Facilitating the openEHR approach – organizational structures for defining high-quality archetypes

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Abstract. Using openEHR archetypes to establish an electronic patient record promises rapid development and system interoperability by using or adopting existing archetypes. However, internationally accepted, high quality archetypes which enable a comprehensive semantic interoperability require adequate development and maintenance processes. Therefore, structures have to be created involving different health professions. In the following we present a model which facilitates and governs distributed but cooperative development and adoption of archetypes by different professionals including peer reviews. Our model consists of a hierarchical structure of professional committees and descriptions of the archetype development process considering these different committees.

Keywords. Computerized medical record systems openEHR archetypes, domain knowledge governance, modeling, quality management.

Introduction

The openEHR architecture for Electronic Health Records (EHRs) is a two level modeling approach based on ‘archetypes’ [1]. Archetypes ‘are reusable, structured models of clinical information concepts that appear in EHRs …’ [2]. Using openEHR [3, 4] means using existing and creating new archetypes. It is a central idea of the openEHR approach to use one archetype in as many systems as possible to reduce time and effort for design and to enable semantic interoperability among different systems [5]. However, building such high-quality archetypes, which are accepted among the particular domain experts, requires appropriate governed development processes [2].

Three prerequisites for reusable, high-quality archetypes

To draw an analogy to other development processes, e.g. for standards or evidence based medicine, three conditions should be fulfilled for development or adoption of an archetype, which are independent from the intended area of application – either for a single hospital, multiple institutions or a complete country:

- The design / modification of an archetype should consider evidence based knowledge and design recommendations.
• The design/modification of an archetype should be peer reviewed. Both design and review should be conducted in a flexible framework.
• Released archetypes should be published in an open-access repository and evaluated in terms of their usability and professional correctness.

The aim of our paper is to analyze the structures and processes that are necessary to assure these three prerequisites. Furthermore we present a model which contains the requested structures and processes as well as their application to enable the international and inter-professional coordination of archetype development and maintenance.

1. Material and Methods

The creation of our model is a design research approach [6]: We systematically combined field reports such as [7] with expert opinions and own experiences. Furthermore we considered experiences from other standards development processes and identified the special requirements of the archetype development process. We consequently carried on the work of Garde et al. who gathered ‘requirements for the development of an archetype repository which provides comprehensive support for archetype development cycles …’ [8]. They conducted workshops on archetype development for clinicians, for their requirement analysis.

2. Results

Basic components of our model are descriptions of necessary structures including a role concept and process descriptions based on these structures.

2.1. Necessary structures

1. Users / user group: Everybody who does or will use a system based on archetypes and everybody who designs or modifies archetypes is called a user. The single users have different professional backgrounds: Physicians, nurses, computer scientists… All users together form the ‘user group’.

2. (Professional) Committees: To facilitate peer review, a hierarchical tree structure of committees has to be established. Every committee represents a particular division of the health domain. Committees closer to the root are more general whereas ‘leaf committees’ are highly specialized. The root node is built by the clinical review board (Figure 1).

A user from the user group can join one or more committees according to his or her professional background and interest. For instance a nurse in an emergency department might join the ‘emergency nursing group’ in the ‘nursing’ branch but also the ‘emergency cooperative care’ group in the ‘cooperative care’ branch.

Every committee (including the clinical review board) has a chair and is responsible for a certain set of archetypes.

3. Clinical review board: The clinical review board is a group of experts with different professional backgrounds representing the different subgroups of the user group including government representatives where appropriate.
4. **Design committee:** The design committee observes that archetypes are sensibly developed and modified from a design point of view. Furthermore, the committee offers all users a ‘technical counseling’. It assembles and provides information material about relevant standards and programming recommendations.

The chair of the design committee is also member of the clinical review board to assist it in design and technical issues. Some members of the design committee could be representatives of companies developing openEHR related technology.

5. **Orphan committee:** This committee takes care of archetypes which at the moment are not assigned to a certain professional committee.

2.2. **Processes descriptions**

Let’s assume someone needs an archetype for a certain problem: He or she first searches the public repository to find a suitable archetype, which works like a typical repository for cooperative software development (e.g. a subversion repository). In the long run, metadata stored in an archetype OWL ontology [2, 9] should ease that search.

If a suitable archetype already exists, it can be directly used. If not, a new archetype has to be designed or, if there has been an advance in medical knowledge, an existing one has to be adopted.

Usually several archetypes are necessary to establish a certain system: Every required archetype has to pass the described processes.

2.2.1. **Designing a new archetype**

1. **Choice of committee:** The user who requires a new archetype has to pass a short description of its intended use to that committee which should be responsible according to his judgment.

   If no committee seems suitable, the user may pass the request to the orphan committee, which then assigns the request to a committee or decides to establish a new committee respectively.

   A user who needs a certain archetype is one possible starting point of this process; another could be that a certain committee sees the need of a special archetype.
2. **Allocation of an archetype:** The requested committee has now to decide whether it is responsible for the archetype or not. If not, it may pass the request to another appropriate committee (which now has to debate its responsibility) or to the Orphan Committee which may assign it to a certain committee that has to accept the assignment.

3. **Review of request:** After declaring the responsibility for a request, the particular committee decides whether to accept the request (which means the request seems to be reasonable to the responsible committee) or not. If the committee declines the request, it informs the enquiring person about the reasons so that he or she is able to modify the request.

   Once an archetype is accepted, the responsible committee has to complete its description in the metadata.

4. **Linkage of further committees / observers:** There may be an additional committee interested, so that a link can be set. This takes place either by request of the responsible committee, the ‘second’ committee or the Orphan Committee.

   We distinguish two kinds of links for reviewing: ‘Minor review links’ and ‘major review links’ (cf. step six). Additionally, the archetype is assigned to a member of the design committee.

   Furthermore any interested user can link himself to the archetype and becomes an ‘observer’. Whenever an ‘observed’ archetype is altered, a linked user gets an email notification containing a summary of the modifications. When users can also link themselves to a certain committee they automatically become observers to all archetypes linked to that committee.

5. **Development and supervision:** Every archetype is developed under the supervision of the responsive committee (certain committee members might be responsible for certain archetypes) and the supervision of the assigned member of the Design Committee. The technical development itself might be done by the user who initiated the request and / or by a member of the responsible committee and / or by a third person.

6. **Review of archetype (responsible and linked committees):** When the persons involved in the development of an archetype finished the archetype, they set the state of the archetype from ‘author draft’ to ‘committee draft’. That is a signal to all committee members to review it and to discuss problems and alternatives. The review of an archetype includes the generation of a validity report and compatibility checks. That applies for all committees, which are ‘major review’-linked to the archetype. Both, major and minor review links may be associated either with a particular archetype (=’archetype links’) or with a particular committee (=’committee links’). Thus, every archetype is automatically linked to all ‘committee linked’ committees.

   If the responsible and all assigned committees agree that there should be certain changes, the state of the archetype is set back to ‘author draft’ so that the developers can implement the suggestions and start another review.

   If there are no more open issues, the archetype-state is set to ‘committee-final’ and the archetype is passed to the committees ‘minor review’ linked to it. They have to come to an agreement whether to accept the proposed archetype or to suggest modifications. In the second case the state of the archetype is set back to ‘author draft’ for revision and step six starts over.

   If all linked committees as well as the primarily responsible committee accept the archetype, it is passed to the superior committee.
If a consensus between the responsible committee and one or more linked committees is not possible, the clinical review board can be called to mediate.

7. Review of an archetype (superior committees): The superior committee discusses the archetype and either accepts it and passes it on to its superior committee or, the state of the archetype is set to ‘author draft’ and the archetype is sent back to the primarily responsible committee for modification. Afterwards the archetype starts again his way up to the root node. With the notification that there is an archetype to review every committee gets a short summary of the changes since the last version.

If a superior committee considers a requested change as a ‘minor change’, it is modified by the developers and reviewed by the responsible committee without starting the complete way up again. It continues its way at the superior committee which requested the minor change.

If an archetype is reviewed by a committee which is not responsible for that archetype, none of the committees which have a committee link to the current committee gets the archetype for review.

8. Publication of an archetype: As soon as the archetype is accepted by the clinical review board, its state is set to ‘final’ and it is transferred into the public repository and accessible by everyone.

To ease the selection of a set of archetypes for a certain purpose from the public repository, a professional committee might compose a set of archetypes suitable for its professional field.

2.2.2. Adoption of an existing archetype

The process of adopting an existing archetype is in line with the design of a new archetype except of step one and two: As an existing archetype is already assigned to a committee, so that committee has just to decide if it accepts the request.

3. Discussion

The proposed theoretical model describes processes and structures to facilitate a cooperative development and extension of openEHR-archetypes including peer review and design control in the large. This should lead to high-quality archetypes. Furthermore, our model is in principally applicable to the design of other (non-archetype) knowledge resources – for instance HL7 CDA [10]. Archetypes, however, offer the advantage of being formal specifications and being intuitively understandable for clinicians.

Having a common, international repository of archetypes, as the model implies, could reduce time and effort for designing archetypes and could advance interoperability among different systems [11]. If introduced at an international level the model could for instance avoid the design of two incompatible archetypes for the same concept. Thus, the model could support fundamental ideas of openEHR.

Nevertheless, the proposed model is a theoretical model, based on an idealized starting point. Therefore, a practical realization is necessary to check its applicability and to optimize the model: As the model contains cycles, infinite loops within the design process might occur. Furthermore, if someone has to review the same archetype a few times, the review quality might decrease. Rules should be established to avoid
structural and quality problems - for instance a limit of the maximum number of
development-and-review iterations.

4. Conclusion and perspective

A cooperative and distributed development and extension of archetypes is necessary to
reduce time for archetype designing and to improve semantic interoperability, but not
easy to perform. The proposed model could help to realize such a scenario. To facilitate
and coordinate the necessary communication among the committees and to integrate
the archetype development process, simple ‘wikis’ and content versioning systems are
not sufficient.

As a first step sufficient tools supporting the described processes and structures
have to be implemented and evaluated in a smaller context. Once tools and model are
well engineered and evaluated, both should be introduced in larger (international)
context.

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