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Abstract

Starting as a rather simple message standard to be used within hospitals, the scope of HL7 has been extended to covering all domains and institutions in health. The most important development of the HL7 standard set was its development towards a model-based message specification methodology and the further movement towards a unified development process: HL7 Version 3. The focus was design for interoperability, which is also the driving aspect of architectural standards such as OMG's CORBA or the CEN EN 13606 Electronic Health Record Communication. The paper gives an overview about the HL7 standard set, comparing it with the principles of advanced information systems architecture.

Keywords:
Health telematics; HL7, Model driven architecture; Electronic health record architecture

1. Introduction

The health systems of all industrial countries are faced with the challenge of improving quality and efficiency of health delivery. The way for meeting these requirements is the introduction of shared care, which is bound to extended communication and cooperation 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' behaviour and functions. Therefore, the application architecture defines the level of interoperability and usability of applications. An 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 Records (EHRs). That information can be used for many different purposes by many different departments and their applications. Following, the EHR is called the core application in healthcare settings.

The paper investigates HL7 from the aspect of advanced interoperability.

2. The HL7 Communication Standard

Following, the HL7 communication standard will be shortly discussed. For more information see [1-4].

2.1 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 which can be done at different levels of interoperability: At the lowest level, mechanical plugs including the voltage and the signals used have been harmonised. We are talking of technical interoperability. At the next level, the data exchanged have been standardised providing data level interoperability. Nevertheless, different terminologies might be used. Therefore, at the next level, terminology must be agreed on. For realising a common understanding, the semantic of terms must be harmonised providing semantic interoperability. At the highest level, concepts and context of information exchanged are harmonised including the service realised 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 standardised.

HL7, an ANSI accredited standards development organisation 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 realize 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.

2.2 HL7 Version 3

HL7 Version 3 means much more than being a new version in the course of development of the standard. HL7 Version 3 follows a new paradigm. And 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?

2.2.1 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 Framework1 (MDF) covering the whole life cycle of the standard specification from development through adaptation and maintenance up to the implementation, use and testing of messages. 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 modelling. 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

[1] 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).

- Introduction of model-based specification of messages on the basis of a Reference Information Model (RIM).

2.2.2 HL7 RIM

The development of HL7 Version 3 has been performed in different phases characterised by important changes. In the first phase, the RIM has been a presentation of all the 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 modelled 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 have been specified but no operations. Because all instances specified in the standard have been defined as RIM object classes, the HL7 modelling approach was a one model approach. Problems bound to that approach became obvious in extensions performed, 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 specialisations:

Entities, i.e. the physical information objects or better the actors of the domain (e.g. organisation, 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 Relationships to manage interactions 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, ID. It is obvious that the core classes for Roles and Participations are specialisations of the corresponding entities, whereby Roles represent competence-related specialisations and Participations represent action-related specialisations.

2.2.3 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 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 specialisations, state diagrams or state transition diagrams are used. After reaching clarifications on the general issues of messages, we may proceed to specify specific messages. Starting point is always the HL7 RIM.

2.2.4 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, organisational, functional, and technological conditions in the related communicating application domains, i.e., of their policies, their concepts, rules, and the knowledge.

For developing domain-specific messages therefore, 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 (DMIM).

2.2.5 Reusable Message Fragments - the CMETs

This short introduction clearly shows the complexity of the method. Furthermore, such messages across domains are hardly to standardise. In that context, certain classes, their specialisations and associations are described as domain-specific information model. If those models of characteristic objects und their relations can be standardised, 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, so enabling interoperability at the level of concepts and knowledge.

Use cases (scenarios) or their verbal variant – the story board are the starting point for message development in HL7 version 3. The harmonisation between globally active developers and implementers at the one hand and the continuous extension regarding the involved domains (chapters) at the other hand is realised via a unique reference model of health care – the HL7 Reference Information Model (RIM). Besides that generic RIM as well as its domain-specific specialisation as the Domain Message Information Model (DMIM), the Refined Message Information Model (RMIM) can be derived. Dynamic and procedural aspects are described using sequence diagrams, state diagrams, activity diagrams, etc.

2.2.6 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 exchange format" must be provided. One opportunity for doing that has been given by the XML Standard Set with its XML Metadata Interchange (XMI) specification as described, e.g., in [5]. Another way is the use of specific tools as practised in HL7. Please mention that not only a UML-like graphical modelling is used by the HL7 community, but also special tools such as Rose Tree© and Microsoft's Visio© (stencils) for message design via Refined Message Information Models (RMIMs) (e.g. for correct, RIM-adequate modelling 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 (Specialisations), 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 a self-developed schema generator.

2.2.7 Specialisation vs. Standardisation

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

2.2.8 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. This includes besides mandatory data also 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.

2.2.9 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, [7]), which is the globally established image communication standard. Contrary to HL7, DICOM realises 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 the 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 CDA Level 2 are especially important.

2.2.10 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 standardised.

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 part 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 artefacts 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.

3. Conclusions

HL7 Version 3 evolved towards a standard set developed according to the clearly defined process, the HDF. All components and functions of architectural standards have been meanwhile established such as reference models and terminologies (RIM, vocabulary), domain-specific references (DMIM), building blocks (CMETs), implementation rules (application roles, ITS) as well as conformance statements for providing practical semantic interoperability. All architectural views needed are meanwhile defined in HL7 Version 3 starting from scenarios up to maintenance and education, including the tools for automatically or at least semi-automatically to define the pieces and aggregate them to running systems [4].

4. References

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