Semantic Interoperability

HL7 Version 3 Compared to Advanced Architecture Standards

B. G. M. E. Blobel, K. Engel, P. Pharow
eHealth Competence Center, University of Regensburg Medical Center, Regensburg, Germany

Summary

Objectives: To meet the challenge for high quality and efficient care, highly specialized and distributed healthcare establishments have to communicate and co-operate in a semantically interoperable way. Information and communication technology must be open, flexible, scalable, knowledge-based and service-oriented as well as secure and safe.
Methods: For enabling semantic interoperability, a unified process for defining and implementing the architecture, i.e. structure and functions of the co-operating systems' components, as well as the approach for knowledge representation, i.e. the used information and its interpretation, algorithms, etc. have to be defined in a harmonized way. Deploying the Generic Component Model, systems and their components, underlying concepts and applied constraints must be formally modeled, strictly separating platform-independent from platform-specific models.
Results: As HL7 Version 3 claims to represent the most successful standard for semantic interoperability, HL7 has been analyzed regarding the requirements for model-driven, service-oriented design of semantic interoperable information systems, thereby moving from a communication to an architecture paradigm. The approach is compared with advanced architectural approaches for information systems such as OMG's CORBA 3 or EHR systems such as GEHR/openEHR and CEN EN 13606 Electronic Health Record Communication.
Conclusion: HL7 Version 3 is maturing towards an architectural approach for semantic interoperability. Despite current differences, there is a close collaboration between the teams involved guaranteeing a convergence between competing approaches.

Keywords
Health telematics, HL7, model-driven architecture, electronic health record architecture, semantic interoperability

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1. Introduction

The health systems of all industrial countries are faced with the challenge of improving quality and efficiency of health delivery. The way to meet these requirements is the introduction of shared care, which is bound to extended communication and co-operation between all healthcare establishments and their information systems. Such communication and collaboration can be provided at different levels of interoperability as shown in the next section. If communication focuses on message exchange, collaboration depends on the applications' behavior and functions. Therefore, the application architecture defines the level of interoperability and usability of applications. Architecture describes the system to be designed, its objectives, its elements, their inter-relationships and functionalities.

Documenting observations regarding data and procedures provides the basic part of health-related information. Applications recording, storing and processing such information are electronic health record (EHR) systems. That information can be used for many different purposes by many different departments and their applications. Following, EHR systems are called the core application in healthcare settings. This is one of the reasons why EHR architectures have been developed and standardized at global level. Therefore, EHR architecture allows best for a comparative analysis of health information systems.

The paper investigates the Health Level Seven (HL7) standard set from an advanced interoperability perspective.

2. Problem and Challenge

For meeting the challenges of improving quality and efficiency of patient's care including homecare and prevention, health information systems have to provide semantic interoperability supporting seamless care. Especially in the context of long-term applications such as EHR systems, several crucial requirements must be realized. Thus, advanced communication and co-operation between different systems and their components in a complex and highly dynamic environment provided in a sustainable way requires:

- openness;
- scalability;
- flexibility;
- portability;
- distribution at Internet level;
- standard conformance;
- service-oriented semantic interoperability;
- appropriate security and privacy services.

For achieving the aforementioned characteristics, the system architecture, i.e. the system's components, their relationships and functionalities, have to meet the following paradigms:

- distribution;
- component-orientation (flexibility, scalability);
- model-driven and service-oriented design;
- separation of platform-independent and platform-specific modeling → separation of logical and technological views (portability);
- specification of reference and domain models at meta-level (semantic interoperability);
- interoperability at service level (concepts, contexts, knowledge);
- common terminology and ontology (semantic interoperability);
- advanced security, safety and privacy services.

3. Modeling Advanced Health Information Systems

Following these introductory thoughts, methods and solutions for advanced health information systems as characterized in the previous section will be explained in some detail.

Real systems have to be described in a formal and therefore simplifying way. For that reason, the system is modeled focusing on an appropriate level of granularity as well as on certain aspects ignoring others for a while. Of course, for implementing a solution, all separated aspects must be integrated into one view thus providing a real and operational solution.

The presented architectural approach has been developed over the last ten years in the authors' former affiliation at the Magdeburg Medical Informatics Department (e.g. [1, 2]). The first Generic Component Model presented the abstraction paths for systems through three viewpoints (business view, logic view, technology view) and the four levels of granularity shown in Figure 1 later on. Meanwhile, this approach has been extended, internationally consolidated and standardized.

Regarding the architectural approach, the systems in question therefore have to follow the ISO 10746 Reference Model – Open Distributed Processing (RM-ODP) [3]. This model defines five different viewpoints for a system and its components:

- the enterprise view describing the purpose of the component, the scenario and the use cases, i.e. the underlying business model;
- the information view establishing the information (classes, associations, behavior) which describes the aforementioned enterprise view;
- the computational view aggregating the basic components to functional units;
- the engineering view characterizing physical distribution and technical details of the components;
- the technology view covering protocols, deployment strategies, maintenance and training.

The former three viewpoints describe platform-independent aspects, while the latter two are platform-specific. Figure 1 shows the abstraction paths for formally describing a system and its components according to an extended RM-ODP. Such complex consideration of components by simplifying viewpoints and appropriate levels of granularity has to be performed for all different domains (e.g. medical, administrative, or financial) a system will be deployed in.

Summarizing the aforementioned principles, a real system must be modeled considering the aspects of a specific domain and simplifying it by being focused on an appropriate level of granularity (composition/decomposition) and its viewpoints of interest.

Summarizing the requirements, future-proof and advanced information systems have to be developed using model-driven and service-oriented architectures according to a clearly defined unified process [4, 5].

All different aspects have to be formulated defining the basic pieces or building blocks (atomic concepts which cannot be subdivided any further without losing their functionality and sense) and appropriate composition rules for both business and information models. For realizing semantic interoperability, all models have to be derived from reference models. Vocabulary must be maintained using internationally agreed upon terminologies and ontologies. Application and usage profiles have to be defined, and conformance statements as well as implementation guidelines need to be deployed to guarantee that the described interoperability becomes technically real [6].

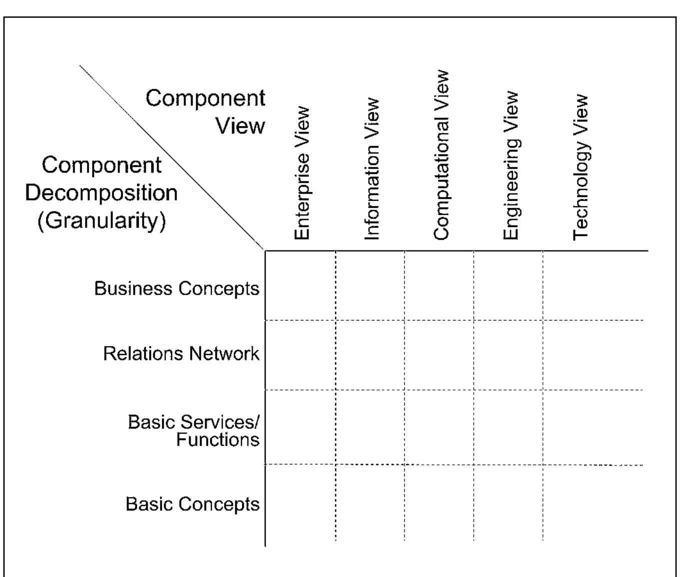

Fig. 1 Abstraction matrix for component-based systems

4. HL7 Standard Set

Following, the HL7 communication standard will be shortly discussed. For more information see [7-9].

4.1 General Principles

The advent of an increasing number of computer systems in combination with complex applications from different vendors raised the challenge to connect those systems. This can be done at different levels of interoperability: At the lowest level, mechanical plugs including voltage and signals have been harmonized. This is called technical interoperability. At the next level, the data that are exchanged have been standardized, thereby providing data level interoperability. Nevertheless, different terminologies might be used. Therefore, at the next level, terminology must be agreed upon. For enabling a common understanding, the semantic of terms must be harmonized, thereby providing semantic interoperability. At the highest level, concepts and context of exchanged information are harmonized including the realized services based on that information. We call this highest level service-oriented interoperability. Furthermore, the design process of systems meeting that level of interoperability must be comprehensively defined and standardized.

HL7, an ANSI (American National Standards Institute) accredited standards development organization with close liaison to ISO TC 215, specifies communication contents and exchange formats on the application layer. In the communication model of ISO for interconnection of open systems (Open System Interconnection, OSI), this layer is the seventh, which led to the name HL7. It is important that the communication solution is independent from the software used as well as the underlying hardware and the chosen network. Thus, the user has the freedom to implement a solution best suited to his needs.

The HL7 communication standard was developed especially for the health care environment and enables communication between meanwhile almost all institutions and fields of health care. With HL7, all important communication tasks of a hospital can be handled and the efficiency of the communication process is decidedly improved.

4.2 HL7 Version 3

HL7 Version 3 means much more than being just a new version in the course of developing the standard. HL7 Version 3 follows a new paradigm. This paradigm change was not a short step but a long-term and contradictory process. This has been demonstrated not only by the frequent change of direction and the obviously endless series of versions of its basic elements. What is the new HL7 Version 3 paradigm's characteristic?

4.2.1 HL7 Version 3 Basics

The HL7 Version 3 communication standard is based on a new and comprehensive development methodology, which has been called the Version 3 Message Development Framework[a] (MDF) covering the whole life cycle of the standard specification from development through adaptation and maintenance up to implementation, use and testing of messages (see section 4.2.11). For that purpose, first techniques of modern software engineering have been deployed within a standard development process such as object-oriented analysis and object-oriented design as well as formal modeling. Following, the development process of HL7 Version 3, its development methodology, available tools to specify HL7 Version 3 messages as well as further perspectives will be considered.

If HL7 Version 2.x strictly follows the message paradigm including ad-hoc development and extensions, HL7 Version 3 implies the following different principles:

- stepwise movement from message to architecture paradigm driving towards the HL7 Development Framework (HDF), and
- introduction of model-based specification of messages on the basis of a Reference Information Model (RIM).

4.2.2 HL7 RIM

The development of HL7 Version 3 has been performed in different phases characterized by important changes. In the first phase, the RIM has been a presentation of all elements specified in the standard by using a partially object-oriented methodology. Items belonging together due to their properties, their use, etc. have been grouped into object classes and modeled as attributes of those classes. Additionally and step by step, use case models and sequence diagrams have been introduced. Following the message paradigm (also called integration type "Interfacing"), only attributes but no operations have been specified. Because all instances specified in the standard have been defined as RIM object classes, the HL7 modeling approach was a one-model approach. Problems bound to that approach became obvious in performed extensions, frequently leading to a re-arrangement of attributes or even classes. Thus, the model was hardly maintainable and extendable. As a consequence, in the second phase the RIM has been changed towards a stepwise abstraction of the RIM reducing it to only a few generic core classes and a movement towards a service paradigm by introducing the Unified Service Action Model (USAM).

The resulting RIM describes six core classes for objects of the health domain as well as the associations between those classes and their specializations:

- **entities**, i.e. the physical information objects or better the actors in the domain (e.g. organization, living subject, materials, location);
- **roles**, played by those entities and therefore assigning them the competence to perform specific actions (e.g. patient, provider, employee, specimen, practitioner);
- **participations** of role-playing entities in specific acts (e.g. performer, author, subject, destination, witness);
- **acts** (e.g. observation, procedure, supply, medication);
- **role links** to manage relationships between entities in their corresponding roles;
- **act relationships** chaining different acts.

The core classes contain some basic attributes such as Type_CD (Class_CD), Concept_Descriptor, Time, Mood (determiner), Status, and ID. It is obvious that the core classes for *roles* and *participations* are specializations of the corresponding entities, whereby *roles* represent competence-related specializations and *participations* represent action-related specializations.

4.2.3 Definition of Domain-specific Messages

First, the scenario considered for a specific communication or co-operation must be highlighted. This is performed by the graphical representation of scenarios using

[a] Because HL7 is now moving from a communication standard based on the communication paradigm towards a comprehensive set of interoperability standards including architectural concepts, decision procedures, visual integration, implementation specifications, etc., this framework is currently extended to the HL7 Development Framework (HDF).

UML use case diagrams. Additionally, the scenario may be described verbally, which is called the HL7 Storyboard. For describing the outcome of actions related to role-specific specializations, state diagrams or state transition diagrams are used. After reaching clarification on the general issues of messages, we may proceed to specify specific messages. The starting point is always the HL7 RIM.

4.2.4 Domain-specific Models

For generating a message, the information (attributes) about the objects (classes) involved must be established, connected in a proper way, and instantiated. The link between RIM classes and the selection or completion of attributes of the corresponding classes depends on legal, organizational, functional, and technological conditions in the related communicating application domains, i.e., on their policies, their concepts, rules, and the knowledge.

For developing domain-specific messages, the classes needed according to the information requirements must be selected and their attributes have to be updated, i.e., non-required attributes must be cancelled and missing attributes must be added: For defining a doctor's order message related to a specific patient, the relation between an entity person playing the role of a physician (instantiated as "Dr. Smith") participating as "order/requester" of an act "laboratory result" (instantiated as "blood test") and an entity person playing the role of a patient (instantiated as "Mr. Miller") with the participation observant must be designed. For that reason, we have to clone the classes from the RIM and update the attributes properly in a Domain Message Information Model (DMIM). The next step in this process is the definition of messages by extracting the required subset of classes out of the parent model resulting in Refined Message Information Models (RMIMs). Walking through this graph with its clones leads to a serialized representation. The binding of the different vocabularies must be provided at the latest during this step.

4.2.5 Reusable Message Fragments – the CMETs

This short introduction clearly shows the complexity of the method. Furthermore, such messages across domains are hardly to standardize. In that context, certain classes, their specializations and associations are described as domain-specific information models. In case those models of characteristic objects and their relations can be standardized, a set of Common Message Element Types (CMETs) can be established which are re-used in different domains.

CMETs are multi-domain information models based on RIM core classes and appropriate associations. Thus, HL7 is moving from one-model approach to a multi-model approach. The advantage of such a procedure is obvious:

Domain-specific requirements and conditions can be consistently described by the RIM using object-oriented and UML-based methods. The resulting architectural components are part of the standard. They can easily be updated or replaced (by local definitions) without any implications on the usability of the other components. Thereby, an open, scalable, maintainable, component-oriented specification can be provided.

The standard's development can happen step by step, extendable to any level of complexity. CMETs represent concepts and knowledge, thus enabling interoperability at the level of concepts and knowledge.

Use cases (scenarios) or their verbal variant – the storyboard – are the starting point for message development in HL7 version 3. The harmonization between globally active developers and implementers on the one hand and the continuous extension regarding the involved domains (chapters) on the other hand is realized via a unique reference model of health care – the HL7 RIM. From that generic RIM, domain-specific specializations as DMIMs as well as RMIMs, but also cross-domain components (CMETs) are derived. Dynamic and procedural aspects are described using sequence diagrams, state diagrams, activity diagrams, etc.

4.2.6 Hierarchical Message Description (HMD)

Starting from models described, the resulting message related to a defined trigger event must be specified. For that purpose, the relation between the different vocabularies, "graphical description of components", "verbal description of components", and presentation using "XML[b] exchange format" must be provided. One opportunity for doing that has been offered by the XML Standard Set with its XML Metadata Interchange (XMI) specification as described, e.g., in [10]. Another way is the use of specific tools as practiced in HL7. Please note that not only a UML-like graphical modeling is used by the HL7 community, but also special tools such as Rose Tree© and Microsoft's Visio© (stencils) for message design via RMIMs (e.g. for correct, RIM-adequate modeling of the domain models or CMETs). RMIMs are results of the walk through the graph (RIM) with its clones and refinements related to classes and attributes. The transformation of a Rational Rose© UML information model as well as the transformation of Visio© Templates by a graphical walk through into a Hierarchical Message Description (HMD) is provided using Woody Beeler's Rose Tree© tools.

The information managed concerns classes, subclasses (specializations), their attributes and data types, associations as well as the latter's cardinalities (multiplicities), which lead to nested message structures and their required or optional components. The HMD of the related message structure is finally transferred into an equivalent XML schema definition using an HL7-specific schema generator.

4.2.7 Specialization vs. Standardization

HL7's version 3 strategy of model-based message definition reduces optionality by modeling and defining every message according to its specific requirements and conditions. Thus, all specified components are required and being served, resulting in a set of similar but specific messages. Therefore, the interoperability striven for may be taken into

[b] Extensible Markup Language

question. The way out of this dilemma should be provided by the following principles:

- reference to a globally acknowledged Reference Information Model;
- specification of an accepted and binding vocabulary for all reference components as well as all domain concepts (knowledge concepts) (definition in the framework of RIM, all DMIMs, RMIMs, etc.);
- development of application roles for characterizing the participation in message interchange;
- definition of requirements profiles, which lead to conformance statements.

4.2.8 Application Roles

Requirements and conditions of interoperating applications related to their data and functionality have to be clearly defined in order to assure communication between them. Besides mandatory data, this also includes the specification of messages and trigger events needed. That specification of functional and data-related requirements and conditions of applications is also called Application Roles.

4.2.9 Conformance Statements

For providing interoperability in a very complex and divergent world, interesting solutions have been developed. Mostly known is DICOM (Digital Imaging and Communication in Medicine, [11]), which is the globally established image communication standard. Contrary to HL7, DICOM realizes interoperability not only at the level of message exchange independent of the level of semantic interpretation, but also at the level of service-oriented interoperability. That linking of communicated data and functions has been defined as Service Object Pairs (SOP) for different modalities within a client-server environment. By that way, an optimal coding (interpretation of the message at the originator side is the same as that at the receiver side) has been guaranteed. The needed equivalence of SOPs, client and server properties, protocols, presentation instructions, etc., is defined by Conformance Statements. Two communicating applications have to meet the corresponding mutual Conformance Statements.

HL7 Version 3 is using an analogue way of defining Conformance Statements. References to a global RIM and a binding vocabulary, messages between two interoperable applications have to follow the corresponding Application Roles as sender and receiver including the assigned responsibilities.

In that context, the current specification of Clinical Templates as well as the work on the Clinical Document Architecture (CDA) Level 2 is especially important.

4.2.10 Contents and Specifications of the HL7 Standard

For assuring interoperability between applications based on the HL7 Version 3 Standard, all messages must be based on the HL7 RIM, on agreed data types as well as on a binding vocabulary. At the domain-specific level, CMETs, RMIMs, the temporal and procedural conditions expressed by Interaction Diagrams or State Diagrams as well as Application Roles, from which trigger events and interactions result, must be standardized.

Because of their different character, standard components are managed in different ways. The HL7 Version 3 methodology, the HL7 RIM as well as the HL7 vocabulary are reference materials of HL7 Version 3 and not ballot issue. Information about HL7 data types, Implementable Technology Specifications (ITS) as well as the chapters containing domain-related specifications are normative parts of the HL7 Version 3 Standard. They need the affirmation of HL7 members.

The Version 3 Publication is an automated process provided on the basis of the artifacts from HL7 Technical Committees (TCs) and Special Interest Groups (SIGs) collected in HL7 databases (repositories). For assuring the consistency of the standard, all specifications are verified with existing specification stored in such a repository. After successful verification, the new specification can be added to the repository.

4.2.11 HL7 Development Framework

The unified process to be followed has been defined within the HL7 Development Framework (HDF), which succeeded the Message Development Framework (MDF) clearly demonstrating the aforementioned movement from a message orientation to an architecture paradigm (see Fig. 2).

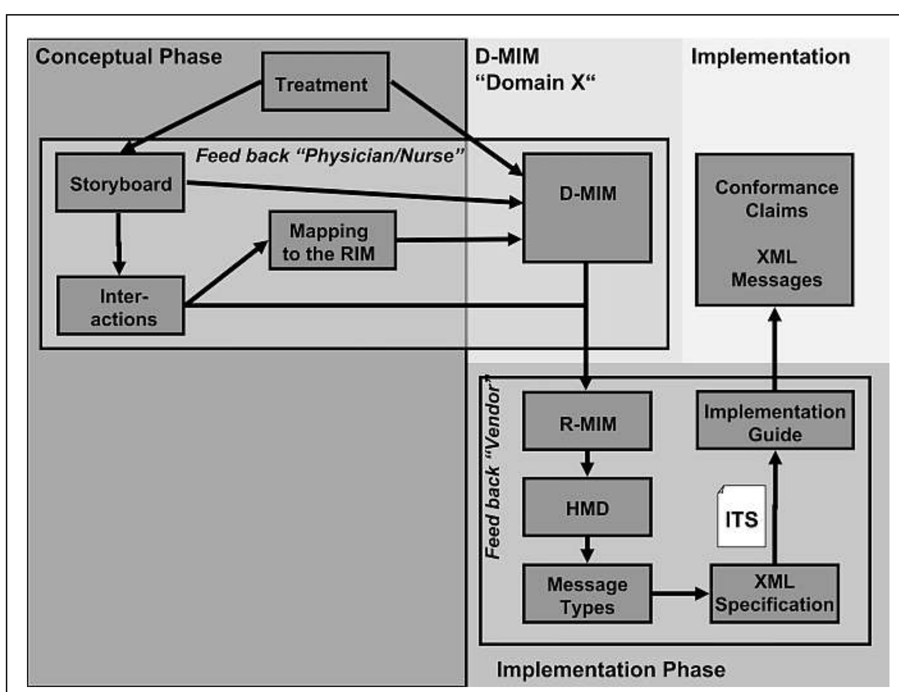

Fig. 2 HL7 modeling overview (after K. Heitmann)

The HL7 Development Framework describing the HL7 Unified Process (similar to the Rational Unified Process – RUP) is currently in its final specification phase. The HDF document contains seven chapters:

- Chapter 1: Project Initiation and Management
- Chapter 2: Requirements Gathering and Analysis
- Chapter 3: Requirements Normalization and Harmonization
- Chapter 4: Specification Design and Packaging
- Chapter 5: Specification Publication and Balloting
- Chapter 6: Specification Refinement and Localization
- Chapter 7: Specification Implementation and Validation

HL7 Version 3 meets all requirements and characteristics mentioned above. Historically starting with the well-known HL7 Reference Information Model (RIM) describing basic information and relationships according to a very generic process model, the domain models developed later on (DMIMs) describe domain-specific aspects. The domain models can be specialized or refined by refined information models (RMIMs) up to the concepts level of reusable building blocks (CMETs). The business needs are verbally described in storyboards. Service-orientation and process models within the business model are specified using, e.g., clinical statements for the clinical domain. Application Roles describe the deployment of the system, Implementable Technology Specifications (ITS) define practical implementation details, and Conformance Statements guarantee real-life interoperability. Moving from a message paradigm to an architectural one, HL7 V3 now meets the stated requirements for developing advanced health information systems [6].

4.3 HL7 Specifications on EHR

Because of the importance of EHR and EHR systems, HL7 is meanwhile also developing EHR-related specifications. This

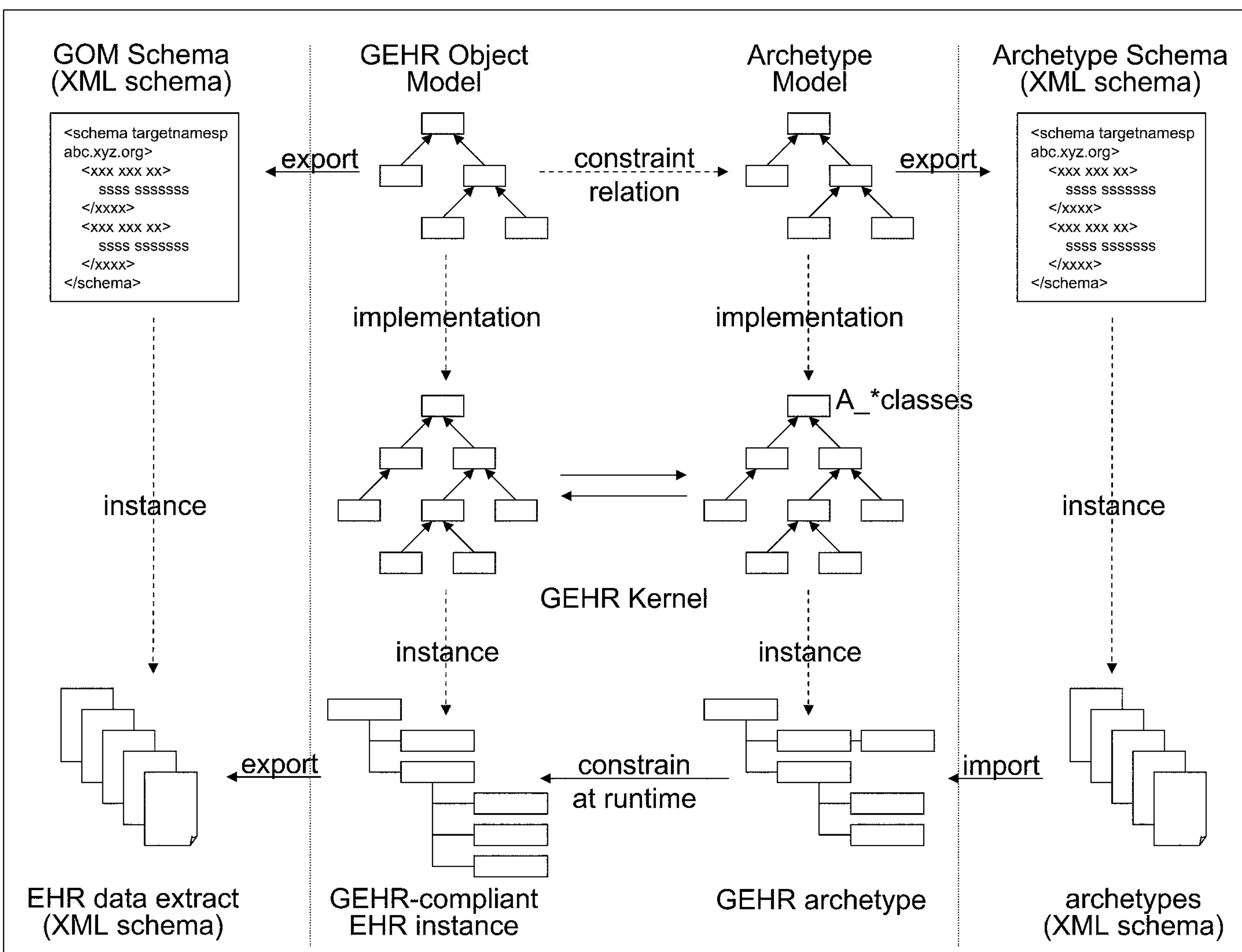

Fig. 3 GEHR/openEHR architecture (after T. Beale [13])

business has started with the development of the XML meta-language. Here, XML has not only been used for providing an open message exchange format, but also for representing clinical documents. As a result, the Clinical Document Architecture (CDA) has been specified and approved as an official ANSI standard. CDA provides an alternative way of aggregating information for communication and co-operation. As messages, also CDA is based on the HL7 RIM. Representing the RIM classes, all CDA elements refer to RIM attributes, data types and codes or their derivates, respectively.

Based on the XML standard set, CDA provides semantics for entities and their roles, but also for documents to be used to represent document structures and hierarchies. Different CDA levels allow for different levels of granularity of presented clinical information. CDA documents are human readable, machine processable, persistent, legally binding, and valid. At the simplest CDA Level 1, a document is represented through a structured header and a body. At Level 2, sections of clinical processes and activities have been separated by markups. CDA Level 3 finally provides basic medical concepts. CDA documents validate against the XML schema for that level. Further constraints can be applied and validated. In this way, the Clinical Document Architecture provides incremental and variable semantic interoperability, which can evolve and mature step by step, so providing a migration path. Clinical Templates represent clinical workflows and higher level concepts using CDA mechanisms. The appropriateness of using message or CDA documents depends, e.g., on content and usage of information expressed. Allowing for aggregation and use of information components too, CDA documents express higher level concepts and are therefore semantically richer than messages. Nevertheless, CDA documents do not yet perform operations, but provide information to applications for providing appropriate functionalities. While CDA currently deploys structural constraints, functional constraints could in principle be established in future developments.

Another recent extension of the HL7 standard set could close the gap between message and architectural paradigm. The HL7 EHR-S Functional Model Draft Standard for Trial Use (DSTU) provides a set of functional requirements and conformance statements to be met by EHR systems. At the highest level, clinical functions, supportive functions and infrastructural services have been separated and fine-grained detailed at each level. Thus, the standard deals with activities and functions provided by this core application. While the HL7 EHR-S Functional Model is a narrative description, its expression using formal languages (meta-languages, interface definition languages and other constraint languages) would allow for automatically processing the statements.

In the next sections, alternative ways of architectural approaches demonstrated at EHRs are presented.

5. GEHR/openEHR

An important approach for specifying and implementing EHR systems based on an advanced architecture is the Australian GEHR (Good Electronic Health Record) project. This initiative started from the earlier European GEHR (Good European Electronic Health Record) project funded by the European Commission, and run by the openEHR Foundation (according to the Open Software Foundation agreement) [12]. It is a problem-oriented approach.

Also the GEHR/openEHR approach is based on the globally accepted HL7 RIM. The models are expressed using the Unified Modeling Language (UML) grammar. The GEHR specification process consists of two parts: the GEHR Object Model (GOM) as a reference model delivering the EHR information container needed on the one side and the GEHR meta-models called Archetypes for expressing the clinical content on the other side. Therefore, GEHR/openEHR provides a dual-model approach. The meta-models bear the medical knowledge in the sense of specific views and restrictions related to healthcare specialties, specific structures and conditions at the organizational level, or even person-specific items. For expressing the constraint models as domain-specific knowledge representation, the Archetype Definition Language (ADL) is used. Regarding RM-ODP, both the information view and the computational view are supported by the current GEHR approach. There are some relations between CDA documents and Clinical Templates on the one hand and GEHR Archetypes on the other.

6. EN 13606 "Electronic Health Record Communication"

The first international standard that dealt with the architecture of EHRs was CEN ENV 13606 "Health Informatics – EHCR Communication" established back in 1999. It first represents a structural approach. The currently valid specification consists of four parts: Part 1 "Extended Architecture", Part 2 "Domain Term List", Part 3 "Distribution Rules", and Part 4 "Messages for the Exchange of Information" [14]. The extended component-based EHR reference architecture is mandated to meet any requirements throughout the EHR's complete lifecycle.

According to CEN ENV 13606, an EHR comprises on the one hand a Root Architectural Component (RAC) and on the other hand a Record Component established by Original Component Complexes (OCC), Selected Component Complexes, Data Items, and Link Items. The OCC consist of four basic components: folders, compositions, headed sections, and clusters, which all can be combined in partially recursive ways. Everything has been defined in one single architectural model, thus characterizing ENV 13606 as the one-model approach.

According to the CEN rules, a CEN ENV must be evaluated again after three years to cancel it in case it's obsolete, to adopt it as it is – now as a European Norm (EN) – or to revise the specification. CEN ENV 13606 is currently under revision to resulting in the five-part EN 13606 "EHR Communication" [14].

The scope of EN 13606 has been extended as follows. In addition to traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and web services. Communication is not only supported inside and between EHR systems but also with other applications and components such as middleware services, moving towards an architecture-centric approach with alerting and decision-support services, agent components including workflow management systems.

The revision is realized re-using other developments and efforts, thereby supporting a convergent strategy between different approaches. Completely changing the old paradigm, now the GEHR/openEHR dual-model approach has been followed. In most of the EN 13606 parts, meta-models will be provided following UML and XML specifications. For aforementioned harmonization reasons, the four-part standard will be rearranged and extended to five.

Part 1 – Reference Model: It provides a generic information model for communicating the electronic health record of virtually any patient, as a refinement of ENV13606 Part 1.

Part 2 – Archetype Interchange Specification: This part describes a generic information model and language for representing and communicating the definition of individual instances of Archetypes.

Part 3 – Reference Archetypes and Term Lists: It offers a range of Archetypes reflecting a diversity of clinical requirements and settings, as a "starter set" for adopters and to illustrate how other clinical domains might similarly be represented (for example by health professional groups), plus relevant enumerated lists (normative or informative) supporting the other parts of this standard. This part will draw on ENV13606 Part 2.

Part 4 – Security Features: It comprises the information model concepts that need to be reflected within individual EHR instances to enable suitable interaction with the security components that are anticipated to be required in any future EHR deployment. This part will draw on ENV13606 Part 3.

Part 5 – Exchange Models: It's a set of models that build on the above parts and can form the basis of message-based or service-based communication, fulfilling the same role as ENV13606 Part 4.

EN 13606 is solely based on the HL7 RIM, a set of data type definitions harmonized between HL7 and CEN, the EHR Domain Information Model and a bunch of Refined Message Information Models dedicated to certain structures and functionalities. The project is focused on structural aspects expressed through platform-independent information models including some conceptual issues represented by the deployed archetype examples. However, it ignores the remaining RM-ODP views, including behavioral aspects of EHR systems.

Figure 4 demonstrates the Reference Model's Extract Package, which is the crucial concept for communicating EHRs. Nevertheless, this Extract concept also meets the EHR architecture requirements in general via the aggregation of all possible EHR Extract instances forming a comprehensive EHR.

7. The CORBA Model Driven Architecture

Within the Object Management Group authorizing CORBA (Common Object Request Broker Architecture), the component paradigm of the European projects was first established in the late nineties. The concepts of Portable Object Adapter (POA) enabling flexible invocations of services, the CORBA Component Model (CCM) with its integrated object persistence, transactionality, multiple interfaces, security, etc., the Metaobject Facility (MOF) and the Model Driven Architecture (MDA) methodology with platform-independent models and platform-dependent derivates which both can be instantiated are the essential building blocks of the latest CORBA 3 methodology applicable for advanced EHR systems. To reflect every single aspect of any application including all ISO RM – ODP views and both the static and dynamic behavior, the meta-models must span not only the range of platforms, but also the range of domains and businesses. For that reasons, MOF has to be based on a comprehensive dictionary regarding the applications. For data the same role is played by the Common Warehouse Metamodel (CWM) [15, 16].

Combining the Generic Component Model approach based on the RM-ODP standard, and the OMG MDA, model-driven, service-oriented and self-organizing information systems architectures can be defined enabling the architectural paradigm introduced for meeting the challenge for future-proof health information systems including EHR systems as shown in Figure 5.

8. Discussion

In the paper, different architectural approaches to health information systems in general and to EHR systems in particular have been presented. They have been evaluated and compared using the Generic Component Model which is based on ISO standards and CORBA developments including their enhancement. While the Generic Component Model provides a general approach for simplifying complex systems covering their structure, their behavior, and their domain-specific concepts as well as knowledge representation, the GEHR/openEHR project is focused on the knowledge and concept representation, and EN 13606 follows first the structural model of the underlying CEN ENV, moving up some conceptual aspects of archetype examples deployed. The architecture-independent HL7 approach first ignored any structural or conceptual aspects of application systems. The early phase of modeling the HL7 artifacts has been determined by the trial of reflecting the existing specification using the new way of representation and ignoring funtional aspects of architectures, which of course failed. Then HL7 has moved to a problem-oriented approach, sensitively dealing with functionalities first by introducing an act and modeling trigger events as well as controls. The activity-driven HL7 Version 3 concept was born. Recently moving to a multi-model approach within one domain, the information domain, a multi-domain approach as well as concept thoughts came in with HL7's EHR-related efforts of CDA and especially of the HL7 EHR-S Functional Model. This process has been accompanied by evolving the HL7 MDF towards an architectural unified process – the HL7 HDF.

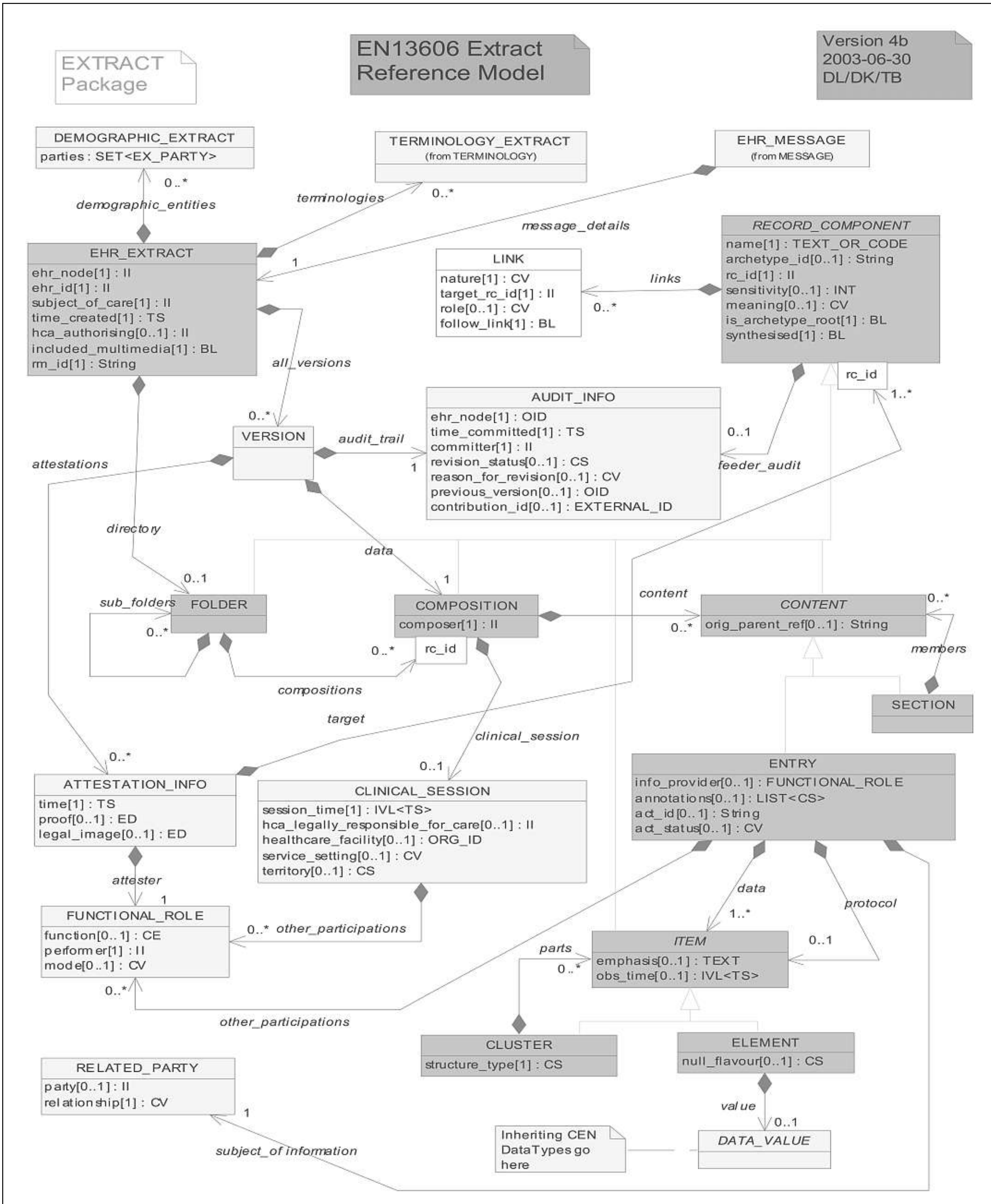

Fig. 4 The extract package defined in EN 13606-1 [14]

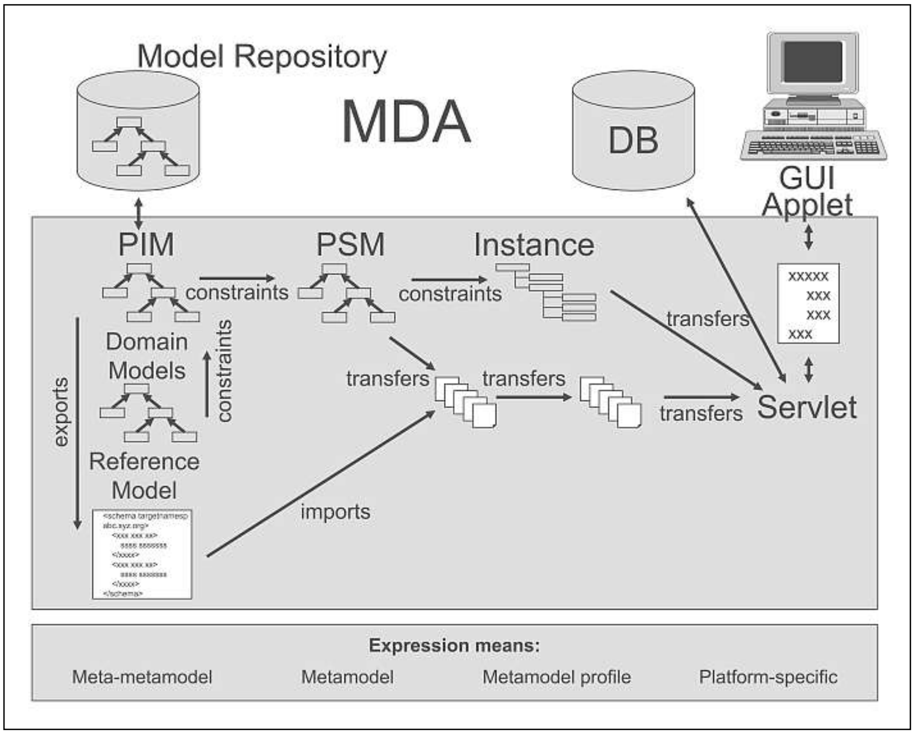

Fig. 5 Model-driven, service-oriented and self-organizing health information systems architectures

Terminology and ontology representing a single domain in the Generic Component Model are inherently covered in the GEHR concept and here as well as in the other approaches related to the SNOMED stuff. In any case, approach-specific work on terminology has been provided in every case.

9. Conclusions

While traditional specifications for health information system architectures have deployed the one-model approach, all advanced solutions presented refer at least to the dual-model approach. The one-model approach reveals some essential weaknesses and problems related to technical, complexity, and management issues [6, 13].

Considering the technical problems of the one-model approach, the mixture of generic and domain-specific knowledge concepts with their own expressions, but also weaknesses in basis class stability must be mentioned. Regarding the complexity problems, the size of the resulting model leads to difficulties in managing so many concepts in parallel, in completing the model which might be unachievable, in standardizing such models and in providing interoperability due to the needed agreement on a huge number of aspects and details.

Related to the management of the one-model approach, different developer and user groups dealing with their own concepts expressed in their specific language must be managed, combined and harmonized. Both EN 13606 and GEHR offer a dual-model approach. The generic part of the EHR concepts concerns the grammar of the IT-system domain which is specified by computer scientists. Health domain-specific concepts representing the domain knowledge are typically specified and maintained by medical experts. In the HL7 case, also the reference model is a domain-specific one. Both groups are characterized by their own terminology and their specific way of thinking, even if both are referencing SNOMED. The dependency of both groups results from the fact that there is only one common development process using a single formalism [6].

Considering the process evolution, on a longer term all approaches will move towards the multi-model approach offered by the Generic Component Model and increasingly narrowed by HL7 Version 3 (not the current CDA that still ignores functionalities expressed by system behavior and is restricted to document-related structures at least in actual specifications). Therefore, HL7 Version 3 is a very advanced approach geared towards semantically interoperable health information system architectures within the international standards world. Nevertheless, close collaboration between Standards Development Organizations (SDOs) and many commonalities in process and basic concepts in general provide convergence between existing projects and paradigms. So, all of the 13606 container classes meanwhile have a corresponding HL7 Act classCode.

Compared with the Generic Component Model, the GEHR/openEHR approach deals with the information viewpoint and some computational aspects based on computation-independent process and concept models according to the enterprise view. It also considers conceptual granularity issues. While the RM-ODP viewpoints in EN 13606 have been managed similarly to GEHR/openEHR, the originally structural granularity has also been extended to conceptual aspects. In both approaches, the enterprise architecture challenge has been ignored more or less. This is also true for the current status of HL7 advanced Version 3 approach, nevertheless aiming to offer most of the features defined in the Generic Component Model.

CORBA's MDA/SOA and even more the proposed approach of the Generic Component Model open the door towards self-organizing health information systems in the sense of an autonomous computing approach. Combined with mobile computing and pervasive computing, the environment for ubiquitous computing needed in personal health settings becomes feasible. First demonstrations of autonomous systems in health have already been successfully implemented in 1999 within the European HARP project [17]. Meanwhile, this advanced process towards Autonomic Computing has been matured within the authors' recent and new affiliations [18].

Contrary to the most advanced concepts presented in the paper, HL7 Version 2.x has been widely introduced and has evolved slowly over a long time. Even if backwards compatibility cannot be guaranteed any more, HL7 Version 3-based applications are an important part of many countries' national health telematics programs. While complexity and educational challenge of semantically interoperable solutions is rather high [19], the multi-model approach allows for the involvement of specialists from many different domains, providing a fruitful environment for future-proof solutions.

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Correspondence to:
Bernd Blobel Ph.D., Associate Professor
eHealth Competence Center
University of Regensburg Medical Center
Franz-Josef-Strauß-Allee 11
93042 Regensburg
Germany
E-mail: bernd.blobel@ehealth-cc.de
http://www.ehealth-cc.de