The certification of the EHR systems according to EuroRec Seal

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ABSTRACT: As in any field, in the e-health domain it is very important that the designing of a computer system should start by establishing a complete set of requirements for the architecture of the future EHR system. The present study integrates the centralization of the results of the survey, following the debate with the representatives of the firms participating to the conference: "The Quality of the EHR Systems - the developers' vision".
KEYWORDS: E-health, interoperability, EuroRec Seal, certification criteria, EHR-Q^{TN}.

Introduction

Today, anywhere in the world, when acquiring a product, let it be software or any other product, it is important that it should have a certification, a warranty that the product meets the norms and the working standards .The national health authorities show currently great interest in improving the quality, the functionality and interoperability of the existing systems on the internal market, interest which led to the development of projects concerning their certification.

What is the certification and what is actually its use? The certification process involves the security, quality, equity and efficiency of the health services, thus the certification process is long and difficult and requires

perseverance. The certification involves not only testing the compliance with the existing standards, but it also gradually ensures the meeting of the functional and security requirements, therefore being a promoter of quality in the field. In this case, standards are only instruments for achieving intermediate goals.

The role of the certification should be that of a "filter" both for the potential buyers to identify their needs and requirements and for the vendors of EHR system to verify the systems they promote regarding meeting the quality requirements and planning further development. Today it is necessary that the certification problem should be solved for the medical information systems, which are quite numerous, although the market should be somehow "filtered" and tested by an organization accredited to "give a license" to these products. E-health represents an area where the need for quality certification is becoming more apparent.

There are a number of e-health projects such as: the electronic settlement of accounts, the electronic prescription, and the projects concerning the disease and care processes management, the simplification of administrative tasks, the interactions with validated databases, and more of this kind, which become dependent on certification. For the healthcare professionals it is difficult to define their own expectations regarding an information system and to implement them and, therefore, when they want to purchase such a system they prefer to rely on the quality label of these products. On the other hand, computer systems suppliers need, when implementing such a system, all the data provided by doctors so that their application should accurately meet the users' requirements.

It is highly unlikely that a developer no matter how professional he might be should implement in a short time all the applicable standards so that they should remain as a point of reference for the sustainable development of EHR systems. This is the role of the EHR quality certification: to fill in the gap between what is expected from EHR systems and what developers are currently able to provide.

1. The EHR-QTN Project

As in any other field, in the e-health area it is also very important that the designing of an information system should begin by establishing a complete set of architectural requirements for the future EHR system. This set of requirements must meet the users' needs on the one hand, and on the other

hand, it must comply with the standards. The implementation of such EHR systems designed to meet both the users and developers' needs represents the practical relevance of the certification model. There are currently various certification systems of the EHR systems, an example of a very good system, yet rigid, is the American one, while in Europe the certification systems from Belgium and Denmark make good examples, each having, however, advantages and disadvantages. Starting from these certification systems, other countries have tried to model such certification systems.

The EuroRec Institute, whose main purpose is to promote the use of high quality Electronic Health Record Systems throughout Europe, provides a collection of quality criteria and instruments to facilitate a consistent approach regarding the certification across Europe. Yet, a set of decision factors remains difficult to achieve.

One of the projects in progress at the EuroRec institute aiming the medical computer systems certification is the EHR-Q^{TN} project.

EHR-Q^{TN} is a type of thematic network project and its main goals is to instruct the medical world all over Europe regarding a systematic and comparable assessment and certification approach of the e-Health products, especially of the Electronic Health Record Systems. This project promotes the certification by organizing national symposia in 27 European countries, by validating the EuroRec functional criteria (approximately 1400 criteria) by translating them into over 20 European languages and by validating the instruments and procedures for the EuroRec certification.

The beneficiaries of this project can be seen in the image below:

Figure 1. The beneficiaries of EHR-QTN

Two reports will be generated during the project:

The first report is a market study for each of the participating countries. The study will provide as complete information as possible about the EHR systems on the market and about the users' associations and the authorities that are possibly involved in promoting the EHR certification.

The second report should document the possible ways to support the certification, regardless of the used method, when requested by the providers, by the authorities or even transnational.

The main goal of the project is to prepare the medical world across Europe for a systematic and comparable assessment and certification approach of the e-Health products regarding actions such as:

- validating and adapting the EuroRec criteria in 27 countries (with emphasis on e-prescription and on the patient's data summary).
- creating the database with the most important organizations involved in the EHR domain (especially providers, including SMEs).
- the inventory of legal issues concerning certification.
- organizing annual international conferences EHR-Q^{TN}
- organizing annual workshops in all 27 countries.

The annual workshops held in the 27 countries involved in the project met the following objectives:

- validating the EuroRec criteria and resources.
- the instruments developed by EuroRec for certifying, documenting and purchasing the EHR systems.
- the procedures for assessing and certifying the EHR systems.

2. The EuroRec Seal 2008-2009

Romania is included among the countries participating in EHR-QTN project as an active member due to the Association ProRec Romania - Romanian Association for the Electronic Health Record Systems.

The first annual workshop in Romania planned in the EHR-Q^{TN} project took place on December 2009 in Bucharest. On this occasion a number of technical, economic and legal issues regarding the development of EHR systems in Romania were analyzed. It was also examined the compliance degree of the Romanian systems with new European quality criteria. The EuroRec Institute made suggestion regarding the new EuroRec Seal Certificates 2010 -2011. The 20 certification criteria of EuroRec Seal 2008-2009 were discussed and submitted to vote. The event was attended by

representatives of the EuroRec Institute, the European Federation for Medical Informatics, Ministry of Health, National Health Insurance House, and the College of Physicians of Romania, the Association for Information Technology and Communications of Romania, the Romanian Medical Association, Association of HL7 and by developers of medical software. The 20 EuroRec 2008-2009 criteria approach generic problems mainly concerning the reliability and credibility of the applications independently of the sanitary organizational environment, being accessible on line. The content of the EuroRec Seal 2008-2009 addresses generic issues such as credibility, reliability, the versions management, confidentiality, access control, the input and displaying of data, all representing a minimal common set of quality criteria, selected by experts, criteria that must be met to obtain the proof of EuroRec quality.

The EuroRec warranty does not define the "best" EHR system and has no ambition to be fully considered; additionally to the common set of criteria other criteria specific to a certain region may be added. 125 candidate criteria (of 1500) were selected, expanding the application domain to recording and displaying the data as well as to managing the access and the authentication.

In the interactive workshop held in Bucharest, the representatives of the participating companies have proposed to debate the issues presented in the table below.

The following table represents the form containing the 20 criteria and related comments that the respondents have mentioned. The voting of the criteria was done according to the importance given by the participants to each criterion. Each participant gave a score between 1 (unimportant) to 5 (extremely important) to each criterion in the survey. The italic statements are no longer included in the new set of criteria EuroRec Seal 2010-2011.

Table 1. EuroRec Seal 2008-2009

ID	Trek ID	Statement regarding the quality functional criterion
1	**GS001537.1**	Each version of a health item has a date and time of registration.
Comment		Which is the acceptable delay?
2	**GS001538.1**	Each version of a health item has a user responsible for the effective data entry identified.
3	**GS001539.1**	Each update of a health item results in a new version of that health item.

ID	Trek ID	Statement regarding the quality functional criterion
Comment		Are all these versions displayable for the user or just for the audit? The last version and a log of the modifications can be kept.
4	**GS001579.2**	Each version of a health item has a status of activity, e.g. active or current, inactive, history or past, completed, discontinued, archived.
Comment		Note: To allow the own defined statuses, not necessarily It would be valuable a standard regarding the semantics of the states for interoperability.
5	**GS001593.2**	Deletion of a health item results in a new version of that health item with a status "deleted".
Comment		It is not compulsory to display the deleted information together with the valid one. Idem 15391. The deletion of the medical information should not be allowed.
6	**GS001594.2**	Each version of a health item has a person responsible for the content of that version. The person responsible for the content can be a user or a third party.
Comment		The responsibility for the content should be the generator of the information.
7	**GS001598.1**	A complete history of the version of a health item can be presented.
8	**GS001901.1**	Each version of a health item has a date of validity.
	Comment	It is not quite clear what it means. The semantics of the “date of validity” is not clear.
9	**GS001945.1**	*The system enables the user to designate individual health items as confidential.*
10	**GS002265.1**	Each health item is uniquely and persistently associated with an identified patient.
11	**GS002266.1**	Each version of a health item is uniquely and persistently identified.
12	**GS002268.1**	Each user is uniquely and persistently identified.
13	**GS002269.1**	The system enables to assign different access rights to a health item (read, write, ...) considering the degree of confidentiality.
14	**GS002281.1**	All patient data can be accessed directly from the patient record.

ID	Trek ID	Statement regarding the quality functional criterion
Comment		Just those having the access right.
15	**GS002307.1**	Each patient and its EHR are uniquely and persistently identified within the system.
16	**GS002415.1**	The system takes the access rights into account when granting access to health items, considering the role of the care provider towards the patient
Comment		Differentiated according to role and politics.
17	**GS002437.3**	The system offers to all the users nationally approved coding lists to assist the structured and coded registration of health items.
18	**GS002672.3**	*The pick lists and reference tables offered by the system are the same for all the users of the same application.*
Comment		It is not ergonomic. The users have the same role.
19	**GS003952.1**	The system does not display deleted health items, audit logs excepted.
Comment		-not interesting
20	**GS003953.1**	*The system does not include deleted health items in clinical documentation or export, for audit purposes excepted.*

The choices expressed by the participants were centralized throughout the event. In the end, during the second session of the workshop "The Quality of EHR- systems – the developers' vision, each criterion was discussed / reviewed. A top of the importance degree of these criteria was displayed using online applications. The graph below represents a top of criteria according to the importance degrees voted by the participants. On the axis OX, there are the 20 criteria and on the axis OY there are results selected according to the significance given by those surveyed.

Minimum scores:

A single statement was voted by those who were in the room with first degree of importance, namely:

- *"Each version of an item of health information has a life time."*

The low importance given to this criterion can be attributed to its ambiguous formulation, the participants arguing that the data registered must remain valid throughout the lifetime of the system. The validity of a

version refers to the mechanism of data versions, as a modification of a data leads to a new version and thus limiting its life.

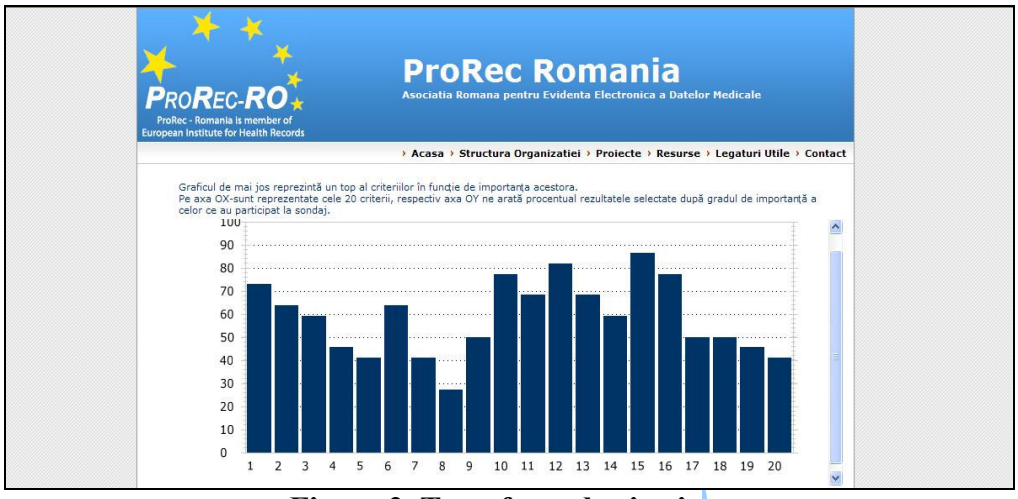

Figure 2. Top of voted criteria

Maximum scores:

All these requirements are found in the set of requirements of 2008 and they represent essential requirements, considered as very important by the participants to the event.

The statements considered by most participants as very important are:

- *"Each version of a medical data is associated with the date and time of registration."*
- *"Each medical information is uniquely associated with a particular patient and persistent."*
- *"Each user is identified uniquely and persistently."*
- *"In the system, each patient and his health report (EHR) are uniquely and persistently identified."*
- *"The system allows access to medical information according to the access rights associated to it, taking into consideration the role of the medical personnel regarding the patient care."*

The warranty 2010-2011 is not specific to a certain organizational sanitary environment; the voting form was distributed to the members of the EHR-QTN (consortium from 25 countries, mainly the ProRec center) and the Web form was distributed to be filled in by "the experts".

Conclusions

- All the participants agreed that these meetings between the developers and users of EHR systems are effective and represent the key to success in implementing efficient EHR systems.
- The transparency of the certification process and the precise determination of the organizations involved in this process are very important.
- It is aimed to exactly establish what a certification involves both nationally and internationally.
- It was found that in Romania the legislative framework is very permissive but poor in specific regulations on EHR systems. Eurorec Seal was seen as a good substitute for the official recognition of this mechanism of EHR systems quality certification.
- The harmonization at the functional level is crucial for the interoperability in data sharing, aiming the data export as the top function of the applications as well as the data interchange, which is a first step, but not the final solution of "the harmonization" of systems.
- EuroRec guarantee represents a good first step towards interoperability by harmonizing the applications.
- There is no contradiction between the activities of HL7, IHE and EuroRec, as they are in fact complementary.
- CCHIT does / coordinates effectively the entire process of:
  - defining requirements.
  - providing the instruments and scenarios to test the compliance.
  - making the tests.
  - issuing the certificates.
- It is very important that the authorities involved in the health field should be active in establishing the standards and criteria for certification.
- EuroRec remains an "independent" organization; the defined quality criteria represent neutral statements having the status of recommendation.

EHR system developers and users have shown interest in applying EuroRec Quality Seal 2010-2011.

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