Health Informatics Meets eHealth
G. Schreier and D. Hayn (Eds.)

doi:10.3233/978-1-61499-858-7-196

Clinical Knowledge Governance Framework for Nationwide Data Infrastructure Projects

Antje WULFF[a,1], Birger HAARBRANDT[a] and Michael MARSCHOLLEK[a]
[a] *Peter L. Reichertz Institute for Medical Informatics, University of Braunschweig and Hannover Medical School, Germany*

Abstract. *Background:* The availability of semantically-enriched and interoperable clinical information models is crucial for reusing once collected data across institutions like aspired in the German HiGHmed project. Funded by the Federal Ministry of Education and Research, this nationwide data infrastructure project adopts the openEHR approach for semantic modelling. Here, strong governance is required to define high-quality and reusable models. *Objectives:* Design of a clinical knowledge governance framework for openEHR modelling in cross-institutional settings like HiGHmed. *Methods:* Analysis of successful practices from international projects, published ideas on archetype governance and own modelling experiences as well as modelling of BPMN processes. *Results:* We designed a framework by presenting archetype variations, roles and responsibilities, IT support and modelling workflows. *Conclusion:* Our framework has great potential to make the openEHR modelling efforts manageable. Because practical experiences are rare, prospectively our work will be predestinated to evaluate the benefits of such structured governance approaches.

Keywords. Knowledge Management, Clinical Governance, openEHR, Health Information Interoperability

1. Introduction

The efficient reuse of once collected data can be described as one of the most pressing obstacles in the field of Medical Informatics. Current efforts not only focus on developing local solutions for data integration but address the challenges of cross-institutional data analytics and data sharing by proposing ideas for nationwide, interoperable data infrastructures. In Germany, a 120 million-worth funding initiative of the Federal Ministry of Education and Research (BMBF) was initiated to strengthen Medical Informatics [1]. As one of the funded projects, the HiGHmed consortia – consisting of three university medical centers in Heidelberg, Goettingen and Hannover – aspires at creating at least three Medical Data Integration Centers (MeDICs) based on a generic and scalable reference architecture for integrating data from care, research and external sources. HiGHmed perceives semantic interoperability as a prerequisite for enabling meaningful exchange of data in federated cross-institutional settings. Hence, much importance is attached to a semantically-enriched, interoperable and harmonized representation of data across institutions. To tackle this challenge, HiGHmed adopts the

[1] Corresponding Author: Antje Wulff, Peter L. Reichertz Institute for Medical Informatics, University of Braunschweig and Hannover Medical School, Carl-Neuberg-Strasse 1, 30625 Hannover, Germany, E-Mail: antje.wulff@plri.de

openEHR approach for semantic modelling. Archetypes are used to define rich and computable metadata models of clinical information by applying constraints on a reference model [2].

As already stated by Garde et al. back in 2007 [3], the development of such clinical information models across institutional borders is challenging and requires close cooperation between stakeholders, data managers and leaders, as well as clearly defined processes and IT support. Strong governance, often referred to as 'Clinical Knowledge Governance' or 'Domain Knowledge Governance' [4], is needed to define high-quality, clinical relevant and reusable archetypes and templates on a cross-institutional level in a timely manner. Already back in 2006, the Australia's National E-Health Transition Authority (NEHTA) stated that 'undisciplined creation and application of archetypes threatens the goal of semantic interoperability' [5]. First practical experiences on implementing national governance schemes for archetypes in Norway support these theoretical considerations towards the urgent need of strict archetype governance [6]. Hence, for national infrastructure projects with the scope and extent of HiGHmed, a structured governance of archetype development and maintenance appears vital in order to "[...] achieve quality, reusability and interoperability in clinical models." [6]. With our work, we wanted to design a clinical knowledge governance framework for openEHR archetype modelling across institutions. This framework should help to optimize both cross-institutional and local modelling processes. Although we designed the framework specifically for HiGHmed, our work might serve interesting ideas for similar local, national or even international data infrastructure projects fostering secondary use of data.

2. Methods

Domain knowledge governance comprises "[...] all tasks related to establishing [...] formal and informal organizational mechanisms and structures in order to systematically influence the building, dissemination and maintaining of knowledge within and between domains" [7]. For learning on governance, we decided to visit European medical institutions active in developing health information exchange networks or national standardization programs. By conducting interviews with experts in Luxembourg (Luxembourg Centre for Systems Biomedicine), the Netherlands (Radboud University Medical Center), Norway (Bergen Nasjonal IKT), Denmark (Center for Innovative Medical Technology for the Odense University Hospital and the University of Southern Denmark), Slovenia (Ministry of Health and University of Ljubljana) and Austria (Medical University of Graz) we successfully identified practices as well as hurdles and pitfalls. Amongst others, we reviewed the results in terms of approaches for system sustainability, organizational structures and change management, use of state-of-the-art technologies, participant and stakeholder involvement and clinical modelling. We complemented the results with our own experiences on openEHR modelling and published work on archetype governance.

Much importance has been attached to the early involvement and recruitment of domain experts like clinicians [6]. In both the site visits and the published work, it became clear that *roles and responsibilities* – especially for model ownership and review activities – (e.g. a national editorial board) should be defined from the very beginning [3,6]. Furthermore, an efficient *IT support* enabling cooperation and collaboration in archetype designing and publication seems to be a well-known key success factor [6]. The definition of clinical information models on a face-to-face basis is cumbersome and

inefficient in nationwide and nearly impossible in international projects [4]. Hence, many of the current openEHR modelling activities over the world (including United Kingdom, New Zealand, Australia, Slovenia and Brazil) rely on efficient governance models backed by dedicated software tools supporting the governance, maintenance and publication of archetypes and related artefacts. A sufficient IT support that allows the collaborative authoring, commenting and reviewing of information models on a cross-institutional level is required. Well-known examples are tools like the web-based Clinical Knowledge Manager (CKM)[1], the LinkEHR Model Manager[2], ART-DECOR®[3] or Simplifier[4] .

A governance framework also should include fundamentals about *types and variations of archetypes* that might occur. As stated by Garde et al. (2007), there will be "[...] significant concept overlaps between the various health care domains [...]" [3] so that archetypes need to be standardized across all institutions to make them compatible. However, not all archetypes need to be standardized across fields, institutions or even nations [3]. Our own experiences on using the openEHR approach for integrating data from clinical application systems [8] also makes us aware of this problem: sometimes, some very specific 'support'-archetypes which are not worth standardizing across the community are needed to integrate data properly. Due to the considerations of Garde et al. [3,4] and our experiences, we decided to include our ideas on possible variations and their treatment in our governance framework.

We consider the design of workflows and processes for archetype modelling in HiGHmed as next step in designing a governance framework. Hereby, all responsibilities, relations and dependencies of tasks and communication needs between roles can be reconstructed. This includes the definition of workflows for specific events like first draft modelling, archetype specializations and reviewing or updating when knowledge changes [3]. For process modelling, we used the Business Process Modelling Notation (BPMN). Based on this approach and considerations, we were able to define an outline for our clinical knowledge governance framework that comprises content on IT support, types and variations of archetypes, roles and responsibilities, and archetype modelling processes.

3. Results

3.1. IT support

A sufficient IT support is needed to support the adoption of governance guidelines for archetype modelling. Because of our first satisfactory experience with the Clinical Knowledge Manager (CKM), we consider it as a tool supporting the governance, maintenance and publication of models and related semantic artefacts. Typical activities supported are requirements gathering, authoring, commenting, reviewing and balloting of information models. The CKM encourage the creation of work groups for each subdomain and provide discussion spaces to ease clinical concept evaluation. By incorporating functions for a rigorous artefact lifecycle management, the status of clinical models is made visible. On the example of the CKM, for HiGHmed one instance

[1] http://www.openehr.org/ckm/
[2] http://www.linkehr.com/
[3] https://www.art-decor.org
[4] https://simplifier.net/

might be available. To foster an efficient collaboration, we recommended dividing this HiGHmed CKM by the help of CKM projects and incubators. All resources which are important across institutions and use cases are presented at the *All Resource* section. We propose to create one incubator for each use case (e.g. Infection Control, Cardiology and Oncology) capsuling domain-specific clinical models. Furthermore, each institution gets its own CKM project for creating and discussing institution-specific models. By this approach, each institution owns its repository of clinical models (e.g. also for storage of archetypes not related to HiGHmed). Of course, archetypes of the overall CKM project and/or the international CKM still can be used within sub projects or incubators by referencing them.

3.2. Types and variations of archetypes

3.2.1. Archetypes important for all institutions and for all use cases

Managed in HiGHmed context by: HiGHmed Modelling Group (see chapter 2.3)
The archetypes of this category play a role in nearly every use case and institution. Archetypes might be promoted to this category when it appears that many use cases aim at designing the same clinical concepts. These archetypes have the potential to be uploaded to the global openEHR CKM and marked as 'published' in the same manner as current global archetypes (like *ACTION.procedure*, *OBSERVATION.blood_pressure*, *EVALUATION.problem_diagnosis*, *CLUSTER.symptom_sign*). When creating a CKM instance in HiGHmed, it is recommended to use these archetypes as a starter kit.

3.2.2. Archetypes important for all institutions but only for specific use cases

Managed in HiGHmed context by: Use Case Modelling Leader
There might be archetypes which are relevant for all institutions in the context of one use case. At this stage, no other use cases are interested in these archetypes. For structuring purposes, these archetypes will be uploaded and managed separately within so-called CKM incubators. Thus, users like domain experts won't be confused by many archetypes they are not interested in.

3.2.3. Archetypes important for one institution

Managed in HiGHmed context by: Local Use case Chief Data Steward
When using the openEHR-based approach for data integration, some 'support'-archetypes are needed because of primary source systems. These archetypes won't be designed as a 'maximum set' of clinical concepts like encouraged by openEHR. However, although they won't bring an added value for the overall openEHR global community, they are crucial for integrating specific data sets in the HiGHmed context.

3.3. Modelling roles, responsibilities and tasks

Well-defined roles, responsibilities and tasks are vital for realizing structured modelling processes as well as for avoiding redundant modelling activities. Figure 1 shows the proposed modelling roles and groups for HiGHmed. Each role can be translated into one of the CKM member roles *Editor* and *Reviewer*.

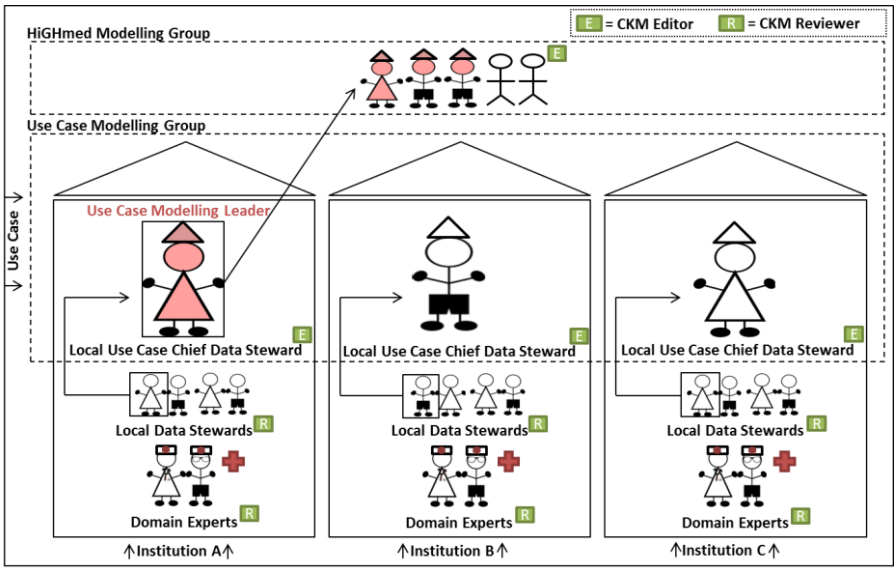

Figure 1. Recommended modelling roles and groups in HiGHmed on the example of three institutions

The superordinate **HiGHmed Modelling Group** (CKM Editor) comprises the leading modelers of the core use cases and modelling experts which are not related to specific use cases. The group should consist of a well-balanced mixture of members from different institutions and use cases. The members should have access to all incubators and use case activities. The core tasks of this group are management of the CKM project including the set-up of initial structures with an archetype starter kit. They lead the modelling and ongoing management of archetypes which are not exclusively related to a specific institution and/or use case (e.g. CKM check outs, change requests, uploads, revisions, invitations, review rounds). This group communicates with the global openEHR community and observes the global openEHR archetype repository.

Every institution should have **Local Data Stewards** (CKM Reviewer) who are responsible for the communication with domain experts to gather information about local requirements. With respects to the current HiGHmed personnel planning, these positions often will be taken over by clinical staff. Local Data Stewards with more technical backgrounds will be available directly out of the Medical Data Integration Centers (MeDICs). The Local Data Stewards don't need to be linked to a specific use case. However, every institution should declare one of the MeDIC-Data Stewards to a **Local Use Case Chief Data Steward** (CKM Editor). Local Data Stewards are responsible for analysis of requirements and local systems and for CKM side activities like administration of the resource center and translations. Moreover, they create first drafts for archetypes and participate in review rounds. They also should be capable of supporting the data integration specialists. The Local Use Case Chief Data Steward is responsible for managing the institution-specific CKM project and uploading archetypes which are exclusively needed locally. He/she leads and manages the Local Data Stewards and their participation in use case specific CKM check outs, change requests, uploads, revisions, invitations and review rounds. Also, he/she requests requirements analyses and forwards the results to the Use Case Modelling Leader. In close cooperation, they model first archetypes and design templates.

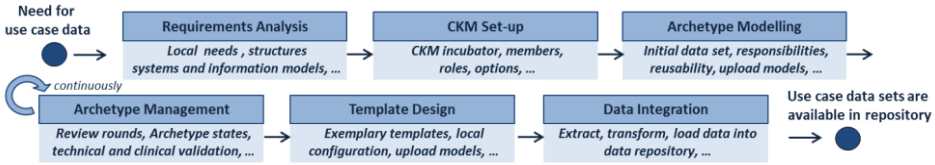

Figure 2. Executive overview of the governance process for modelling in HiGHmed

For each use case, a **Use Case Modelling Group** consisting of all Local Use Case Chief Data Stewards will be formed. This group defines one of its members as Use Case Modelling Leader who is responsible for the management of the cross-institutional but use case specific modelling activities. As **Use Case Modelling Leader** (CKM Editor), he/she will participate in the HiGHmed Modelling Group. He/she takes over the lead and management of the Local Use Case Chief Data Steward, the summarizing of local requirements, the definition of relevant clinical concepts and the realization or delegation of modelling tasks. In CKM, he/she creates the CKM use case incubator and its initial structure and coordinates CKM check outs, change requests, uploads, revisions, invitations and review rounds for use case specific archetypes.

The availability of **Domain Experts** (CKM Reviewer), e.g. clinicians or technicians, is crucial for an adequate requirements analysis, the modelling of first drafts and the review of archetypes by providing domain or technical knowledge. Some of the Local Data Stewards might be clinicians and, thus, domain experts. However, ideally, there are other experts which are neither part of the Use Case Modelling Group nor the HiGHmed Modelling Group.

3.4. Collaborative and coordinated modelling approach

The allocation, relations and dependencies of tasks and communication needs between roles are presented as archetype modelling workflow (uploaded on ResearchGate[1]).

A high-level view of the process is presented in Figure 2. The process starts by any need to standardize data items and reuse them. The needs will be determined by the selected use cases and by the input of stakeholders (like researchers, clinicians or industry partners). The need will be transferred to the Data Stewards so that new Use Case Chief Data Stewards and cross-institutional Use Case Modelling Groups can be set up. The HiGHmed Modelling Group will be informed about the new use case and its Use Case Modelling Leader. Simultaneously, a use case CKM incubator will be set up. Then, the leader will request for requirements of institution-specific needs, structures and systems by asking the Use Case Chief Data Stewards. Local Data Stewards will work closely with the Local Domain Experts to gather information. The analysis results will be documented by creating mind maps or first draft archetypes. After the requirements of all institutions will have been gathered, the actual modelling process will start. In close cooperation with the Use Case Modelling Group, the Use Case Modelling Leader will combine the local analysis results and will work out relevant clinical concepts. Then, it will be checked whether these concepts are exclusively needed at one institution only. In that case, the corresponding Local Use Case Chief Data Steward will take over the ongoing design and management of the archetype. The continuous monitoring of such cases as well as the proposal of specifications for institution-specific archetypes instead

[1] https://www.researchgate.net/publication/322519762_Archetype_Modelling_Workflow

of the development of new archetypes are core tasks of the Use Case Modelling Leader. The modelling process will be continued by searching in the HiGHmed CKM or the global CKM for suitable archetypes that already exist. If available, the archetype will be uploaded to the incubator as 'referenced archetype'. If not, a first draft archetype is created de novo. This means, that an archetype class as well as appropriate elements, entry features and terminology bindings will be created. At this step, it has to be checked whether other standard definitions (e.g. by HL7) can be used for archetype design. The archetype will be uploaded to the incubator or the institution-specific CKM project. When a new first draft will have been uploaded, the HiGHmed Modelling Group will be automatically informed by the CKM in order to check for redundant concepts and/or archetypes across institutions and use cases. If a redundant archetype occurs, the HiGHmed Modelling Group will take over the continuous management of this archetype from the Use Case Modelling Leader. The archetype will be included into the HiGHmed CKM project space and will change to a 'reference archetype' within the incubators.

The sub process *Manage Archetype* summarizes the most important activities throughout an archetype lifecycle. Here, the initiation of review rounds are of particular importance because through this the Local Data Stewards and Domain Experts will be empowered "[...] to create and change the knowledge inherent in archetypes, thus controlling the way EHRs [Electronic Health Records] are built up using designed structures to express the required clinical data [...]" [3]. It is recommended to reduce the number of face-to-face meetings between domain experts of different institutions as far as possible, e.g. only for setting up general goals of their use case. Any other discussions should be held within the CKM. After the archetype will have been approved, the Local Use Case Chief Data Stewards will start to design und upload templates by using the formerly approved archetypes. Exemplary templates can be discussed within the Use Case Modelling Group and reused across institutions but, in general, templates should be designed and uploaded within an institution-specific space.

4. Discussion

Our work contributes a novel framework for clinical knowledge governance in nationwide data infrastructure projects like HiGHmed. By analyzing related work on clinical knowledge governance as well as by visiting different sites and using their experiences on standardization projects (openEHR, FHIR, CDA, EDIFACT and others) –, we were able to carefully work out the key aspects that need to be covered in such a framework. We successfully gathered potential archetype variations, proposed roles and responsibilities and IT support, and outlined a workflow for archetype creation and approval.

For HiGHmed, the availability of high-quality and reusable archetypes is crucial for the achievement of the superordinate project objectives. By reusing once collected data, new and high-performing solutions for medical data analytics can be developed in order to accentuate the benefits of increased digitalization in medicine for patients, clinicians and researchers. As a prerequisite, data has to be integrated safely, accurate and semantically enriched to ensure the correct interpretation by humans and machines across institutions. Due to the inherent complexity of the clinical domain, modelling processes can be time-consuming. In our opinion, these efforts are manageable when following a structured modelling approach as proposed. By defining clear responsibilities and workflows not only the quality of final archetypes can be increased

but the development time of archetypes can possibly be decreased. Additionally, the initial modelling efforts might decrease in future as soon as a high-quality stack of published and reusable archetypes is available.

We agree with Garde et al. [3,4] and Bakke [6] that IT support plays a key role in governance. We appreciate that a major part of archetype governance can be covered by sufficient tools like the CKM. It has been reported that the use of the CKM facilitates and encourages the involvement of clinicians and domain experts in clinical information modelling [6]. For other standardization efforts similar tools for supporting collaborative work on models are available (e.g. ART-DECOR® provides template editors for HL7 V3/CDA templates, a value set editor and a terminology browser, lifecycle management features and others). These tools are also helpful for our approach because existing definitions can be searched and used as information input for archetype design. However, because HiGHmed adopts the openEHR approach for semantic modelling, we are in need of an openEHR-based governance tool. Furthermore, we think that such tools only can be used efficiently when modelling rules, roles and responsibilities – regardless of the standard or tool decision – are clearly defined and communicated beforehand. Hence, we decided to put more effort into governance than just implementing IT support. Because everyone has to understand the centerpiece of our framework – the modelling approach – we set up an internal modelling and governance workshop in HiGHmed.

We are aware that our work lacks in practical evaluation of the clinical governance framework. Currently, the long-term establishment and practicability of our approach is not assessable yet but we strive at implementing and optimizing the presented framework within the HiGHmed project as well as publishing evaluation results. We will define criteria to evaluate the impact of the framework. Important measures might be the time to archetype publishing as well as the model quality. Furthermore, the amount of redundant models, the transparency and sharing of models and the rate of reused archetypes with and without such a framework could be meaningful measures. Overall, we see a great opportunity to evaluate the use of clinical governance frameworks in nationwide projects of such extent for the first time.

5. References

[1] Bundesministerium für Bildung und Forschung, Digitalisierung in der Medizin: Medizininformatik, https://www.bmbf.de/de/medizininformatik-3342.html, last access: 10.1.2018.
[2] The HiGHmed Consortium, HiGHmed, http://highmed.org/, last access: 10.1.2018.
[3] S. Garde, P. Knaup, E. Hovenga, S. Heard, Towards semantic interoperability for electronic health records, Methods Inf Med. 46(3) (2007), 332–343.
[4] S. Garde, Clinical knowledge governance: The international perspective. Stud Health Technol Inform. 193 (2013), 269–281.
[5] National E-Health Transition Authority, Review of Shared Electronic Health Record Standards - Version 1.0 (2016).
[6] S. Ljosland Bakke, National governance of archetypes in Norway. Stud Health Technol Inform. 216 (2015), 1091.
[7] S. Garde, S. Heard, E. Hovenga, Archetypes in Electronic Health Records: Making the case and showing the path for domain knowledge governance, in: HIC 2005: 13th Australian Health Informatics Conference. H. Grain and M. Wise M, editors. Health Informatics Society of Australia, Melbourne Brunswick East, 2005.
[8] B. Haarbrandt, E. Tute, M. Marschollek, Automated population of an i2b2 clinical data warehouse from an openEHR-based data repository, Journal of Biomedical Informatics, 63 (2016), 277-294.