Creating ISO/EN 13606 Archetypes based on Clinical Information Needs

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Abstract. Archetypes model individual EHR contents and build the base of the dual-model approach used in the ISO/EN 13606 EHR architecture. We present an approach to create archetypes using an iterative development process. It includes automated generation of electronic case report forms from archetypes. We evaluated our approach by developing 128 archetypes which represent 446 clinical information items from the diabetes domain.

Keywords. EHR, ISO/EN 13606, Archetypes, semantic interoperability

Introduction

Cross-organizational electronic health record (EHR) communication, which enables authorized healthcare providers to access all relevant patient data regardless of where the data were created, will constitute a key component of future health care. A key requirement for EHR communication is semantic interoperability. Semantic interoperability communicates meaning and hereby aims to ensure that the communicated information is understood in exactly the same way by the sender and the recipient [1]. The ISO/EN 13606 EHR architecture standard [2, 3] is a framework for achieving semantic interoperability. In February 2010, part 5 of 13606 was ratified by CEN and ISO as the last of 5 parts. Since then the complete 13606 has the status of an official European and International standard. ISO/EN 13606 is based on the dual-model approach which combines a static reference model and archetypes to represent EHR contents.

Archetypes are used to model individual EHR contents by constraining the reference model. They form an important layer for semantic interoperability between communicating EHR systems. When supported by suitable tools, the archetype concept allows medical domain experts and computer scientists to jointly and efficiently model EHR contents in a computer processable form.

In the following we present an approach to create ISO/EN 13606 archetypes using an iterative development process. It includes an automated generation of electronic case report forms (eCRFs) from archetypes which enables immediate testing and creation of

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EHR data compliant to the reference model and archetypes. We evaluated our approach by developing 128 archetypes which represent 446 clinical information items. These items were collected in an analysis of the information needs of physicians when treating diabetes patients [4].

The development of the archetypes as well as the analysis of information needs in the treatment of diabetes are parts of the EHR-ARCHE[2] project. In this project we examine to what extent dual-model based EHR architectures can support EHR users in selectively retrieving information that is relevant in their respective search context and thus avoid information overload.

1. Method

For the development of the archetypes we propose an approach which adapts an iterative software development model [5] to the archetype domain (see **Figure 1**). It extends an existing approach described in [6] in a way that adds an iterative archetype refinement and especially supports the participation of medical domain experts in the development of archetypes.

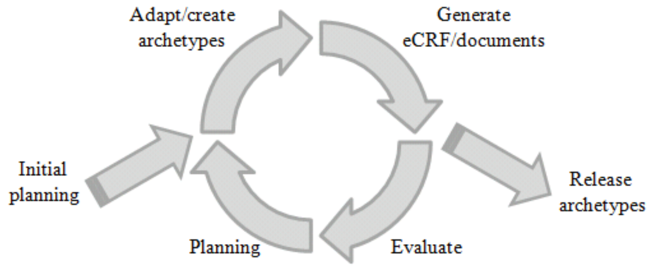

Figure 1. Iterative archetype development model. Based on the required clinical information items and existing archetypes the initial planning is done. Using the results of the planning step, archetypes are created and adapted. From these archetypes eCRFs are automatically generated that can be used to test archetypes and create test EHR documents. Based on the evaluation of the results, the required changes are planned and the cycle continues until the archetypes can finally be released.

1.1. Initial planning

The initial design of archetypes combines the first two steps of [6]. In the first step "Define high level archetype concepts", the medical concepts that should be described with archetypes have to be structured and organized. This organization can be done as a mind map or a table representing the hierarchical order. During this phase the medical domain expert and the computer scientist are working together very closely, hence a format that is understood by both parties should be chosen.

In the second step "Check for existing reference archetypes", archetypes that match the medical concepts are searched. By specializing existing archetypes uncontrolled growth of archetypes can be prevented and semantic interoperability with EHR systems which already use these archetypes is made possible. Furthermore existing archetypes already have numerous refinement and revision cycles, which make them a valuable source.

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[2] http://www.meduniwien.ac.at/msi/arche/

1.2. Creation and adaptation of archetypes

Based on the results of the planning new archetypes are created or existing archetypes are specialized and refined. The archetype coding is done by computer scientists. Even though we employ visual archetype editors in this step as recommended in [6], several properties of archetypes (e.g. inheritance, cardinalities) still remain rather unfamiliar for medical domain experts.

1.3. Generation of eCRFs and creation of documents

Extending the approach in [6], we apply a tool that allows on-the-fly eCRF generation from archetypes and thus the creation of archetype conformant EHR data. Using the well known concepts of forms and documents, medical domain experts can hereby more easily evaluate the archetypes, e.g. spot missing elements or wrong cardinalities.

Further the generation of an eCRF from an archetype ensures a formal correctness of the archetype in various facets. The correctness of the archetype definition language (ADL) specification [2, 3] of the archetype and the conformance to the reference model and data types are typically already checked in the archetype editor. Our tool further checks whether external archetypes referred to in slots and specializations are present, and whether archetype node names, translations, and term bindings are correctly defined.

Both, the testing of archetypes via eCRFs and their formal verification are means to improve the quality of the archetypes.

1.4. Evaluation and planning

The evaluation step may lead to further planning and refinement of the archetypes. The evaluation relies on the information obtained during the formal verification of the archetype and the information obtained by the medical domain expert when applying the eCRFs. The results of the evaluation flow into the next development cycle. The latter starts with planning the required changes. This step needs a close collaboration between the computer scientist and the medical domain expert.

1.5. Release Archetypes

After the last adaptations have been made the archetype can be released. OpenEHR archetypes should be submitted to the Clinical Review Board of openEHR. For ISO/EN 13606 no such infrastructure exists yet it is important that all partners exchanging information based on the ISO/EN 13606 standard have access to the archetypes to enable semantic interoperability.

2. Results

The initial planning was based on 446 clinical information items which were collected in an analysis of the information needs of physicians when treating diabetes patients [4]. These information items were structured hierarchically, i.e. higher level groupings of related finer-grained items were already identified in this step.

Based on this hierarchical list, existing archetypes were searched. For ISO/EN 13606 no archetypes are publicly available, hence we could only rely on openEHR archetypes. Available resources included the openEHR Clinical Knowledge Manager[3], the openEHR SVN repository[4] and the NHS SVN repository[5]. For roughly one quarter of the clinical information items existing openEHR archetypes were found.

Originally we planned to convert the existing openEHR reference archetypes into ISO/EN 13606 archetypes using [7] and specialize these archetypes according to our requirements. However, we finally decided to refrain from this idea. The main reason was that the openEHR approach includes the concept of templates, which allows existing archetypes to be further constrained and thus customized for local purposes. As a result openEHR archetypes are designed to include the maximum set of potentially relevant items for a particular medical concept. The ISO/EN 13606 standard however does not support the template mechanism. Therefore we would have had to reduce the typically extensive openEHR archetypes to those few items relevant for our context by specializing the converted openEHR archetype and setting the cardinality of most items to zero. As this seemed as a laborious and also not really convincing approach, we decided to create our own set of archetypes and replicate those structures of existing archetypes that were relevant in our context. Still, the openEHR archetypes found were a valuable source during the archetype creation and complemented our clinical information items.

Archetypes were imported into a tool developed in the course of the EHR-ARCHE project which allowed the automatic generation of eCRFs (compare section 1.3). The documents collected via the eCRFs can either be stored locally during testing or synchronized with an IHE XDS [8] repository using the SENSE [9] framework.

The creation of the test documents and the evaluation using the eCRFs was done by a medical domain expert located in Hall/Tyrol. The results were documented using a text file. Computer scientists in Vienna created and adapted the archetypes for the next iteration cycle based on this information.

Our approach was tested with 128 ISO/EN 13606 archetypes that represent 446 information needs. The archetypes were created using the linkEHR archetype editor [10] and translated to German and English. The composition of archetypes (350 times) using the ADL slot mechanism and specialization of archetypes (40 times) were intensively employed. In **Figure 2** this is illustrated for the “family history” archetype.

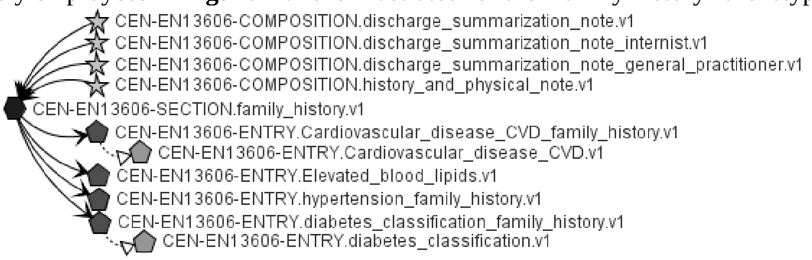

Figure 2. Example of “Family History” archetype. This archetype occurs in 4 COMPOSITION archetypes as slot and has 4 ENTRY archetypes referenced via slots (black line and dark arrow). Two of these ENTRY archetypes are specializations of other ENTRY archetypes (dashed line and white arrow).

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3 http://openehr.org/knowledge/

4 http://www.openehr.org/svn/knowledge/archetypes/

5 https://svn.connectingforhealth.nhs.uk/svn/public/nhscontentmodels/TRUNK/cm/

In our test setting the medical domain expert and the computer scientist were geographically separated. After the initial planning where a close collaboration between the two was needed, all other steps were done asynchronously which allowed free time management for both parties. At the average each archetype underwent 2 – 3 development cycles.

3. Discussion and further steps

In our method for archetype development we emanate from an approach described in [6]. In particular, our steps Initial planning, Creation and adaptation of archetypes, and Release Archetypes are conformant to [6]. We extend their approach by adding the concept of an iterative archetype refinement which is derived from general software development models. Further we added the steps Generation of eCRFs and creation of documents as well as Evaluation and planning to the development process. By automatically generating eCRFs from archetypes and creating EHR documents via the eCRFs, medical domain experts could easily evaluate the archetypes. The iterative archetype refinement then provided for the integration of changes identified in the evaluation. These additions of the approach proved useful for the integration of medical domain experts in the development of archetypes and helped to raise the archetypes' quality.

Several tools have been published for the automatic creation of eCRFs from archetypes [11-13]. We decided to develop our own tool, as we needed a 13606 environment instead of an openEHR one [12]. We further did not want to be limited by the conditions of a particular EHR system in which the eCRFs are created [11]. The system described in [13] came closest to our needs. However, we desired a direct integration of the tool in our IHE XDS environment to enable immediate processing of the EHR documents created via the eCRFs.

We identified a problem in our method when trying to reuse openEHR archetypes in the context of the ISO/EN 13606 standard. As explained in section 2, openEHR archetypes typically cover the maximum set of potentially relevant information items for a medical concept. They are then "reduced" to the needs of a particular setting via openEHR templates. As the template concept does not exist in the ISO/EN 13606 standard, openEHR archetypes are frequently too "overloaded" for an efficient reuse in a 13606-based domain. Although we replicated relevant parts of the openEHR archetypes in our ISO/EN 13606 archetypes, we hereby lost the formal relation to the source archetypes.

We developed an archetype repository in which we stored all 128 archetypes. During further progress of the EHR-ARCHE project we plan to offer public access to the archetype repository via the project homepage. In the next step of the project we will create a set of EHR documents based on our archetypes. These EHR documents will later form the test set for selectively retrieving relevant information in a particular search context by means of an archetype-based query mechanism.

Acknowledgement

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