Collaborative Patient Centred eHealth
E. De Clercq et al. (Eds.)
IOS Press, 2008

doi:10.3233/978-1-58603-922-6-82

Certification of Electronic Health Record systems and the Importance of the Validation of Clinical Archetypes

Georges DE MOOR [a], Dipak KALRA [b], Jos DEVLIES [c]
[a] *Dept. of Medical Informatics and Statistics, Ghent University, Ghent*
[b] *CHIME, University College, London*
[c] *The EuroRec Institute, Ghent*

Abstract. If Electronic Health Record (EHR) systems are to provide an effective contribution to healthcare across Europe, a set of benchmarks need to be set to ensure the quality of such systems. This article describes the results of the EU funded QRec- project and emphasizes the need for validation of clinical archetypes to support the semantic interoperability between EHR systems and other interacting eHealth applications.

Keywords: Electronic Health Record, Quality, Certification, Clinical Archetypes

1. Introduction

ICT has the potential to make a significant contribution to the better management of healthcare provision. This cannot be achieved without the availability of trustworthy Electronic Health Record systems (EHRs) that provide all necessary clinical information requirements thus enabling the sharing of timely and up-to-date patients' medical data to support "high quality care" and "continuity of care". Interoperability and security to protect the privacy of persons and the confidentiality of patients' data are also prime requirements for such EHRs.

The EuroRec Institute is a not for profit organization (http://www.eurorec.org) promoting the development and use of high quality EHR systems. One of its main missions is to support the development of EHR systems quality labeling and certification.

EuroRec is organized as a permanent network of National ProRec centers in Europe and is liaising at international level with other bodies such as CEN/BT and CEN/TC251, ISO/TC215, WHO, openEHR, HIMSS, CCHIT and Canada Info Highways.

The EuroRec Institute provides services to the following types of stakeholders: industry (the developers and vendors), healthcare providers, (the buyers), health care authorities and policy makers, and patients.

2. The Rationale for the QRec-Project and for Quality Labeling and EHR systems' Certification in General

Investment in healthcare ICT has been comparatively low compared with other sectors. High investment risk for purchasers and low definition of European market requirements for suppliers has contributed to this. This is particularly the case for large-scale investment for electronic health record systems at regional or national levels.

Given the increasing complexity of EHR systems requirements and the risk of system deficiencies or failure to meet expectations, there is a need for an assessment process to assure the quality (cf. safety and privacy issues) of EHRs on the market and to ensure their interoperability with other systems. Without an agreed set of functional criteria to underpin the introduction of robust and sustainable EHRs, major ICT investments are potentially at risk.

Given a set of quality criteria around which suppliers and their healthcare customers can collaborate openly, the introduction of effective EHR solutions across European member state boundaries becomes a reality.

Several EU member states have already proceeded with EHR systems quality labeling and/or certification, but these attempts differ in scope, in legal framework under which they operate, in policies (legal and financial incentives), in organization and perhaps most importantly in the quality criteria used for benchmarking. Harmonization therefore appears to be a must.

EuroRec's "QRec" Specific Support Action (IST-27370-SSA, 2006-2008) has therefore addressed both the certification criteria and the certification procedures. EuroRec and partners have developed formal methods and created the mechanisms for the quality labeling and certification of EHR systems hereby focusing in a first stage on primary and acute hospital-care settings [1]. The longer term strategy is to encompass in a later stage also other eHealth software products and services (in particular decision support systems and other modules that interact with EHR systems) [2;3].

3. The QRec Deliverables

The QRec project ended June 2008 and has delivered:

- A first series of validated, fully indexed and translated (in 12 languages) quality criteria and functional requirements (+ 1500) for EHR systems;
- A typology of indexes : business functions ((50 in 8 subcategories), care settings (18 in 3 subcategories) and component types (18 in 4 subcategories);
- A quality assurance approach of EHR archetypes (i.e. formal sharable models of clinical domain concepts; cf. openEHR/EN 13606 archetypes, see further) for enabling the semantic interoperability in e-Health;
- A repository of European and International coding systems in use for EHRs, as well as an inventory of EHRs related international standards;
- Test scenarios and proposed certification mechanisms enabling both self-certification (e.g. by the industry itself) and external certification (e.g. by health care authorities or other recognized bodies);

A series of tools (the EuroRec Composer, Certifier, Documenter, Procurer and Scripter) for profiling EHRs for national certification processes, for product documentation or for procurement purposes (see figure 1).

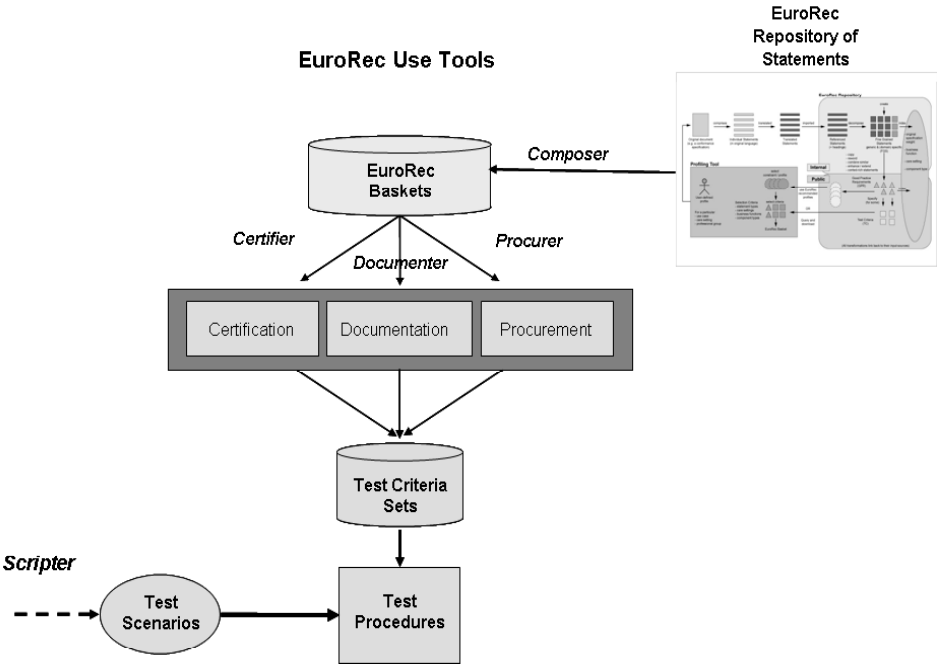

Figure 1: The EuroRec Use Tools

The different use tools can be described as follows:

The Q-REC ***Composer*™** enables the licensee to select the required criteria (the EuroRec Fine Grained Statements), to create a "QRec basket" to be used in a certification session, in product documentation or in a procurement document.

The Q-REC ***Certifier*™** enables the licensee to structure the selected Fine Grained Statements (of a Q-REC Basket) by completing them with aspects of importance within the given certification context (e.g. criteria to be considered as mandatory versus optional).

The Q-REC ***Scripter*™** enables the licensee to write scenarios for a given certification or procurement. Each of the scenarios is linked with the Fine Grained Statements of relevance.

The Q-REC ***Documenter*™** enables the licensee to select and structure Fine Grained Statements of (a Q-REC Basket) in a way that they can integrated in product documentation (and hereby using more standardised descriptive statements).

The Q-REC ***Procurer*™** enables the licensee to structure the selected Fine Grained Statements (of a Q-REC Basket) by completing them with aspects of importance within the given procurement context and with other information enabling the correct interpretation of the procurement.

4. Semantic Interoperability and Clinical Archetypes

Considering the importance of semantic interoperability in eHealth, one of EuroRec's further activities will be to play a role in the validation of clinical archetypes. The following part therefore introduces and illustrates clinical archetypes.

Clinical archetypes are a formal, rigorous and standardised (interoperable) specification for an agreed consensus or best practice representation of clinical data structures (within an electronic health record) [4]. They provide a standardised way of specifying EHR clinical data hierarchies and the kinds of data values that may be stored within each kind of entry. An archetype defines (or constrains) relationships between data values within an EHR data structure, expressed as algorithms, formulae or rules. An archetype may logically include other archetypes, and may be a specialization of another archetype. In order for it to be managed and used appropriately, its metadata needs to define its core concept, purpose and use, evidence basis, authorship, versioning and maintenance information.

Figure 2 shows an example of the content of an archetype. This illustrates a hierarchical data structure representing the components of the documentation of an adverse reaction, usually to medication. Each line represents a data item that may be entered within a patient's EHR to document one allergy. The main data items are the therapeutic agent (e.g. penicillin) and its category (e.g. penicillins). Additional details are provided using the subsequent items, such as the details of the reaction and how certain the observer is that the reaction has indeed been caused by the drug. For each node in the archetype hierarchy the icon adjacent to the name indicates the data type of the patient-specific value: textual, coded, date or time, quantity etc. When authoring an archetype, additional details need to be provided about each node such as the number of occurrences that are permitted within instances of EHR data, the terminology values that may be used, numeric ranges and measurement units. This archetype therefore defines the "shape" within an EHR for representing adverse reactions, and thereby offers some predictability to any application or system component that needs to query EHR data to obtain adverse reaction information.

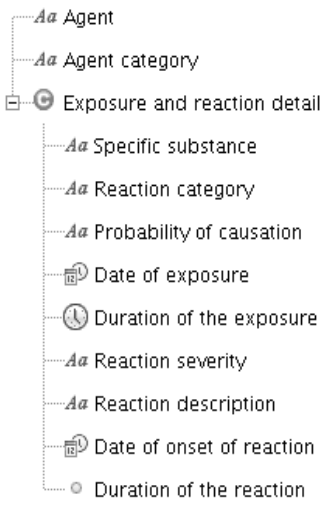

Figure 2: Schematic diagram of an archetype for adverse reaction (to medication)

The requirement for clinical teams to share patient record information to support longitudinal continuing care and to follow multi-professional care pathways is well recognised [5;6]. Delivering shared regional or national Electronic Health Records is now central to every e-Health programme. It is also recognised that the support of shared care through records that are only human readable is not sufficient: patient safety management and the pursuit of evidence based care require computable information that can be linked to and queried by alerting components, decision support and clinical pathway systems [7-11]. The efficient management of health services and the support of public health and clinical research through audits and population analyses also require EHRs that can semantically be processed. All these purposes of use ideally require that the clinical findings within EHRs are represented and organised consistently across vendor products and communities of use: semantic interoperability [12].

Two methods to support semantic interoperability for electronic health records are available today: messages and archetypes/templates.

Messages

An older way to support semantic interoperability is the use of messages.

It is a characteristic of messages (EDIFACT, DICOM, HL7v2, HL7v3) that in one message specification (message standard) several viewpoints are defined rather than just one:

- Enterprise viewpoint will contain the use case, i.e. the standardised work process;
- Information viewpoint contains the Message Information Model;
- Computational viewpoint is about the choreography of messages in the interaction schemas;
- Engineering viewpoint is the level where the XML schema is defined.

In any message specification changes can occur at any or all layers. Work processes change, new data elements need to be stored or exchanged, new interfaces are needed, etc. Even the smallest change will lead to a new version of the message. Since the implementation of messages in all EHR-systems in a uniform way (e.g. via the IHE process) is time and money consuming, it is clear that messages do not facilitate innovation because the flexibility and adaptability of this technology is poor, which has historically defended the case for an architectural approach to representing the electronic health record [13-16].

Archetypes/Templates based on ISO EN13606 and openEHR

In healthcare, archetypes and templates express the requirements from the Enterprise viewpoint level as constraints on the Reference Model. The Reference Model of the EN13606/*open*EHR is not the same as the Reference Information Model of HL7 and is a very generic model of any health record or document [17]. The resulting collection of defined archetypes and templates constitute the Information Viewpoint.

The European standard EN13606 defines how archetypes and templates are produced in a standardised way. Therefore the European EHR-standard is operative on the Information Viewpoint level only. *open*EHR has extended the European EHR-standard to the Computational Viewpoint so that EN13606 conformant EHR-systems become possible (other standards will govern the other ODP layers).

Archetypes and templates can play a key role in semantic interoperability [18]. Archetypes define what is maximally documented in the world about a specific health record entity. Templates define what in a specific context at a specific point in time, will be stored, retrieved, presented, exchanged and archived. In part, clinical meaning within an EHR will be expressed through the structure of the archetype/template, and in part the meaning will be expressed through codes from coding systems. A way to view this metaphorically is:

- codes are the words in a dictionary;
- the structure of the archetype/template is the grammar;
- with both codes and archetypes sentences can be formed that make or do not make sense;
- but archetypes define what makes sense;
- and templates define what makes sense in a specific context.

In the case of EN13606/*open*EHR archetypes provide a lot of flexibility and adaptability. Using archetypes, healthcare providers can define and re-define at any moment templates that are needed in their work process at that point in time. Systems based on archetypes and templates support easy customization and localization, and rapid evolution to meet new clinical requirements [19].

Clinical archetypes are thus a knowledge representation that defines the way in which an EHR Reference Model is to be applied to represent particular clinical entities (i.e. particular kinds of finding, assessment, hypothesis, plan or intervention). An archetype defines a data structure, including optionality and multiplicity, data value constraints, and relevant bindings to natural language and terminology systems.

Figure 3 shows an example of an archetype for adverse reaction to medication, authored using an archetype editor developed by the University of Linköping in Sweden (this editor is available as open source software from openEHR) (http://www.openehr.org).

This figure shows, in the main central panel, a hierarchical data structure that represents the components of the documentation of an adverse reaction, for example the type of reaction and its severity. The drug to which this reaction arises is represented within a cluster called “Administration information” (not expanded in this screen shot). For each node in the hierarchy the icon used indicates the data type of the patient-specific value: textual, coded, date or time, quantity etc. The right hand panes show (upper pane) the number of occurrences that are permitted within instances of EHR data and, for coded entries (lower pane), the terminology values that may be used. Other panes (not shown) permit other constraints to be applied such as numeric ranges and measurement units.

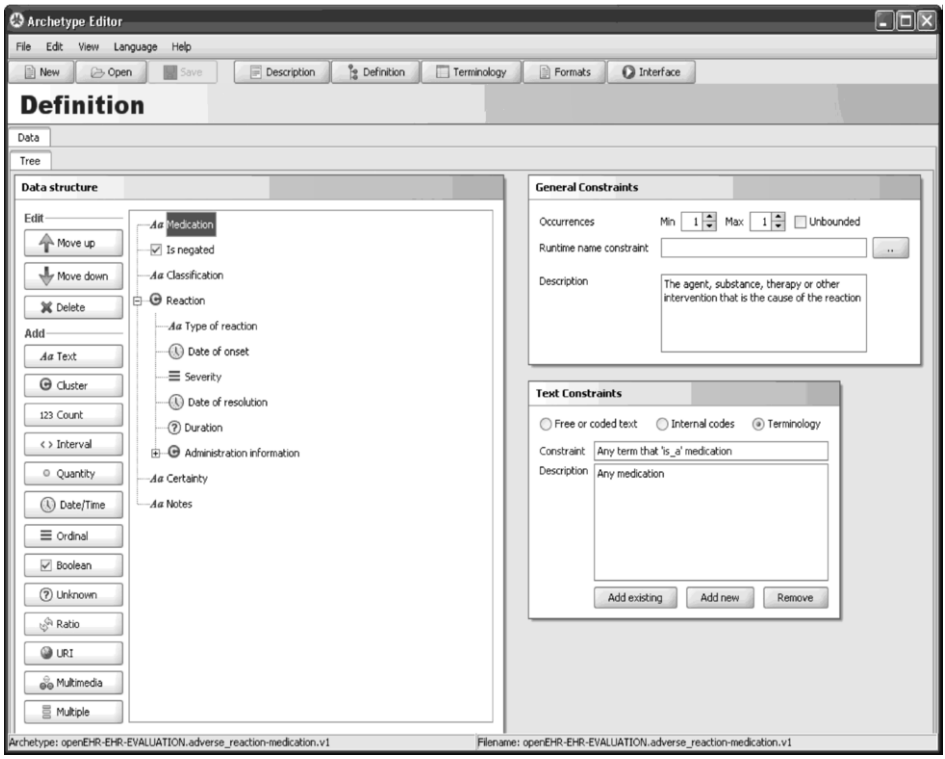

Figure 3: Example screen showing the main portion of an archetype for adverse reaction (to medication)

5. Validation of Clinical Archetypes

To support semantic interoperability clinical archetypes need to be shared and used consistently by EHR system vendors and their users, so that the EHR data they create is consistently organised [20]. Archetypes therefore need to be shared and managed as a common knowledge asset, and incorporated into the design of clinical applications, rather like a terminology system. Many of the formalisms and tools needed for archetypes to be a global resource are now in place.

One notable challenge in designing libraries of archetypes to meet broad areas of clinical practice, for example to cover the complete clinical information needs of a speciality or professional discipline, is to ensure that archetypes are evidence based or meet *de facto* agreed clinical needs (e.g. established by consensus, or reflecting existing practice). Given that many archetypes may be needed to cover a given domain, it is also important for them to be mutually consistent and bind to terminology systems in appropriate and consistent ways. This is necessary in order to minimise the diversity of ways in which a given kind of EHR data might be represented.

The authors therefore believe that clinical archetypes need to be quality assured, since they will direct the ways in which clinical data are captured, processed and communicated. It is important that the design of individual archetypes is an accurate and faithful reflection of good practice for the clinical disciplines in which each of them might be used. They need to be optimally designed for their purpose, and

considered trustworthy within their intended communities of use. This requires not only sound methodologies for designing each archetype in accordance with, for example, published clinical guidelines or peer consensus, but rigorous and robust processes for validating any given archetype against its clinical evidence base and in the context of other archetypes alongside which it might be used. Pan-European (or international) applicability will be an increasingly-important requirement for good quality archetypes.

If record-sharing communities are to construct safe EHR instances in accordance with archetypes, and to trust EHR data conforming to archetypes, a formal process of verification and certification is needed for archetypes that provide assurance of their suitability and safety. The EuroRec Institute is partnering the *open*EHR Foundation in developing governance practices for archetype development, and the quality criteria and editorial policies by which certified libraries of archetypes can be recognised.

As part of the quality labelling and certification of EHR-systems, it may take joint responsibility for the governance of archetypes and templates alongside the *open*EHR Foundation, since these artefacts play an extremely important role in semantic interoperability in Europe. EuroRec is starting discussions with bodies like the Commission, CEN/TC251, ISO/TC215 and *open*EHR in order to create a framework where all can become responsible for a defined aspect in their natural roles.

6. EuroRec's Future Plans

The EuroRec Institute has expressed its ambition to become a European Agency responsible for the Certification of EHR systems and for semantic interoperability for related eHealth applications. It therefore will continue to invest in the future**:**

- by maintaining and enriching its central repository of validated certification criteria;
- in the study of the quality criteria related to the secondary use of EHRs as potential e-sources for e.g. e-Clinical Trials and other e-Research;
- by investigating the certification of EHRs in other care settings (e.g. e-homecare and personal health records);
- in the validation of clinical archetypes.

As the barriers between the different types of Electronic Health Record systems and other eHealth related applications are fading away, EuroRec also intends to broaden its future scope of work to the quality labeling of other types of eHealth systems, including e.g. Decision Support Systems: good clinical care needs the combination of health records and medical knowledge [21;22].

7. Conclusions

The time has arrived to go one step further and to pilot and implement in Europe (including in the Eastern European Member States) the EHRs quality labeling and certification process – in compliance – with the 'good practice requirements' elaborated by EuroRec. A number of Member States (already certifying at their own national level) are also demanding to join in a more European wide effort. All this

could start through piloting and implementing the EuroRec solutions (e.g. through the objective 6.2 of the CIP programme in FP7).

There is also widespread and world-wide recognition that a formalised and scalable means of defining and sharing clinical data structures is needed to achieve the value of investment in e-Health. Clinical archetypes are gaining acceptance as the best of breed and best supported approach for defining these structures, reflected in its international standardization [4;23].

Large and comprehensive sets of archetypes are needed that cover whole clinical domains in a systematic and inclusive way, catering for the inevitable diversity of use cases and users but helping to foster consensus and best practice. For these to be endorsed by health systems, implemented by vendors and trusted by end users, these archetypes need to be quality assured and to be published and maintained by reliable certified sources.

References

[1] De Moor GJE. Improving the Quality of Health Record Systems. eStrategies Projects. British Publishers. 2007; 28-29
[2] De Moor GJE. Certification of Electronic Health Record Systems in Europe. European Parliament Magazine. 2008; 109-110
[3] De Moor GJE. Improving EHR Systems through Quality Labeling. Healthcare IT Management. 2008; Vol 3; Issue 2; 29-30
[4] International Standards Organization ISO/EN 13606
[5] Dodd W. and Fortune J. An electronic patient record project in the United Kingdom: can it succeed? Greenes, R. A. and others, eds. Medinfo 8. 1995; 301-304
[6] Vari S.G., Brugal G., Godo F., Bercic B., Nagy G., Avar G., Adelh D., and Lagouarde P. Regional and international integrated telemedicine network for organ transplant (HC 4028 & IN 4028 European Commission DGXIII). Proceedings / AMIA Annual Symposium. 2000; 873-7
[7] Bates D.W., Cohen M., Leape L.L., Overhage J.M., Shabot M.M., and Sheridan T. Reducing the frequency of errors in medicine using information technology. J Am Med Inform Assoc. Jul 2001-Aug 2001; 8(4):299-308
[8] Weed L.L. Clinical judgment revisited. Methods of Information in Medicine. Dec 1999; 38:279-86
[9] Straus S.E. and Sackett D.L. Using research findings in clinical practice. BMJ. Aug 1998; 317(7154):339-42
[10] Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Volk L, Spurr C, Khorasani R, Tanasijevic M, Middleton B. Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality. J Am Med Inform Assoc 2003, 10: 523-530
[11] O'Connell R, Poljak A, Powsner S. Forms that Inform. Methods of Information in Medicine 2004; 43: 247-255
[12] Lewalle P, Rodrigues J, Zanstra P, Ustun B, Kalra D, Surjan G, Rector A, Stroetmann V, Virtanen M. A deployment and research roadmap for semantic interoperability: the EU SemanticHEALTH project. In Andersen S, Klein G, Schultz S, Arts J, Mazzoleni C. eHealth Beyond the Horizon – Get IT There - Proceedings of MIE2008. Studies in Health Technology and Informatics, Volume 136: 635 - 640. IOS Press, Amsterdam, 2008. ISBN 978-1-58603-864-9
[13] McDonald C.J., Overhage J.M., Dexter P., Takesue B., and Suico J.G. What is done, what is needed and what is realistic to expect from medical informatics standards. International Journal of Medical Informatics. Feb 1998; 48(1-3):5-12
[14] Shortliffe E.H. The evolution of health-care records in the era of the Internet. Medinfo 9. 1998; 1 Suppl:8-14
[15] Dolin R.H. Outcome analysis: considerations for an electronic health record. MD Computing. Jan 1997-Feb 1997; 14(1):50-6
[16] Dudeck J. Aspects of implementing and harmonizing healthcare communication standards. International Journal of Medical Informatics. Feb 1998; 48(1-3):163-71
[17] Kalra D. Electronic Health Record standards. Methods of Information in Medicine 2006; 45 Suppl 1: S136-44

[18] Kalra D, Blobel B. Semantic Interoperability of EHR Systems. In Bos L, Blobel B (eds) Medical and Care Compunetics 4. Studies in Health Technology and Informatics, Volume 127: 231 - 245. IOS Press, Amsterdam, 2007. ISBN 978-1-58603-751-2
[19] Beale T. Archetypes Constraint-based Domain Models for Future- proof Information Systems. The openEHR Foundation 2001. Available from: http://www.openehr.org/publications/archetypes/archetypes_beale_web_2000.pdf (Last accessed August 2008)
[20] Kalra D, Tapuria A, Freriks G, Mennerat F, Devlies J. Management and maintenance policies for EHR interoperability resources. Q-REC Project no. IST 027370, Deliverable 3.3. The European Commission, Brussels, 2008. [36 pages]
[21] Kalra D. Clinical foundations and information architecture for the implementation of a federated health record service. PhD Thesis. Univ. London. 2003
[22] Kalra D. Barriers, approaches and research priorities for semantic interoperability in support of clinical care. SemanticHealth Project no. IST 027328, Deliverable 4.1. The European Commission, Brussels, 2007. [33 pages]
[23] Kalra D, Lloyd D. ISO 13606 Electronic Health Record Communication Part 1: Reference Model. ISO TC/215, Geneva. 2008. [99 pages]