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Using Archetypes for Defining CDA Templates

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Abstract. While HL7 CDA is a widely adopted standard for the documentation of clinical information, the archetype approach proposed by CEN/ISO 13606 and openEHR is gaining recognition as a means of describing domain models and medical knowledge. This paper describes our efforts in combining both standards. Using archetypes as an alternative for defining CDA templates permit new possibilities all based on the formal nature of archetypes and their ability to merge into the same artifact medical knowledge and technical requirements for semantic interoperability of electronic health records. We describe the process followed for the normalization of existing legacy data in a hospital environment, from the importation of the HL7 CDA model into an archetype to obtain normalized CDA data instances.

Keywords. Archetype, HL7 CDA, Clinical model, Electronic health record.

Introduction

One of the barriers to the adoption of standards for semantic interoperability of health information is the existence of different norms covering the same or similar scope. Each of them has its own advantages and disadvantages, but, is there a way to combine some of the characteristics of those standards to improve their usage? The work reported in this paper shows how a cooperative approach can be used between two of the most prominent international standards for semantic interoperability of clinical information. On the one hand the HL7 Clinical Document Architecture (CDA), that currently is the most widely adopted standard for the representation of clinical information in the form of XML documents. On the other hand, the dual model approach of CEN/ISO 13606 and openEHR, based on the use of a Reference Model (RM) for representing data instances and an Archetype Model (AM) for representing clinical concepts.

The proposed approach combines both standard, by using archetypes as template definitions of HL7 CDA documents. Current template model used by HL7 v3 has some limitations that could be solved by using archetypes. To mention a few, templates provide limited reuse capabilities (they do not include an inheritance mechanism and only support the inclusion of references to external components by explicit naming

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them). They also provide a less elaborated definition of the semantics of the clinical model (only by constraining an attribute code to a particular coded value) and do not support multilingualism either. Finally, the constraining expressivity of templates is limited in comparison with archetypes (only lists of possible values can be defined for primitive types) [1].

Previous experiences combining archetypes with CDA documents were centered in the problem of harmonization between the CDA reference model and the openEHR reference model [2][3]. This approach required a big effort for the definition of mappings between different reference models, which might be extremely difficult. In contrast, our proposal is focused on demonstrating the benefits of the archetype approach by directly constraining the CDA RMIM, not entering into the issue of transformations between different standards.

With a similar philosophy, several efforts have been initiated in the international community, under the generic name of Detailed Clinical Models (DCM) [4]. In late 2011, a joint effort under the Clinical Information Model Initiative (CIMI) agreed on using the archetype approach as the technical approach for defining clinical models [5]. All these efforts tend to work on the basis of a generic RM, compatible with any standard RM. While it is still to be seen the feasibility of this approach, the use of archetypes directly over HL7 CDA represents a first step to it.

1. Methods

1.1. HL7 CDA

HL7 CDA [6] defines a model for the persistence of clinical documents based in the HL7 v3 Reference Information Model (RIM). A CDA document is an XML that can contain any kind of clinical content in a narrative form (in XHTML) and also structured in coded entries such as Observation, Procedure, Organizer, Supply, Encounter, Substance, Act, etc.

Given that HL7 CDA has a generic structure, a mechanism is needed for defining specific schemas or document types. This role is covered by templates. A template is a definition (usually in the form of Schematron or implementation guides) that describes a configuration or combination of the CDA classes, and constraints on the attribute values. It gives instructions and validation rules for the creation of specific CDA instances for a particular clinical domain.

1.2. Archetypes

The archetype approach or dual model architecture is currently part of CEN/ISO 13606 norm [7] and the openEHR specifications (www.openehr.org). Archetypes are definitions of domain-level concepts (clinical models) in a formal syntax, which provide a powerful, reusable and interoperable mechanism for managing the creation, description, validation and query of EHRs. For each domain concept, a definition can be developed in terms of constraints on structure, types and values of classes of an object-oriented (OO) reference model. Examples of archetypes include prescriptions, health problems, differential diagnosis, pregnancy reports or blood pressure observations. With the appropriate tooling, health professionals can interpret and define archetypes directly, without the intervention of technical people. Archetypes are

reusable (they can be specialized to better fit the requirements or be aggregated to create more complex archetypes). Archetypes are also multilingual; they can be defined in different languages for human readability. Finally, archetypes serve as a link between an information structure (reference model) and the terminologies or ontologies that semantically describe that information.

1.3. LinkEHR Studio

The work reported in this paper has been developed using LinkEHR Studio (www.linkehr.com), a tool for the definition of archetypes. LinkEHR Studio is able to import any reference model and use it for defining archetypes. The second functionality of this tool is to help in the transformation and normalization of existing legacy data into standardized data that are compliant with both the reference model and the archetype definitions. Detailed information about LinkEHR can be found at [8] and [9].

1.4. Methodology description

The methodology used is based on three basic steps. First, it is needed to agree on the information that is desired to be modeled into the archetypes. In the second step, the HL7 CDA RM in the form of its official XML Schema is imported into LinkEHR. After analyzing it, the tool will be able to define new archetypes based on that RM. Finally, the third step consists in defining mappings between the archetypes and the legacy data schemas. LinkEHR Studio will automatically generate a transformation script that can be used to normalize and transform existing data into CDA documents.

2. Results

The proposed approach has been applied to support the continuity of care for patients with Chronic Kidney Disease (CKD) within the Hospital Universitario Virgen del Rocío (HUVR). When patient is diagnosed CKD by the nephrology department, they receive their hemodialysis sessions in the hospital until they are stable. Once they are stabilized, patients are transferred to external centers to receive hemodialysis sessions.

HUVR has an EHR that contains more than 1.7 million patient records, 9.5 million encounters and 6.8 million reports and test results. This project aimed to increase the HUVR capability of monitoring the treatment received by more than 500 patients in 8 external centers. The project will provide a solution for accessing patients' existing information from external centers. As a consequence, it is expected to improve patient safety with reduction of medical errors and variability in clinical practice.

2.1. Information structures definition

The first step of the project was to define the clinical information data sets to be used. Health professionals selected the set of information needed for the CKD scenario, based in their knowledge of the domain. In our case, the information to be shared was defined by HUVR nephrology department, in order to inform the external centers about the patient hemodialysis session settings, including also the most relevant information as patient record summary and laboratory results.

2.2. Archetype development process

After analyzing the information specified by the nephrology department and having the HL7 CDA RM imported into LinkEHR, three different main archetypes were defined, namely Referral Document, Hemodialysis Prescription and Hemodialysis Monitoring. Generic archetypes for CDA Header, Observation, Organizer and SubstanceAdministration entries were also defined in order to be specialized in specific contexts later on. For instance, the generic Observation entry archetype determined types of data, codes and terminology applied in that entry. Furthermore, it assigned moodCode, classCode, templateId and codeSystem. This generic Observation entry archetype can be reused and specialized as many times as required to cover all the required concepts that nephrology department defined. In the specialization process the entry was constrained to a specific displayName and code of the selected terminology. Given that the entry value usually depends on the specific patient, in most cases the specialization only assigned a data type.

2.3. CDA archetype mapping to legacy data sources

Using LinkEHR Studio, the primitive attributes of the archetypes were mapped to the data source schemas. Once those mappings were finished, the tool automatically generated an XQuery script that transforms XML instances of legacy data into normalized XML CDA instances. This script was deployed at the EHR system and is executed each time a hemodialysis-related document is requested.

3. Discussion

3.1. HL7 CDA reference model support

LinkEHR Studio has the ability to import any XML Schema as the definition of a RM, to be used afterwards for the definition of clinical archetypes. As explained before, while an archetype defines constraint over an OO RM, HL7 CDA XML Schema is a document-oriented model. This made necessary to make some decisions on how to adapt the XML Schema specifications to a pure OO model during the importation process of the Schema into the tool.

For example, the "Choice" structure in XML Schema allows the definition of alternatives of elements even if both are also defined as mandatory (e.g. a choice between structuredBody and nonXMLBody). In an OO model, these elements become optional attributes of a class, so that it becomes a responsibility of the archetype designer to decide which one will be the mandatory.

3.2. CDA archetype definition and deployment

The adopted approach favored faster development of CDA and consistence across entries and documents. As it was previously identified by [1], the archetype approach adds inheritance and nesting capabilities as well as improved semantic definition capabilities that can successfully be applied to the CDA RM. For instance, based on the close relationship between hemodialysis prescription and hemodialysis monitoring documents the archetype reusability ratio is more than 50%. As a consequence, the amount of time saved in the development of these documents has been significant.

Although the archetype development process is usually simple, if generic archetypes were already published to be reused, the development would have been close to straightforward. As a consequence it might be recommendable to publish HL7 templates also in archetype format in order to reuse the knowledge of the implementers' community. Moreover, it will facilitate the definition of semantic structures in a computable format that is increasingly accepted in health informatics. Following this recommendation, we have published all the developed archetypes of this project at the CDA archetypes work group of the EN 13606 Association [10].

4. Conclusions

The developed work is a first step towards a framework for defining clinical concepts for different standards or reference models. Having archetypes as a basic semantic resource, new tools could be developed to automatically generate other useful resources such as Schematron validation scripts or implementation guides. Regarding the use of this approach in real deployments, the main barrier is to find an effective methodology for the governance of the clinical models in order to avoid re-definitions of concepts and maximize their reuse.

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References

- Bointer K, Duftschmid G. HL7 Template Model and EN/ISO 13606 Archetype Object Model A Comparison. Stud Health Technol Inform. IOS Press, 2009; 150: 249
- [2] Browne E. Archetypes for HL7 CDA Documents. October 2008 (pp. 1-9). www.openehr.org
- [3] Frankel H. Using archetypes with HL7 messages and clinical documents. HL7 Working Group Meeting. 2011
- [4] Goossen WT, Goossen-Baremans A. Bridging the HL7 template-13606 archetype gap with detailed clinical models. Stud Health Technol Inform. 2010; 160(2): 932-936.
- [5] Clinical Information Modelling Initiative. Press Release. Dec. 2011. http://www.openehr.org/326-OE
- [6] Dolin BH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A. HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc 2006; 13:30-39
- [7] ISO 13606-2:2008. Health informatics- Electronic health record communication- Part 2: Archetype interchange specification
- [8] Maldonado JA, Moner D, Boscá D, Fernández-Breis JT, Angulo C, Robles M. LinkEHR-Ed: A multireference model archetype editor based on formal semantics, Int. J. Med. Inform. 2009; 78(8):559-70
- [9] Maldonado JA, Costa CM, Moner D, Menárguez-Tortosa M, Boscá D, Miñarro Giménez JA, Fernández-Breis JT, Robles M.. Using the ResearchEHR platform to facilitate the practical application of the EHR standards. J Biomed Inform 2011; doi:10.1016/j.jbi.2011.11.004
- [10] http://www.en13606.org/resources/files/cat_view/54-work-groups/63-wg-8-cda-archetypes (Last Accessed May 2012)