Quality certification of the medical information systems - An overview -

Simona Apostol
"Tibiscus" University of Timişoara, România
Cosmin-Ovidiu Câtu
"Victor Babeş" University of Medicine and Pharmacy, Timişoara, România
Mircea Focşa
"Victor Babeş" University of Medicine and Pharmacy, Timişoara , România

ABSTRACT. Resistance to change is something specifically human, being an easy thing to understand, but it has to be overcome now, and not as it happens, after generations. The certification process currently exists in many areas. Certification may be organized under different legal frameworks, it can be ensured by involving different types of organizations, public and private, but the common element remains the recognition of the key role it plays in the process of certification of quality assurance.
KEYWORDS: EHR - quality, certification, standards.

Introduction

The large volume of data and medical information, accessed and processed in real time, led to the development of numerous modern and efficient health systems characterized by a variety of types and degrees of structuring.

The importance the medical systems have within the medical information systems led both to their adoption in a relatively short time and to the development of standards and quality control methods designed to support this process.

The standards development in order to ensure the perfect interoperability of the EHR systems has led to the outline of some architectural models and interconnection methods which have finally resulted in a high level of market fragmentation.

It is this phenomenon that led to the introduction of certification, aiming to achieve standards gradually starting from developers and real possibilities and considering the functionality required by users.

The certification role is not to check compliance with standards in force but only deals with assessing the functionality of applications.

1 Why certified information systems?

In most European countries, electronic health records (EHR-Electronic Health Record) has increasingly become a central point for the national development strategies of medical informatics.

Storing and sharing medical data, in an increasing volume led to an interest for the development and adoption of interoperability standards.

Entering records in the database of patients is an act by which its authors are responsible for the actions they have taken, or not, in order to take care of the patient's health and are not the subject of a chaotic accumulation of data about them.

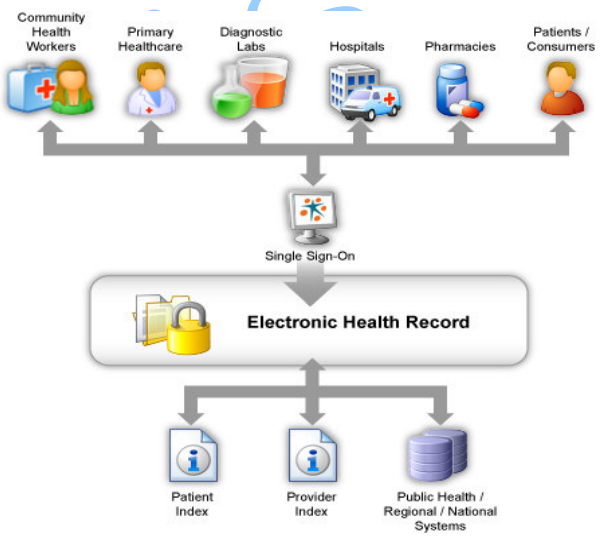

Figure 1. Integrating EHR into the medical data flow

The completeness and accessibility of the patients' health records for providing necessary information are crucial to the medical act. The electronic medical data record becomes a complex process involving a close relationship between the health systems and different influence factors

involved directly or indirectly in the EHR integration into the medical data and information flow.

The modern medical act requires the integration of modern medical information from multiple sources, the EHR representing the core to collect and to access the patient data in a distributed computing system.

An EHR system must not be prescriptive but, on the contrary, it must obtain an optimal balance between systematic / structured recording of data and the holistic nature of the described health phenomena. It should allow freedom of expression; ensure the structured interpretation of each entry, to be supported by a common terminology for expressing medical content.

A large number of such requirements are related to applications and systems that will retrieve medical data, will process them, providing the medical decision support, the alerts and the reminders, and will ultimately provide to the doctor integrated views or detailed medical data on the patient.

2 Issuing the set of requirements for the EHR certification

Worldwide, there are currently several methods for the EHR systems certification, each with advantages and disadvantages, both their objectives and their implementation policies are different, some are optional, others are compulsory with certain incentives for physicians using the certified systems.

The EHR quality certification systems have been implemented in several European countries, a very valuable model being the one developed in the U.S. by the CCHIT (Certification Commission for Healthcare Information Technology).

We should also mention the important role played by other organizations, the mechanism for testing the interoperability of EHR promoted in many countries of the world by the Organization for the Integration of the Industrial Products in the Healthcare system (IHE - Integrating the Healthcare Enterprise).

The IHE initiative comes from the developers of systems, by assessing the interoperability level the existing systems can provide, ultimately achieving the basis for the adoption of better EHR systems.

The adoption of the EHR systems in Romania remained somewhat behind the international developments, it is explained by the lack of both an adequate legal framework and financial mechanisms designed to encourage this process.

Another obstacle in the certification evolution is represented by both the poor quality of many of the implemented products and the lack of a mechanism providing the quality of the EHR systems implemented in Romania.

In an attempt to fill the gap, a number of European countries, including Romania, have already started to adopt schemes / certification requirements.

As in any other field, in e-health it is very important that the design of a computer system begins with establishing a complete set of requirements on the architecture of a future EHR system.

This set of requirements, must meet the users' needs on the one hand and, on the other hand, must comply with standards in force. The implementation of such HER systems designed to meet both the needs of users and developers is relevant to the certification model.

The first step in developing the European requirements for the EHR certification was the composition of a collection of nearly 1,400 requirements published in Belgium, Ireland, Denmark, UK and USA.

7 basic functions associated with the level of primary and outpatients' care have been defined; these requirements have been selected by the criterion of functionality.

Of the 1400 requirements only 188 were subjected to an analysis of compliance with the legislation in force.

Of these requirements, some have been grouped, others divided, some deleted or moved to another topic and others reformulated depending on the individual cases reported.

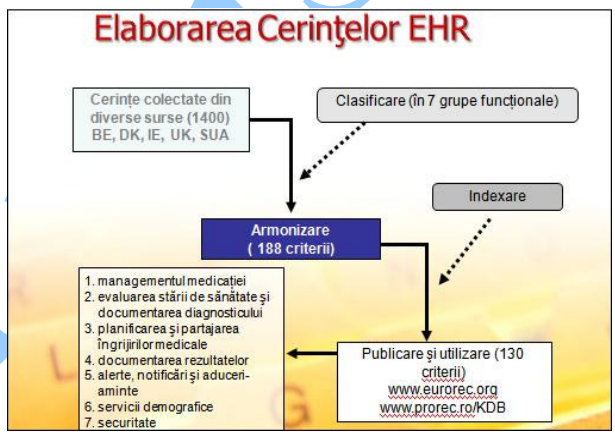

Figure 2. Issuing the EHR requirements

Finally, only 130 requirements were grouped into 63 topics, which cover the 7 categories of the functional criteria.

The initial set of criteria has been adjusted with requests from various other sources. Each requirement was decomposed to a minimum degree of granularity, thus obtaining the set of "granulated requirements", indexed and then translated into over 12 languages. By aggregating the granular

requirements "The best practice recommendations" have been defined behind the creation of unit test scripts of the European EHR systems quality.

The modern medical act requires the integration of modern medical information from multiple sources, the EHR representing the core to collect and to access the patient data in a distributed computing system.

3 Activities and projects aimed at certifying the quality of the EHR systems

In Romania, the quality certification process started by analyzing the internationally existing achievements, paying particular attention to certification models already successfully implemented in Belgium, Denmark and USA.

Following this analysis and in conjunction with Eurorec proposals to the implementation of a certification system unique in Europe, a Romanian certification pattern has been issued. Its validity remains to be tested in some pilot studies; the final model must receive the approval of the legal authorities and the support of the most developers and users of the EHR systems.

Both the framework analysis for the EHR systems and the definition of the requirements and the methodology of the ERH quality certification in our country were made in conjunction with the results of research conducted by the European project QRec.

The QRec Project

In 2004, under the EuroRec coordination, a consortium of ProRec centers in Europe was formed aiming to submit a proposal towards the European Commission to finance a project with specific support actions under FP6.

The project was signed in December 2005 and launched in January 2006.

We started from the experience of some countries (Belgium, Denmark, UK, Ireland, France ...) that several years ago began the assessment and / or certification process of the EHR systems, and especially of those for primary care.

But we noticed many differences in the stated aim of the legal framework under which they were operating, policies and organizations involved and perhaps most importantly, in terms of quality and compliance criteria used for evaluation.

These differences are beneficial to a point but also present a great risk, so efforts are needed to harmonize the certification mechanisms and means to avoid further fragmentation of the European market for the EHR products.

This is why Eurorec, together with the Prorec national centers began the QRec project for the development of a unique system of certification at the European level, starting from current achievements and taking into account the differences between different countries or cultures.

The major objective of QRec was to create a mechanism for certification of electronic files for Health system in Europe that can be effective, reliable and able to work using its own forces and resources.

By the QRec project, EuroRec made a "central repository" containing the 1400 "valid" quality criteria together with other relevant materials and developed a set of useful tools for harmonizing both the certification process, the products' documentation and the specifications' purchase for the EHR systems.

Eurorec does not intend to impose a particular pattern or specific criteria for certification; it only wants to promote through all the possible channels the progressive adoption of some consistent and comparable methods for assessing the quality of the EHR systems.

EuroRec can be considered a service provider for both the assessment and the certification of the EHR.

The EHR -QTN project

The EHR-QTN is a thematic type network project that aims to prepare the medical world all over Europe for a systematic and comparable assessment and certification of eHealth products, especially the Systems of Electronic Record of the Medical Data.

The project fits within the 1.6 draft of the second call for CIP-ICT PSP Programs: "Improving the Certification of the eHealth products" with particular reference to 'quality requirements set by EuroRec starting from the best practices. "

EuroRec provides a collection of quality criteria and instruments meant to facilitate a consistent approach on certification across Europe.

The project is part of Framework Programme 7 and promotes certification by organizing national conferences in 27 European countries, by the validation of the EuroRec functional criteria (1400 criteria), their translation in more than 20 European languages and by the validation of both the tools and the procedures for the EuroRec certification.

The beneficiaries of this project are presented in fig. 3.

Figure 3. The beneficiaries of the EHR-QTN

Actions of this project include:

- validate and adapt the EuroRec criteria in 25 countries (with emphasis on e-prescription and patient data summary)
- create the database with the most important organizations involved in the EHR (especially suppliers, including Small and Medium-Sized Enterprises (SMEs))
- inventory of the certification legal aspects
- organize annual workshops in all the 25 countries, addressing the following topics:
  - validation of both the EuroRec criteria and resources
  - tools developed by EuroRec for certifying, documenting and purchase the EHR systems
  - procedures for assessing and certifying the EHR systems

Conclusion

EHR systems certification:

- is a powerful confirmation mechanism that systems are robust enough to deliver the anticipated benefits.
- reduces the risk for buyers and thereby it accelerates the adoption of interoperable systems and higher quality.
- comes to fill the current gap between the potential developers and the users' requirements.

- must be applied gradually, gradually increasing pressure on developers

Buyers of the EHR systems (family doctors, hospital directors) have reported difficulties faced in assessing the quality of these products and their interoperability or data portability.

It is hoped that the implementation of the certification schemes would eventually lead both to increased quality of the medical care and to improve the quality of life.

Bibliography

[E+03] **M. Eichelberg, E. Poiseau, B. Wein and J. Riesmeier** – *IHE Europe: extending the IHE initiative to the European healthcare market. In Medical Imaging Imaging 2003: PACS and Integrated Medical Information Systems: Design and Evaluation. H. K. Huang and O. M. Ratib*, EDS.Vol. 5033. SPIE, 1—10, 2003

[Foc07] **M. Focşa** – *Certificarea calităţii Sistemelor de Evidenţă Electronică a Datelor Medicale*, Ed. Fokart, Timişoara, 2007

[ihe09] *http://www.rsna.org/informatics/ihe.cfm*, accesed December 2009

[ihe10] *http://www.ihe.net*, accesed February 2010

[pro10] *http://www.prorec.ro/EHRQTN.php*
http://www.prorec.ro/PDF/WQTN2009/P1%20Focsa%20EuroRec.pdf, accesed March 2010

[Rep05] *Report from the CEN/ISSS eHealth Standardization Focus Group Current and future standardization issues in the eHealth domain: Achieving interoperability*, 2005.

[Ro04] **A. Rossi Mori** – *Integrated clinical information systems: an essential resource – an opportunity for International cooperation*, Swiss Medical Informatics Journal, Spring 2004

[VM98] **J. H. Van Bemmel, M. A. Musen (Editors)** – *The Handbook of Medical Informatics*, Springer-Verlag, New York, 1998