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Analysis and Evaluation of EHR Approaches

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Abstract. EHR systems are core applications in any eHealth/pHealth environment and represent basic services for health telematics platforms. Many projects are performed at the level of Standards Developing Organizations or national programs, respectively, for defining EHR architectures as well as related design, implementation, and deployment processes. Claiming to meet the challenge for semantic interoperability and offering the right pathway, the resulting documents and specifications are sometimes controversial and even inconsistent. Based on a long tradition in the EHR domain, on the collective experience of academic groups such as the EFMI EHR Working Group, and on an active involvement at CEN, ISO, HL7 and several national projects around the globe, an analysis and evaluation study has been performed using the Generic Component Model reference architecture. Strengths and weaknesses of the different approaches as well as migration pathways for re-using and harmonizing the available materials are offered.

Keywords. EHR, Architecture, Models, Semantic Interoperability, Standards, National Projects.

Introduction

The requirements for safe and high quality care as well as efficiency and productivity of health systems under the well-known constraining conditions are expected to be realized by increasingly distributed and specialized health services that become strongly oriented on the actual personal health status and the needs of the subject of care. Those health services are provided independent of time, localization, and distribution of resources in a highly communicative and collaborative way called eHealth. eHealth or personal health must be supported by basic technology paradigms of mobile computing for ubiquitous communications, of pervasive computing for comprehensive, and of pervasive care as well as autonomic computing for adaptive personalized system design enabling ubiquitous care altogether. Intentional communication and cooperation needs shared information for deriving collaborative actions which have to be observed for Quality Assurance (QA) purposes starting the information cycle again and again. Principles and consequences considering the entire information cycle for meeting the semantic interoperability challenge are extendedly discussed in [1]. According to the

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objectives and requirements of the actors involved in communication and cooperation, different levels for interoperability shall be provided thereby extending the interoperability chain up to the subject of care as demonstrated in the personal care paradigm's context [2]. Depending on the business case requiring interactions between systems, the following interoperability levels can be distinguished: technical interoperability (e.g. technical Plug&Play, signal & protocol compatibility); structural interoperability (e.g. simple EDI, envelops); syntactic interoperability (e.g. messages, clinical documents, agreed vocabulary); semantic interoperability (e.g. advanced messaging, common information model and terminology); organizational/service interoperability (e.g. the common business process). The information about status and processes directly or indirectly related to the subject of care has to be documented in a computer-readable format, and stored in repositories - the Electronic Health Record (EHR). Such EHRs have to be implemented in EHR systems which are sets of components for realizing the mechanisms for creating, using, storing, and retrieving an EHR. EHRs and EHR systems for eHealth have to be based on an EHR architecture defining a model of generic properties required for every EHR to be communicable, comprehensive, useful, effective, and ethically-legally binding bewaring its integrity independent of platforms and systems as well as national specialties over the time [3], [4].

1. Characteristics of Semantically Interoperable EHR Architectures

For providing advanced and sustainable communication and cooperation, architectures for sustainable Health Information Systems (HIS) such as EHR systems have to be open, scalable, flexible, portable, distributed, standard-conform, semantically interoperable, service-oriented, user-accepted, applicable to any media, and lawful. Therefore, the following architectural paradigms have to be met: distribution; component-orientation; a model-driven and service-oriented design considering concepts, context, and knowledge; comprehensive business modeling; separation of platform-independent and platform-specific modeling (thus separating logical from technological view); agreed reference terminologies and ontologies; unified development process, and advanced security and privacy services embedded in the architecture. The aforementioned architectural paradigms are reflected in the Generic Component Model (GCM) which provides a multi-model approach to any system architecture [5]. Developed at the Magdeburg Medical Informatics Department in the early nineties, it can be used as reference architecture for analyzing, designing, and implementing EHR architectures characterized by their components, functionalities, and relationships but also for developing migration strategies [5], [6].

The respective reference architecture design is characterized by three dimensions (see Figure 1):

- the composition and decomposition of its components reflecting the complex functionality; from an enterprise viewpoint (explained in the next statement), it's the business process (workflow);
- the unified development process referring to the viewpoint of the ISO 10746 Information Technology – Open Distributed Processing – Reference Model [7] starting with the extended business modeling of the enterprise view, the information view as its informational reflection, and the computational view as the reasonable functional aggregation of the components all three reflecting the platform-independent modeling and continuing with the platform-specific

models of the engineering view and the technology view, all five views summarized as development process (e.g. the Rational Unified Process – RUP);
- the isolation and integration of the domain touched by the EHR (medical, administrative/organizational, legal, etc.).

EHR systems as well as standards and projects defining them have to be assessed in reference to the GCM reference architecture. So, the usability of the analyzed approach, the gaps, and the capability for migration can be evaluated; the respective migration paths can be derived.

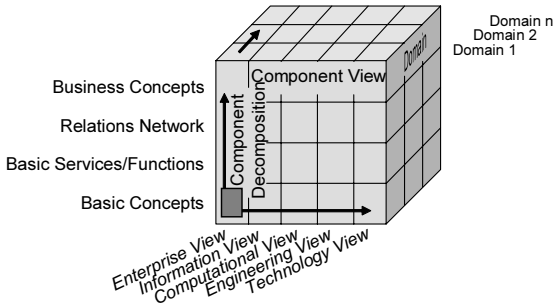

Figure 1. The Generic Component Model

2. EHR-Related Standards

Currently, three different streams for specification and implementation of advanced EHR architectures exist that have their roots in legacy systems, traditional imaginations, and methodologies: data approach (data representation), concept approach (concept and knowledge representation), and process/services approach (business process and service representation).

Because of their rational roots, all approaches have their -at least temporary- right to exist. All approaches undergo further development offering a convergence. As the GCM considers all aforementioned aspects, the distance of evaluated approaches to the GCM as well as the reflection of the presented principles allow for the evaluation of developed or emerging solutions as well as for description of missing characteristics.

Regarding EHR approaches as standards, specifications, or national projects, the following ones have to be investigated as the most important ones: the HL7 standards suite [8] with the HL7 RIM, HL7 v3, HL7 HDF, CDA, etc. most of them established, or under establishment, in ISO TC 215; ISO/EN 13606 “Health informatics – EHR communications” [9]; the GEHR [10] and openEHR Foundations [11] projects; IHE approaches [12] but also service-oriented approaches such as CORBA components [13]; Web services, etc. The analysis only focuses on the architectural approaches ignoring national or project-specific specialties on implementation details, legal aspects, or priorities followed in some countries and their related projects.

3. Results

Using the Generic Component Model, the different standards and projects influencing the global EHR development have systematically been evaluated. The results are summarized in Table 1. While in the study [14] all characteristics have been analyzed in detail, the table only reflects coarse grained quality parameters not considering either how the different aspects elaborated have been harmonized within the standards (quality and consistency). Due to the complexity of the ISO organization, standards might

be referenced responding to some of the GCM requirements not inter-relating with EHR specifications, however, while the HL7 standard set provides such inter-relationships as well as formal collaboration and joint projects solving those inter-relations between SDOs. In that context, the unified process, separations of viewpoints, and the completeness of referencing ISO 10746-2 [7] have to be mentioned which are met in HL7 but not in CEN/ISO or openEHR, even if standards such as ISO EN 12967 [15] are sometimes miss-referenced there.

Table 1. Comparison of available EHR approaches (availability: P-partial, Y-yes, N-no, F-future)

GCM Characteristics	HL7 Standards	CCR	EN/ISO 13606	openEHR	IHE XDS	DICOM SR
Development Process						
Unified process	Y	N	N	N	N	N
Business modeling	Y	N	N	N	P	N
Service orientation	P	N	N	N	P	N
View separation	P	N	N	N	N	N
Completion of ISO 10746-2	Y	N	N	N	N	N
System Architecture						
Reference information model	Y	N	Y	Y	Y	Y
Meta model	P	N	N	N	N	N
Model transformation framework	Y	N	N	N	N	N
Concept representation	Y	P	Y	Y	N	Y
Consistency of components	N	Y	Y		Y	Y
Open concept representation language	Y	Y	N	N	N	N
Composition/decomposition	Y	N	N	N	N	N
Signature/Certificate-enabled	N	Y	N	N	Y	Y
Machine-processeable	P	P	P	P	Y	Y
Multi-Domain Suitability						
Domain-independent	N	N	N	N	N	N
Domain separation	N	N	N	N	N	P
Model multiplicity	n	1	2	2	2	2
Ontology driven	N	N	Y	Y	N	N
Vocabulary	Y	N	N	N	N	N
Reference to terminology	Y	Y	Y	Y	Y	Y
Communication security services	N	Y	N	N	Y	Y
Application security services	N	Y	P	N	N	N
Inclusion of medical devices	Y	N	F	N	F	Y
Specialty-related	N	Y	N	N	Y	N
Multimedia-enabled	P	P	N	N	Y	Y
Feasibility						
Visualization support	Y	Y	N	N	N	N
Final specification available	N	Y	N	N	Y	Y
Implemented	Y	Y	N	P	Y	Y
Commercial products available	Y	Y	N	N	Y	Y

4. Discussion and Conclusions

The core application EHR is in the center of considerations for all European (e.g. EC eHealth Action Plan) and national (UK, Denmark, USA, Finland, Australia, Canada) eHealth Programmes. With the move by a paradigm change from organization-centered to process-controlled care and even further towards personalized healthcare, comprehensive communication and cooperation between all participants in the process including semantic interoperability between supporting information systems is inevitable.

Different advanced approaches for future-proof architectures, EHR specifications, and the implementation of semantically interoperable EHR systems (e.g. HL7 Version 3 Standard Set with CDA, CCD, EHR-S Functional Model, EHR Interoperability Model [8], GEHR [10] /openEHR [11], EN/ISO 13606 [9], and CCR [16]) have been demonstrated, discussed, and evaluated using the GCM as reference architecture for sustainable and semantically interoperable health information systems [5].

The HL7 Version 3 methodology in connection with the definition of system requirements by the EHR-S Functional Model and the EHR-S Interoperability Model (it

remains a question to the author why both models have not been brought together) provides the best approach so far to GCM without solving domain-crossing aspects and the connection of non-ICT views to ICT views. Furthermore, the formal business process specification and the dynamic behavioral/functional aspects of the components are still missing. The service-orientation missing could be overcome by current efforts of the SOA SIG in liaison [9]. Additionally, present concept representations have not been adequately integrated, probably due to a missing HL7 ontology. Surmounting the many solution islands, the complex HL7 Standards family could -in collaboration with CEN, openEHR and CORBA- demonstrate some progress.

The second rather comprehensive approach to semantic interoperability is EN/ISO 13606 [9], even if many deficiencies and inconsistencies have yet to be overcome. Contrary to the HL7 Version 3 approach, the problem of semantic composition / decomposition is insufficiently solved there. The same counts for business processes. On the other hand, the project orientates right from its beginning to the architecture paradigm despite of the irritating title, and it goes beyond the HL7 approach in this perspective. GEHR/openEHR [10], [11] has to be evaluated partly analogue to EN/ISO 13606 due to the close connections and the common knowledge representation based on Archetypes. It constraints itself in essence to parts 2 and 3, however.

These two promising approaches suffer from the complexity of the healthcare domain. So, it will take some time before a critical mass of model-based services (metamodels at different levels or Archetypes, respectively, as well as tools for instantiation) will be available for revolutionizing health. Since 2001, different pathways have been followed. While EN/ISO 13606 still focuses on its architectural approach, the openEHR Foundation project focuses on concepts bound to the clinical process leading to different structural components. At the same time, commonalities with HL7 CDA and HL7 Clinical Templates are increasing [8].

Contrary to HL7 Version 3 Standard Set and EN/ISO 13606, CCR [16] provides an immediately applicable record solution without claiming semantic interoperability, however. All ways offered allow for migration using the GCM. A closer cooperation between standards bodies is absolutely helpful and thus required. During the evolution, the user community has to decide which interim solutions are acceptable.

The necessity of meeting all paradigms of the GCM has been emphasized through experience from national projects in different countries the author has been involved in. Having been the internationally leading programme for introducing a national EHR for quite a long time, the Danish approach started with the underlying business processes in an exemplary way. The problem of structural and functional composition / decomposition has been ignored, however. This deficiency stopped the project now resulting in a comprehensive restart. Other projects and standards including the ones discussed here ignore the business processes, at the same time providing reasonable solutions for the other aspects. This has adverse effects as well in case the gaps have not been single-mindedly closed [17].

An important requirement for achieving semantic interoperability has been the establishment of a unified process including the definition of conformance statements as well as the quality assurance for specifications and implementations. Here, projects such as the European Q-REC led by the EuroRec Institute, and the work of the US Certification Commission for Health Information Technology (CCHIT) do push testing, quality labeling, or certification, respectively, of EHR specifications and EHR systems [18], [19].

Currently, not any single specification investigated meets from an insider's perspective the requirements for semantic interoperability at service level – but this is what almost all of them claim to do. The maturity of the approaches is very different whereby history of specifications and originating organizations, the chosen paradigm as well as scope and objectives are of importance. Maturing and harmonizing the present approaches in accordance with the GCM will provide the sustainable solution. Thereby, all architectural paradigms have to be met. Such component-based and service-oriented approach will lead to a layer of infrastructural services supporting creation, deployment, and maintenance of EHR systems. Most of the national strategies promote such development.

The eHealth Competence Center (eHCC) located at the University of Regensburg Medical Center is involved in most of the international standardization activities and national programs related to EHR. While the work in many regions of the globe is ongoing and -more or less- evolved, the German EHR development starting with the bIT4health (better IT for better health care) project that was launched some years ago by the German Federal Ministry for Health is comparably immature. Recently, the eHCC was appointed to specify the German EHR architecture.

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