Managing Archetypes for Sustainable and Semantically Interoperable Electronic Health Records

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Abstract

Background: *With the release of openEHR Version 1.0 a common Electronic Health Records (EHR) architecture has been defined to pursue the aim of semantic interoperability of Electronic Health Records. Archetypes as clinical content models play a key role in this approach, but their development and maintenance needs to be managed by Knowledge Governance in order to avoid incompatibilities.* **Objectives:** *To analyse the functional requirements for supporting Domain Knowledge Governance with Information Technology (like authoring or updating archetypes) and present a prototype implementation.* **Methods:** *Requirements analysis using the Unified Modeling Language (UML) and incremental prototyping. A series of archetype workshops were also conducted.* **Results:** *For a web-based Archetype Repository, a total of four top-level use cases and 23 refining use cases for 5 different actors were found to be essential. A prototype implementing some of these use cases has been developed and an example process for the coordinated development of archetypes defined.* **Discussion:** *We believe that Domain Knowledge Governance is necessary independent of the actual approach and methodology chosen for EHR systems. Appropriate information technology is required to support a clear process for authoring archetypes.* **Conclusion:** *High-quality archetypes with high-quality clinical content are the key to semantic interoperability of clinical systems. Domain Knowledge Governance is the key to high quality archetypes. A comprehensive Archetype Repository will render comprehensive Domain Knowledge Governance feasible and efficient.*

Keywords: Electronic health records, *open***EHR, archetypes, semantic interoperability, computerized medical record systems**

1. Introduction

With patients being increasingly mobile and treatments and health care providers increasingly specialized, interoperability of Electronic Health Records (EHRs) has become critical for sustaining current processes. Patient data can be relevant for over 100 years, thus interoperability and sustainability of patient data is critically important. Not only will sustainability and interoperability save money, we also expect a significant positive clinical impact (cp. e.g. [1]). According to

Haux, a lot of research and application is necessary to further develop and investigate architectures and infrastructures for Health Information Systems, in order to identify sustainable approaches [2]. With the release of the *open*EHR 1.0 specifications (http://www.openEHR.org) in 2006, there is a common information and knowledge model for Electronic Health Records available that is believed to be able to solve some of the still prevailing problems of semantic interoperability and sustainability of clinical systems. It can also provide a common basis for decision support, data mining and other requirements in the health sector. Standardising knowledge is essential for achieving semantic interoperability between systems, and in general standardizing documentation systems means standardizing the underlying terminology system [3]. This in turn means standardizing concepts, relations between concepts and the linguistic designations for these concepts [4]. This is often done by creating Clinical Data Sets and is a tedious task - simply put, the bigger the scope or the applicable region, the bigger the effort [5]. More and more stakeholders in Australia and internationally choose archetypes as a means to define clinical knowledge [6]. Archetypes [7] are models of clinical concepts, for example an archetype on blood pressure measurement would comprehensively and formally describe what a clinician needs to know about a blood pressure measurement, including its clinically safe interpretation.

In 2005, we defined 'Domain Knowledge Governance' as comprising

"…all tasks related to establishing or influencing formal and informal organizational mechanisms and structures in order to systematically influence the building, dissemination, and maintaining of knowledge within and between domains." [5]

We argued that systematic Domain Knowledge Governance is essential to achieve semantic interoperability [8]. In addition, in order to adequately support systematic Domain Knowledge

Governance, we believe that sophisticated Information Technology support is essential. Domain Knowledge should ideally be governed with an international scope, and the key experts in each clinical field should be consulted to develop comprehensive and high-quality archetypes. These experts also need to work in an interdisciplinary cooperative way with other experts – depending on the scope of the archetype under development. Developed archetypes need to be reviewed by other experts to ensure their completeness and relevance to evidence-based clinical practice.

In this context, the aim of this paper is to

- analyse the functional requirements for supporting Domain Knowledge Governance with Information Technology on the basis of archetypes.

- present a prototype implementation for a web-based Archetype Repository to manage the authoring and updating of archetypes.

2. Methods

In order to gather the requirements for the development of an archetype repository which provides comprehensive support for archetype development cycles, we carried out a comprehensive requirements analysis. A series of workshops on archetype development for clinicians were conducted by two of the authors (Garde, Hovenga) and among many other activities an archetype "road show" was conducted by Heard. Based on this, as well as face-to-face and telephone discussion with members of ISO/TC 215, the EHR Taskforce of the European Committee for Standardization (CEN), IT14-9 the Standards Australia Electronic Health Record Committee, and founding members of the *open*EHR Foundation, we were able to establish a set of requirements for an archetype repository. To document the results of this requirement analyses and prototype specification we applied

the Unified Modelling Language (UML) to create an initial model capturing the requirements.

Several versions of a prototype Archetype Finder (which implements a subset of the required functionality) were developed to facilitate further refinement of the requirements for an archetype repository. The Archetype Finder was developed using the Web Ontology Language (OWL, [9]) and the Protégé OWL Plug-In [10] to develop and maintain an Archetype Ontology which provides the necessary meta-information on archetypes. In addition, we used Borland JBuilder 2006®, Java™ Servlet 2.3 Technology, and Apache Tomcat 4.1.31 as the servlet container.

3. High-level scenario

Figure 1 provides a high-level overview of the scenario for an Archetype repository. An Archetype Repository is used for three high-level functionalities:

- As a development space for archetypes
- As a governance space for archetypes
- As the prime source for archetypes

Once archetypes are developed they will usually be transferred to local Archetype Repositories that serve as the source of archetypes for any EHR application. Usually no modifications of archetypes would be made here – all localisations are made in 'Templates'. Templates are beyond the scope of this paper, but essentially Templates further constrain archetypes to make archetypes useful in a local environment without endangering semantic interoperability.

4. Actors

During our requirements analysis for the development of an archetype repository, we identified five primary roles (actors): Lead Developer, Reviewer, Unprivileged User, Archetype
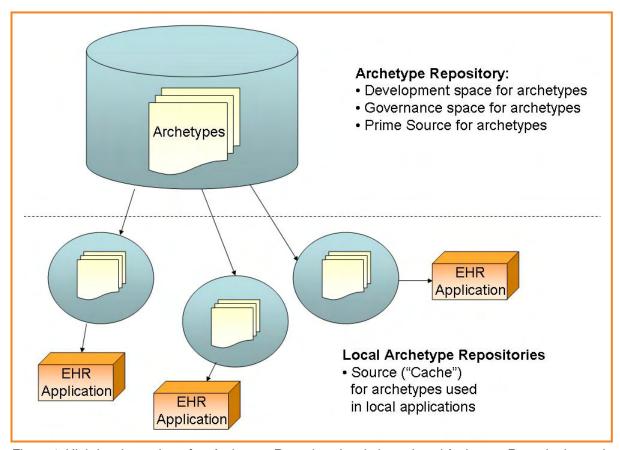
Figure 1: High-level overview of an Archetype Repository in relation to Local Archetype Repositories and EHR applications.

Admin and System Admin. These actors and their responsibilities are presented in Table 1.

These actors collaborate to identify areas of interest for archetype development, get the persons with the right expertise to lead to the development of archetypes in their area or contribute to it as a reviewer, etc.

5. Use Cases

The identified actors make use of the four top-level use cases presented in Figure 2.

5.1 Search archetypes

The capability to efficiently search for existing archetypes is a key requirement to support Domain Knowledge Governance. Without this, we endanger semantic interoperability by the development of overlapping and incompatible archetypes. This search has

Actor	Responsibility
Lead Developer	A lead developer is responsible for the coordination of the development/update of specific archetypes. The Lead Developer usually is the one to develop the initial draft for an archetype.
Reviewer	Reviewers are assigned to individual archetypes and review these archetypes, discuss them, and eventually approve them together with the archetypes.
Unprivileged User	Unprivileged user can usually only view or otherwise access published archetypes (archetype versions).
Archetype Admin	The Archetype Admin is responsible for identifying archetypes that are due for review or for other reasons need to be reviewed and assign appropriate Lead Developers and Reviewers to archetypes. An Archetype Admin can be Archetype Admin for all archetypes or a selection of archetypes.
System Admin	The System Admin is mainly responsible for appropriate user administration.

Table 1: Overview of the Actors of the system and their responsibilities during archetype development.
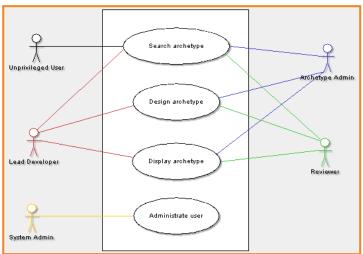
Figure 2: Top-level UML Use Case Diagram for the Archetype Repository.

to be based not only on data and metadata inherent in the archetypes, but also on additional meta-information on the archetype like its purpose or its applicability and relevance to a certain area in health. This ensures that people from the relevant areas can contribute to the development of new archetypes and ensure that existing archetypes are broad enough in scope to be relevant and useful for various areas in health care, thus improving semantic interoperability.

5.2 Design archetypes

The top-level use case to design archetypes is the most comprehensive and complex of the use cases presented. For this reason, we present a comprehensive use case diagram to support an integrated archetype design process in Figure 3.

5.3 Display archetypes

Displaying archetypes can serve different purposes and thus different approaches are required to fulfill the user needs. Firstly, for a simple presentation that is not cluttered with any technical or pseudo-technical information, is required for clinicians to have a quick look at an archetype and give feedback on the clinical aspects of the modeled archetype. For this, an HTML presentation of the archetype is a suit-

able solution. Secondly, for archetype lead developers with some understanding of *open*EHR and the archetype modeling philosophy, an Archetype Editor is required that makes the power of archetypes accessible. Thirdly, overview presentations to be able to quickly locate archetypes are required for reviewers and unprivileged users. Fourthly, an archetype workbench suitable for technicians to work with, for example to debug existing archetypes, is necessary.

5.4 Administrate users

This use case involves the background administration of users of the archetype repository. This use case is not explored in more detail in this paper but in the end comes down to conventional user administration including assigning of roles, background support etc.

6. Archetype Development Process

Figure 4 presents an example of a possible development process for a set of archetypes. Archetype admins define new areas for archetype development. They then find and assign lead developers to this area. Lead developers are content experts in this area and also to a certain degree familiar with

the archetype methodology. After the lead developer has defined an initial archetype or set of archetypes, reviewers are invited to give formal feedback and propose changes. Once the lead developer believes an archetype is sufficiently mature, s/he publishes the archetype draft for public comment by unprivileged users. Both reviewers and lead developers review the feedback and informal change proposals received and create formal change proposals that are discussed with fellow reviewers. The final decision in this particular scenario lies with the lead developer of the archetype. We call this approach flexible standardization. Other approaches such as formal vote on archetypes by lead developers and reviewers are possible (see also Figure 3).

7. Prototype Implementation

At present, considerable functionality of the 4 top-level use cases are implemented as prototypes:
- Use Case *Search archetype*: The Archetype Finder[1] (see Figure 5) currently implements most of the required functionality in this use case. However, currently archetypes are not being marked with a next review date and consequently archetypes due for review can currently not be automatically identified. The Archetype Finder is based on an Archetype Ontology developed and maintained using the Ontology Web Ontology Language (OWL, [9]) and the Protégé OWL Plug-In [10]. The user interface is automatically derived from this ontology, i.e. changes in structure and content of the Archetype Ontology are immediately reflected in the Archetype Finder.
- Use Case *Design archetype*: The editing functionality is implemented by the Archetype Editor. The Ocean Archetype
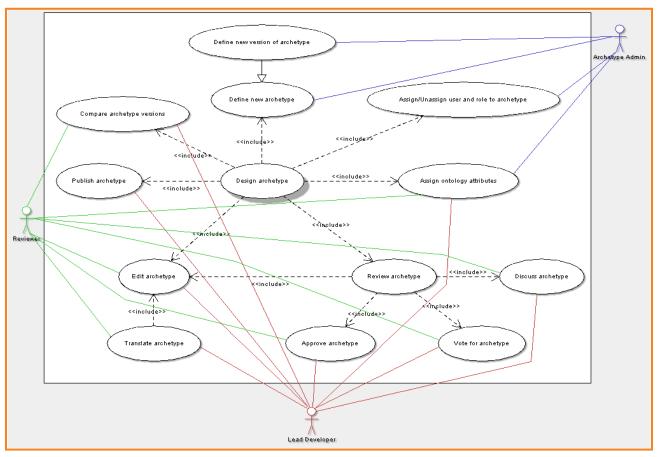
Figure 3: UML Use Case Diagram that details the Design archetype *use case.*

Editor is a tool to support the authoring of archetypes as part of the *open*EHR initiative and the CEN EHR standardisations. In addition, a Java-based Archetype Editor (http://www.imt.liu.se/mi/ehr/) developed by Linköping University, Sweden, as well as the Archetype Workbench provide support for this. Both the Ocean Archetype Editor and the Archetype Workbench are available at http://www.openEHR.org or precompiled at http://oceaninformatics.biz. However many design aspects apart from editing and translating archetypes, for example comprehensive review functions, approval and publishing mechanism, are

so far not supported by these tools. A tight integration with the repository is being strived for.

• Use Case *Display archetype*: This use case is basically fulfilled by Archetype Finder, Archetype Editor and Archetype Workbench for slightly different purposes as discussed in Section 4.3. The Archetype Finder uses resources from the Archetype Editor for HTML-rendition of archetypes. Also, Ocean Informatics' Archetype Mindmap[2] is a useful tool for locating archetypes.

• Use Case *Administrate user:* This use case is not supported by any of the tools so far as this only becomes relevant for an integrated archetype reposi-

tory.

Figure 5 presents a screenshot of the English version of the Archetype Finder. Figure 6 shows a screenshot of the Archetype finder in Farsi. Full multi-language support including Unicode and support for Right-To-Left-Languages has been developed. Currently, the Archetype Finder is also available in German, Spanish, and Turkish. The Search capability of the Archetype Finder includes search in the data and metadata of archetypes. This is based on an OWL ontology, which contains all the necessary information on registered archetypes. Archetypes are automatically registered in the ontology when they become available and all meta-data that can be extracted automatically from the archetype (for example archetype ID,

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[2] *http://svn.openehr.org/knowledge/archetypes/dev/html/en/ArchetypeMap.html for official* open*EHR archetypes and http://svn.openehr.org/knowledge/archetypes/dev-uk-nhs/html/en/ArchetypeMap.gif for archetypes developed and/or used by the UK's National Health Service (NHS).*
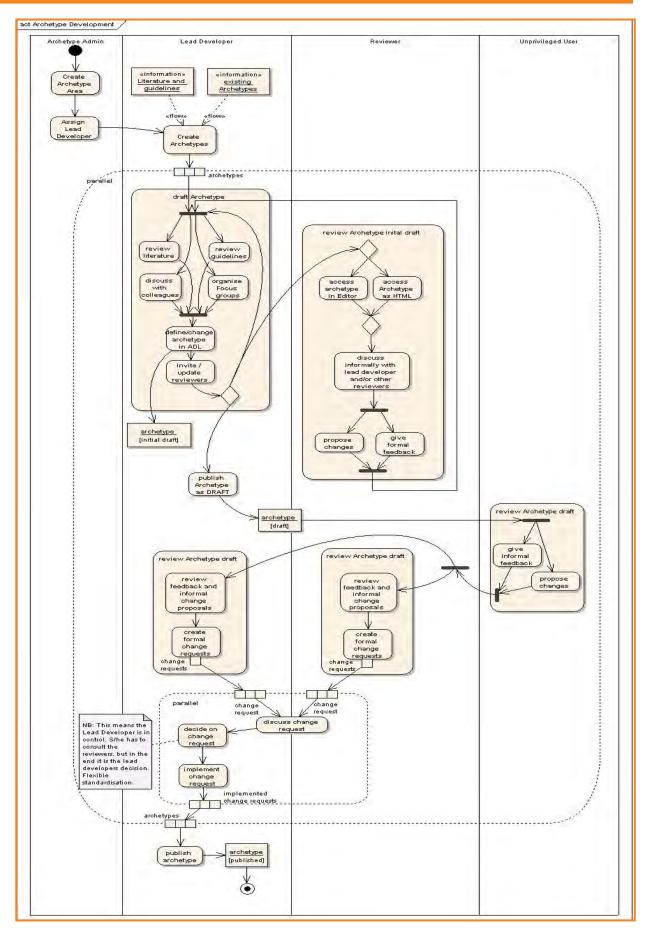
Figure 4: An UML 2.1 Activity Diagram showing an example process for the development of a set of archetypes. Activities and Actions within a (dotted) Expansion Region are executed for each incoming object (i.e. archetype and change request, respectively).
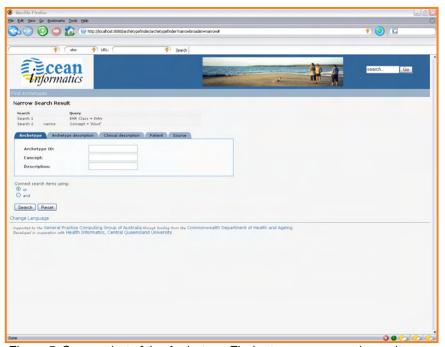
Figure 5: Screenshot of the Archetype Finder to narrow search results.

concept, author, …) is registered in the ontology and further meta-data can be added to the ontology manually later. Currently a repository exists for official *open*EHR archetypes and similar arrangements can be made to register archetypes on national or regional levels, as for example for the UK's National Health Service (NHS). Figure 7 shows part of the OWL ontology for the Archetype Finder as displayed by Protégé.

8. Discussion

A framework for managing archetypes, identifying which archetypes need standardisation, which are domain specific, etc. will enable comprehensive systematic domain knowledge governance. For this we need to establish and train multidisciplinary teams for coordinated, collaborative archetype development. Much of this framework can be supported by information technology as analysed in this paper. A formal OWL Archetype Ontology can provide the necessary meta-information on archetypes for Domain Knowledge Governance and also support reasoning to automatically find similar archetypes.

If an EHR application (see Figure 1) is not able to find an archetype used as a basis for some data (for example a patient from a different health service transfers her/his EHR), the local archetype repository could automatically

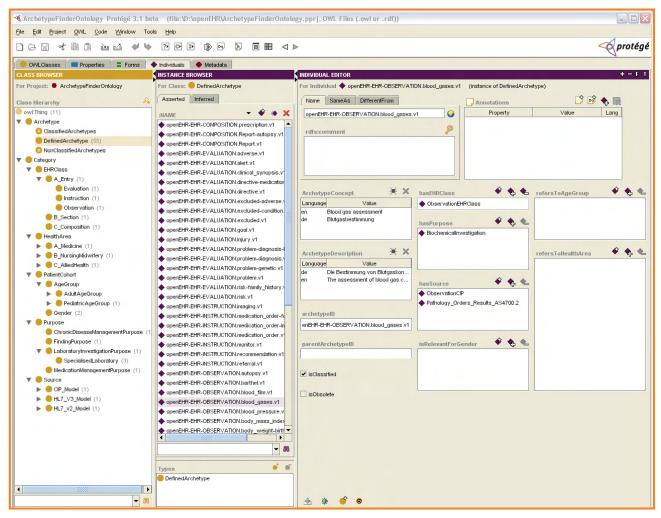*Figure 6: Screenshot of the Archetype Finder in Farsi.*

Figure 7: The OWL-ontology behind the Archetype Finder. The ontology was defined using the Protégé OWL plugin from Stanford University.

find and access archetypes from the central Archetype Repository, for example using web-service technology, and make the archetype available to the application. However, even if the base archetype is not found, the application will still be able to display the patient data.

Drawing the right line between long and tedious but essential standardisation processes and flexibility and innovation is important for archetype authoring. One good example is the specialisation of a sector-wide arche-type to suit a specific field – this will maximise interoperability while 'standardising diversity' in a process we call 'flexible standardisation'. Until the development of an international standard for managing international sharing of archetypes, central national repositories are needed for the local management of archetypes. To sustain this approach, an independent umbrella organization is recommended ([11]).

Information, knowledge management and communication technologies are crucial enablers of system change that can play a vital role in substantially transforming healthcare systems and prevent their failure. We believe that an Archetype Repository enables the development of high quality archetypes in a similar way as the Wiki-technology has been an enabler for one of the most comprehensive and up-to-date encyclopaedias, the Wikipedia (http://www.wikipedia.org)[3]. For this, many components already exist, some of them need some refinement or extension, which mainly is a question of the appropriate funding. There is grow-

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[3] *Please note that the governance structure of an Archetype Repository will be considerably different from the open governance structure of Wikipedia. While broad input to archetypes is considered to be very valuable, an overarching editorial team will oversee the development of archetypes in various specialist areas, with official feedback from registered domain experts and the potential to comment for anybody interested. For stability, only compatible changes can be made to published archetypes, otherwise a new version of the archetype has to be developed.*

ing consensus, willingness and ability in the international community to support these activities. Also more integration with existing tools is needed, for example tightly integrating the repository with existing tools like the Archetype Editor using web services. First steps towards this have been taken.

Clear roles, responsibilities and processes as defined in this paper have to be implemented and enforced. A common (web-based) platform is needed for this purpose. To be able to sustain this approach, there needs to be an international vision for comprehensive semantic interoperability, based on national business models. The World Health Organisation (WHO) has requested such international collaboration [12] – and indeed good examples include the openEHR (http://www.openEHR.org), HL7 (http://www.hl7.org), and the joint Detailed Clinical Models (DCM, http://detailedclinicalmodels.org) initiatives.

Also, interoperability benefit studies begin to appear eventually (e.g. [1]) on which national business models can be based. Sustainability on the other hand is in our opinion not yet sufficiently regarded as a business driver (see [11]).

In summary, some essential governance requirements for archetypes are:

- independence (e.g. realised by an independent umbrella organisation; ensures the reusability of archetypes)
- sustainability and longevity (right business models, umbrella organisation, an approach to the development of 'good' archetypes)
- responsiveness to change (flexible standardisation)

With regard to our implicit argument for *open*EHR archetypes as *the* model for clinical content, some argue that the exact technology is immaterial and that it does not matter whether there is one "master-model" for clinical content (such as archetypes) because converting concrete clinical content that is

expressed in one model to another is usually not problematic. Others (like us) argue that without it many conversions can only be done manually and thus automation and the precision that comes with it is lost, as well as an unnecessary layer of complexity being introduced.

9. Conclusion

High-quality archetypes with high-quality clinical content are the key to semantic interoperability of clinical systems. Domain Knowledge Governance with a clear process for authoring, updating, managing and disseminating archetypes, as well as archetype version control, is the key to high quality archetypes. A comprehensive Archetype Repository will provide the mechanisms to render comprehensive Domain Knowledge Governance feasible and efficient.

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