that the system's architecture is thoroughly described in the system documentation.

4.2 Communication

Communicability of the EHCR is one of the major requirements. While preservation of context and content is an architectural requirement related to communication, there are many others that relate to issues discussed below.

From a technical point of view (hence relevant when describing EHCRSs), electronic communication falls apart in three categories. E-mail as such adds little to an EHCRS, simply because this kind of communication is between persons, the computer (or system) simple being there to behave as a kind of telephone. Electronic Data Interchange (EDI) at the other hand, is a far more useful paradigm when embedded in an EHCRS. It allows the automatic integration of reports or other data in the record, while at the same orders can be generated that themselves can be processed automatically by receiving systems. Web-communication as third paradigm is useful to access external information repositories, while it is increasingly used to build EHCRSs around as well [6].

Communication is closely related to interoperability of systems. The "old" distinction between "interfaced systems" (systems individually responsible for their own databases exchange information in order to cooperate) and "integrated systems" (systems working on the same database) will probably become obsolete in the light of the "virtual EHCR" [7]. But interoperability as such will remain a major criteria for good EHCRSs.

4.3 Data input

From a technical point of view, data input refers to the technology used to enter data into an EHCRS. Typing on a keyboard is the most commonly used approach for entering free text, while

pointing devices such as the mouse or light-pen are more comfortable when a system is heavily menu-driven and built around picking-lists with controlled vocabularies. Converting paper documents to images by scanning can help to turn a HCR into an EHCR, but without subsequent converting the images to text by OCR techniques, the added value is rather limited. The same holds for voice-input without proper voice recognition.

An important characteristic for an EHCRS is what facilities it offers to allow data to be entered at the time they are available. Point-of-care or bed-side computing is a useful paradigm in this context. Also knowledge supported data-entry tools can help users to speed up or improve the quality of their registrations. Valuable techniques are data validation, predictive data entry, or embedding of clinical dialogue models. These techniques bring us to the issue of the EHCR's content proper.

4.4 Data content

Many papers describe the kind of data that are to be registered in an EHCR, some from a standardisation perspective [8], others on more technical or scientific grounds [9]. Prior to define a framework for modelling the EHCR, a clinical account is given by Rector et al [10, 11]. An essential criteria is that the record should give a faithful account of the clinician's understanding. Data should be formulated in terms that are found natural. Conflicting statements must be allowed and also uncertain and negative statements must be accepted. Descriptions should be given at any arbitrary level of detail and at the clinicians' natural level of abstraction. Once entered, data should be there permanent. Though this description fits the characteristics of free text registration, the authors argue that also structured data entry paradigms should fulfil these requirements.

Permanence of data does not imply that after some time, "old" data are not to be seen from a different perspective. The "clinical history" of a patient grows. "Active" data become "passive" as part of the patient's past clinical history. EHCRSs should provide mechanisms to change the status of such data.

A good EHCRS should allow data to be entered or viewed according to various paradigms: longitudinal (e.g. progress notes), problem-oriented (POMR), SOAP-based, episode centred or report based. Especially in multi-user systems, the user must be able to switch from one paradigm to another, or, as an example, view data entered according to the POMR-technique, as longitudinal progress notes.

4.5 Encoding

In the light of faithful clinical data entry, and also with the requirements on communicability in mind, much emphasis is to be put on clinical encoding. The rationale for clinical coding is to associate concepts with precise meanings to patient data. Coding patient data means that a physician (or professional encoder) has to describe the patient data by means of concepts available in the coding system to be used. The requirements to be met in order to perform the coding task adequately are [12] : 1) a perfect understanding of the meaning of the patient data (the source concepts), 2) a perfect understanding of the meaning of the concepts available in the concept system (the target concepts), 3) at least a certain level of similarity and coherence between the source concepts and target concepts, 4) facilities to search the concept system for the target concept(s) that match(es) a given source concept as closely as possible. This can only be realised when the EHCRS has additional functionalities to assist the clinician in his coding task [13].

4.6 Terminology

Terminology is now recognised to be an important building block for the realisation of a comprehensive, communicable and secure electronic healthcare record, the contents of which are to be understood in the same sense by all [14]. EHCRSs must integrate meta-terminologies for EHCR items and sections (e.g. "patient history", "physical examination", ...) as well as terminologies for record content, more specifically the descriptive type of information. The terminologies used in a specific EHCRS must be formally organised, and used by a sufficient number of other systems, preferably all. The complexity of formal terminological systems probably will force EHCRS developers to integrate these specialised tools in their software instead of building them from scratch. Traditional nomenclatures and classification systems play only a secondary role in this picture as they have been designed for humans, and not for machines. Also the use of natural language processing software inside EHCRSs will become mandatory in the near future [15].

4.7 Knowledge coupling

Medicine is becoming too complex to be dealt with properly by individuals. To assist clinical decision making, EHCRSs should provide mechanisms for easy access to external information sources such as literature databases, drug interaction knowledge bases, systems for evidence based care, etc. Access should be initiated by data available in the EHCR such that queries (and subsequent answers) can be as precise as possible for the problem at hand. This of course can only be realised when the requirements with respect to communication, data entry and encoding are fulfilled. An additional requirement is speed, especially when these services are used during a patient encounter.

4.8 Safety, security and confidentiality

Data in the EHCR are so called "sensitive" and require adequate safety and security mechanisms in place. But in the same way as a lack of security mechanisms is a threat for healthcare telematics applications - including the use of EHCRSs - security maniacs are a threat for progress as well. There is a need for "reasonable" safety and security mechanisms in EHCRSs that don't interfere too much with the basic activities EHCRSs are designed for.

EHCRSs should provide non-cumbersome facilities related to access-control, data-availability and integrity, authentication and non-repudiation. Access and data-manipulation logging (based on username and password) is mandatory, especially in multi-user systems. It should be known (to authorised people) at all times who did what with the data. Manipulation logging allows easy detection of misuse of the system, be it on purpose (in which case legal actions can be taken) or involuntary (in which case this might be an indication that additional training in using the system is required).

Manipulation logging can also be used to inform patients on who accessed their data, hence being a useful mechanism to detect privacy violation. Also the right of the patient to have access to his data, must be taken into account when developing an EHCRS, as well as the user's right for privacy. Otherwise, the EHCR might end up to be an empty shell.

4.9 The multimedia patient record

As the EHCR is intended to be composed of different types of data, EHCRSs must be able to cope with multimedia data as well. This includes biophysical signals (EEG, cardiograms), still images (scanned documents, pictures, radiographs), video (endoscopy, holter readings) as sounds

(hart sounds, digitised voice). Generation of multimedia data requires specialised equipment that of course is not part of an EHCRS. The EHCRS should however be able to receive data from such devices. Multimodal viewers at the other hand do have to be seen as part of an EHCRS.

4.10 Conformance to standards

From 1990 to 1995, CEN/TC251 has been very active in the development of standards for healthcare informatics [16]. Real implementations of these standards in products available on the market, are however scarce. The issue of openness of systems makes many developers think in terms of competition rather than complementarity. They forget that one tenth of a big cake, can be much larger than half of a small one. We are convinced that good EHCRSs adhere to as many standards as possible. Better too many than too few. The lack of industrial interest should be compensated by user demands.

4.11 Functional criteria

Keeping electronic healthcare records is not the primary task of clinicians. EHCR manipulation should NOT take a substantial amount of the physicians working time. As a consequence, EHCRSs should be designed such that they fit in the physician's routine practice whether working alone or in team. Hence there is a need for work flow and cabinet automation, forcing an EHCRS to cope with tasks such as billing, accounting, medico-legal assessments, and planning. Whereas in large institutions these functionalities should come from dedicated systems interfaced with the EHCR, for GP systems, they should be integrated.

4.12 Developer related criteria

EHCR systems come not on their own, but are designed by people, hopefully happily collaborating in a trustworthy company. Purchasing a particular system should not only be based on quality criteria related to the actual system, but also related to the developer. Questions one must get answers on are f.i. the solvability and stability of the company. Is the system offered "plug and pray" or are services available for installation, hot-line support or training ? What is the installed base of the company ? Have they a policy for trial versions or limited-time demo's ? To what extent are they familiar with new technologies and do they participate in R&D en standardisation projects ? How is their QA organised and do they allow an escrow on system-critical entities such as the data-structures or sources of their product ?

5. Success criteria for criteria development

Criteria development for the EHCR or EHCRSs - how passionate discussions might be - are not a matter of religion. The various actors all have their own ideas, demands and requirements. Within one group of actors, e.g. vendors or users, it is even not simple to obtain consensus, let alone amongst different groups. The PROREC approach to this issue is both psychological and pragmatic, and based on the following principles: 1) think in terms of responsibilities instead of rights and interests, 2) accept the competence of others in their particular domain, 3) don't underestimate the own shortcomings in other actors' domains, 4) start with the development of criteria in areas where most competence is available, and 5) prefer win-win situations over zero-sum games.

Developing criteria for a European EHCR and European EHCRSs, should be a European endeavour. Many users (or buyers as in hospitals they might be different people) suffer from xenomania and the not-invented-here syndrome at the same time, two attitudes that are serious barriers towards the development of a European consensus in the domain of EHCR criteria. Nevertheless, Europe has quite a number of assets. Many Member States have a long standing tradition in high quality EHCR systems. Our multi-lingual and multi-cultural environment is a guarantee towards better understanding after harmonisation of view points. Quality instead of money is the main drive. Europeans cherish depth instead of superficiality.

6. Conclusion

In this paper, we discussed a number of issues that are to be considered when defining quality criteria for the electronic healthcare record and electronic healthcare record systems. For a few of them, we clearly indicated the direction in which options are to be taken. For others, this cannot be done without taking into account the specific environment in which the EHCR is going to be used. National differences amongst Member States at macro level, and the various ways in which individual clinicians operate at micro level, provide sufficient evidence to believe that never one single electronic healthcare record system will be able to dominate the market. But the dream of one Common European Electronic Healthcare Record (seen independent from a particular system) is more close than ever.

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