

„The“ Electronic Health Record: Standardization and Implementation

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1 Introduction

Electronic patient record systems (EPRS) are doubtless a key component of every institutional healthcare information system (HCIS). With their capability of storing patient related data concerning patient related facts like problems, diagnoses, illness history etc. together with data concerning medical activities and their results like “Medical treatment planning by Dr. X: treatment plan” or “Taking an ECG by Dr. Y: ECG” EPRS are a central means of documentation, information exchange and collaboration in a modern healthcare organization. Like EPRS for HCIS, electronic health record systems (EHRS) are a key component of current and coming health telematic platforms. EHRS are a means for exchanging health data concerning an individual person between communication partners within the healthcare sector controlled by the individuals the communicated data are belonging to. EHRS are integrating EPRS of healthcare organisations as well as the personal health record of the person itself including for example illness related diary entries. The objectives of an EHRS are diverse, but as for EPRS the main objective is clearly to support the treatment of patients by provision of information needed for decisions by health care professionals.

Problems concerning the introduction of EHRS as a part of a regional, nationwide or at best worldwide health telematic platform are diverse and so “the” EHRS does not exist yet. The major problem is the huge amount of different proprietary or standardized interfaces information systems to be potentially integrated today are using: message or interface standards like HL 7, EDIFACT, DICOM, rather content oriented standards like LOINC, ICD-10, ICPM or hybrid approaches like CEN 13606, openEHR to name but a few.

Standards are the key for a successful implementation of any EHRS. Four layers of standardization can be recognized. The content layer and the structure layer both are concerned with the standardization of the elements of an EHR, that are meant to be exchanged between communication partners. The content layer addresses aspects of coding the content of EHR-Element using terminological systems like classifications or controlled vocabularies. The structure layer focuses on regulations concerning the structure of communicated EHR-Elements,

e.g. XML-files following corresponding DTDs or XML-Schemes. The border between structure and content layer is often blurred, because several content oriented aspects of e.g. a discharge letter are usually modelled by defining its structure. The two remaining layers are the technological and the organizational layer.

The technological layer contains regulations concerning aspects like software and hardware components, distribution, objects and services, the PKI etc. The organizational layer focuses on organizational changes caused by the usage of an EHRS: business processes, guidelines, protocols, roles, PKI etc.

Organizational and technological regulations are even more dependent on national strategies as regulations on the structural or content layer and therefore the rest of the paper deals with standardization activities concerned mainly with the structural and the content layer.

2 Standardization

Internationally and nationally several institutions and organizations are concerned with standardization of EHR(S): ISO/TC 215 (esp. WG 1), CEN/TC251 (esp. WG 1), openEHR, OMG, HL 7, IHE, DICOM (esp. DICOM-SR), ANSI, ASTM, CPRI, Standards Australia, Standards NZ SC606 WG 3 to name but a few. ISO is most important but ISO/TC 215 Working Group 1 “Health Records and Modelling Coordination”

(http://secure.cihi.ca/en/infostand_ihisd_isowg1_e.html) up to now concentrates on requirements for an EHRS on a rather generic level [1]. Actual activities are related to the definition, scope and context of an EHR [2]. Four other activities or standards are much more oriented on implementation issues and will be discussed in the following: openEHR, HL 7 CDA, CEN 13606 and DICOM-SR.

2.1 openEHR (open Electronic Health Record)

openEHR (www.openehr.org) is a not-for-profit company that was established in 1999 by the University College London (esp. the Centre for Health Informatics & Multiprofessional Education: CHIME) and the Australian

company Ocean Informatics. Its objective is to promote development and usage of EHR(S) within the clinical process, based on implementation experience. For this purpose, openEHR is actively participating in international standardization organizations (e.g. ISO, CEN, HL7) inputting proposals for the specification and development of EHR components. The focus of these specifications is not only concentrated on content and structure of an EHR but includes technological aspects too.

OpenEHR bases on the results of the GEHR-Project, an EU-Project of the Advanced Informatics in Medicine Programme (1991-1995). GEHR originally is an acronym for “Good European Health Record” respectively later “Good Electronic Health Record”. 21 European countries participated in this project that produced a multi-media architecture for EHR consisting of the GEHR Object Model (GOM), the GEHR Exchange Format, and specifications for accessing and integration tools. Prototypes accompanied the specifications. The final deliverable can be downloaded from [3]. Following GEHR several projects extended and refined its results (e.g. the projects Synapses 1996-98 and SynEx 1998-2000 funded by the EU) or dealt with the promotion of EHR usage (the EU funded EHCR Support Action from 1997-2000). All these projects influenced the openEHR specifications that can be downloaded from the openEHR website (www.openehr.org).

The main specification is the openEHR EHR Reference Model [4]. It is concerned with EHR structure and content. An openEHR EHR is a hierarchical structure of folders, each consisting of versioned transactions and change messages (contributions). Folders are meant to divide e.g. administrative from medical events or episodes. Transactions are patient related events like consultations, hospital stays etc. or rather persistent information like the problem list or the family anamnesis. Transactions are referencing content consisting of entries that can be structured using organizer objects. An organizer object can be used e.g. for arranging entries following the SOAP concept (Subjective/Objective/Assessment/Plan). Entries may be observations, instructions or evaluations. Because of being subject to changes transactions can be modified producing versions of them.

These versioned transactions are a mapping of the complete lifecycle of transactions and their modifications.

The openEHR approach is adopting a two model approach. Beside providing an object model (the GOM) for structuring EHR components the archetype concept is proposed for depicting clinical content. Archetypes are formal models of clinically relevant EHR elements defining their data structure and terminological basis in a form suitable for verifying. To define e.g. a report of an ECG analysis, an archetype schema would be defined and published. Even if the schema and the EHR elements constructed using a schema can be exported as an XML document, the core components of an EHR are transactions rather than documents. The openEHR approach is worth being observed not only because of its presence within current standardization activities but also because of subsuming a huge amount of experience evolving from several projects concerned with the specification and implementation of EHR(S).

2.2 HL 7 CDA (Clinical Document Architecture)

HL 7 (www.hl7.org) is a not-for-profit and ANSI accredited organization with headquarter in the USA and affiliate organizations in several countries around the world. HL 7 is attended to the development of standards for the message oriented exchange of information between health information (sub)systems. Its current version 3 focuses on defining messages based on a common object oriented Reference Information Model (RIM). The idea of using the same mechanism for the specification of the exchange of EHR components is obvious and so the Clinical Document Architecture emerged [5]. It specifies XML documents as EHR components based on a three layer approach. Every CDA document consist of a header and a body, which contents are relating to the RIM dependent of CDA layer the document is affiliated to. CDA layer 1 only demands for the header being consistent to the RIM: it consists of information concerning the patient the document is related to, its addressee, its author, its initiating event etc. No further structures are demanded by Level 1 i.e. the layer 1 body is free to contain any information needed. Level 2 demands some kind of structuring of the body consistent to the RIM mainly to define course grained specifications of document types. Level 3 demands for full compliance to the RIM. Even if CDA Version 1 is an ANSI standard since November 2000 (ANSI/HL7 CDA R1.0-2000), the architecture is subject to intensive refinement. Especially the modifications to the RIM demand for adaptations.

The forthcoming Version 2 of CDA will incorporate the RIM adoption and further specifications including HL7 templates, external references etc. The most impressive feature of the CDA is its ability to allow for being standard compatible with the relative small amount of work for constructing the header. The gradual adaptation to subsequent levels of compatibility can be implemented afterwards step by step. Especially in an environment of heterogeneous systems, standardization of EHR documents can be done gradually and driven by demand.

2.3 CEN 13606

CEN TC 251 WG 1 (www.cenc251.org) published the European pre-standard ENV 13606 “Electronic Healthcare Record Communication” 1999/2000 with the objective to enhance interoperability of EHRs. It bases on the former pre-standard prENV 12265 “Electronic Healthcare Record Architecture (EHRCA)” that itself was

influenced by the results of the GEHR project. It is a four part standard. Part 1 “Extended Architecture” addresses structural aspects of an EHR similar to the GOM of GEHR. Part 2 “Domain Termlist” provides mechanisms for content representation within EHR elements. Part 3 “Distribution Rules” addresses security principles esp. concerning the access to EHR elements. Part 4 “Messages for the Exchange of Information” addresses the exchange of EHR elements between EHRs.

Because of being complex and hard to implement the CEN 13606 lacks of success in producing interoperable EHRs until now [6]. Currently a task force works on a revision of the CEN 13606 standard. The revision will consist of five parts. Part 1 “Reference Model” -a refinement of the former part 1- will contain a generic information model for communicating the EHR of a patient. Recently published for discussion [6] it promotes a two model approach taking into account influences from HL 7 CDA and openEHR. Part 2 “Archetype Interchange Specification” will contain a generic information model and language for representing and communicating the definition of archetype instances. Part 3 “Reference Archetypes and Term Lists” will include a “starter set” of archetypes reflecting a diversity of clinical requirements and settings based on the former part 2. Part 4 “Security features” [7] adapts the former Part 3. Part 5 “Exchange Models” will adapt the former part 4.

2.4 DICOM-SR

DICOM is the standard for generation, presentation, communication and archiving of medical images. DICOM-SR is an enhancement of DICOM to combine images with corresponding reports [8]. The core idea is to use the DICOM related infrastructure of network services, PACS etc. for storing and communicating structured reports. These reports are represented by a hierarchical document tree consisting of typed nodes. The semantics of each node is provided by naming them using suitable code systems like SNOMED or ICD-10. Beside the father-son relationship of nodes further semantic relationships can be applied to nodes. Templates are used to define document types. DICOM-SR like DICOM is not a XML based document oriented standard.

3 Implementation

Internationally, several distinct approaches implementing EHRs are explored. In Australia a initiative called HealthConnect (www.health.gov.au/healthconnect) has been established to introduce a nationwide EHRs. A two year lasting project has been initiated to explore several approaches which ended last summer. The extensive project results are published on the web site stated above. Australia is an example for focussing on openEHR. The UK has taken a similar approach of performing a huge evaluation project before deciding: the Electronic Record Development and Implementation Programme (ERDIP) ended 2003. Its results can be downloaded from[9]. HL 7 CDA as well as openEHR have been evaluated positively in different ERDIP subprojects. One example for the adoption of the CDA approach for regional health information systems is the SCIPHOX project in Germany [10]. Combining ECG data with CDA using external links has been examined in the HYGEIANet Project in Crete [11]. Projects based on CDA have been initiated in Finland (Satakunta Macro Pilot), the USA (Mayo Clinic), Canada (e-Claims), the European Union (PICNIC), Argentina (Buenos Aires Project) etc. [12]. DICOM-SR focuses on the imaging sector. Prototypes are existing (e.g. [13]).

4 Conclusion

HL 7 (CDA) and openEHR are intensively influencing EHR standardization and implementation worldwide and should be observed attentively. The current revision of the European CEN 13606 standard takes into account concepts of both approaches. DICOM-SR currently focuses on the imaging The DICOM-SR activities have to be watched whether they will focus on arbitrary clinical documents.

References

- [1] ISO/TS 18308: Health Informatics – Requirements for an Electronic Health Record Architecture, 2003
- [2] ISO TC 215/WG 1: Health Informatics - Electronic Health Record- Definition, Scope and Context, Draft Technical Report, 16.3.2004
- [3] www.chime.ucl.ac.uk/work-areas/ehrs/GEHR/GEHRdeliverables.htm
- [4] The openEHR EHR Reference Model – Revision 4.3.2, The openEHR Foundation, 2003 (www.openEHR.org)
- [5] Dolin RH, Alschuler L, Beebe C et al.:The HL7 Clinical Document Architecture. JAMIA 8(6):552-69, 2001
- [6] CEN prEN 13606-1:2003 (E) “Health informatics - Electronic health record communication - Part 1: Reference model”, Draft 17/09/2003
- [7] CEN prEN 13606-4:2003 (E) “Health informatics - Electronic health record communication - Part 4: Security requirements and distribution rules”, Version 0.4 for Discussion, 09/2003
- [8] Hussein R, Engelmann U, Schroeter A, Meinzer HP.: DICOM Structured Reporting: Part 1. Overview and Characteristics. Radiographics 24(3):891-6, 2004

- [9] www.nhsia.nhs.uk/erdip/pages/publications/
- [10] Heitmann KU, Schweiger R, Dudeck J: Discharge and referral data exchange using global standards-the SCIPHOX project in Germany. *International Journal of Medical Informatics* (2003) 70, 195-203
- [11] Chronaki CE, Lelis P, Demou C, Tsiknakis M, Orphanoudakis SC: "An HL7/CDA Framework for the design and deployment of telemedicine services." *Proceedings of IEEE EMBC 2001, Instambul, Turkey. 25-28 Oct, 2001*
- [12] Alschuler L.: Clinical Document Architecture – CDA – Introductory Tutorial, Presentation at the HL7 International CDA Conference, Berlin, October 7-9, 2002 (www.hl7.de/cda2002/absbiopres/cdaintro.pdf).
- [13] Riesmeier J, Eichelberg M, Kleber K et al.: DICOM Structured Reporting: a Prototype Implementation, in: *Proc. CARS 2001, Elsevier, 752-756, 2001*

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