Generification in change: the complexity of modelling the healthcare domain.

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Abstract. In this paper we explore the concept of "generification" through a Model-Driven Development (MDD) approach. We claim that the concept of generification is in change as the MDD approach, exemplified by the openEHR framework, gives a network of voluntary clinical users a prominent role in the generification process. The customization is no longer "in the hands" of the vendor, and needs to be formalized for the public healthcare service to take the ownership of the generification process and the standarization of clinical information. Empirically, we have followed the development of a new EPR system adhering to MDD methodology from 2012 to 2016.

Introduction

At present, Electronic Patient Record (EPR) Systems have largely replaced the paper-based patient record in Western healthcare services. Nevertheless, patient information is often spread over different systems and stored in unintegrated applications, which complicate realization of political ambitions like sharing and reuse of patient data to increase quality and patient safety (European Commission and Directorate-General for Health and Food Safety, 2015; National ICT - Action 48, 2014). Moreover, most of todays' EPRs are built using "single-level" methodologies, in which both information and knowledge concepts are built into

one level of object and data models, making them hard to change according to ever changing needs in the sector (Beale, 2002).

On this backdrop, a promising strategy for dealing with these challenges is to increase the level of abstraction in the development process through model-driven development (MDD) (Selic, 2003). In healthcare, the openEHR standard (Beale and Heard, 2007) is a promising MDD approach for electronic healthcare records (Martínez-Costa et al., 2009; Lopez and Blobel, 2009). It is a two-level modelling approach within a service-oriented architecture and it allows clinical personnel to be directly involved in defining the semantics of clinical information systems. In OpenEHR, a small and standardized reference model represents the first level while structured models of the use domain—the archetypes—represent the second level.

Archetypes are thus not part of the software or database of a system. An archetype is a re-usable, formal definition of domain level information. A fundamental aim of the archetype approach is to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way EHRs are built up using designed structures to express the required clinical data. The essence is that clinical personnel now become enrolled as the customizers of an EPR-system, responsible for defining certain data-objects (Blobel et al., 2014). Consequently, this approach gives a high degree of local configurability for users and domain experts (Garde et al., 2007: 336).

Pollock and Williams (2008) have described the vendors' strategy of customization as "generification", in terms of making a generic system work in several settings. The concept of generification gives valuable insight about how a vendor align user request to make generic ERP systems tailored to different organizations. Generification involves social processes of ordering, prioritizing, and persuading users in order to motivate them to use similar versions of the same system that is installed in different organizations (Pollock & Williams, 2008). In the MDD approach the customization is handed to the users by the modeling the domain. Accordingly, the concept of "generification" is in change. In this paper we explore the concept through a MDD approach giving a network of voluntary clinical users a prominent role in the generification process (Beale and Heard, 2007; Beale and Heard, 2008; Christensen and Ellingsen, 2016; Pollock and Williams, 2008) Based on this, we ask: ***How do the MDD approach of EPR systems change the concept of generification?***

Empirically, we have followed the development of a new EPR system adhering to the MDD methodology from 2012 to 2016. The project took place in the Northern Norway Health Region, in which The Northern Norway Health Authority decided in 2011 to invest in new clinical ICT systems for all the 11 hospitals in the region. The overall aim of the procurement was to replace an existing, largely free-text-based EPR with a semantic interoperable EPR enabling

advanced process- and decision support within and between the hospitals in the region. DIPS ASA was chosen as the principal vendor of the new EPR.

The research is grounded in an ethnographic-inspired study (Klein and Myers, 1999), and the analysis was guided by a provisional understanding of the nexuses in which the artefact, attendant practices and knowledges were being created.

Case

The Vendor's need for a generification strategy

DIPS had since year 2000 grown from the smallest to the largest EPR vendor in Norway. Currently, they enjoys approximately 86 percent of the Norwegian hospital-based EPR market. Their system, DIPS Classic, contains 500 features/functions, 7, 5 million lines of code and has approximately 82 000 users. However, in response to national strategies for ICT in health care, and to cope with increasingly requests for changes in their system, they decided in 2011 to use the openEHR architecture for its EPR for the future. This would also make it possible for DIPS to become a vendor on the International market.

> "Very much of what we had developed in the period 2008-2011 - was good functionality, but all the screens and modules were hardcoded, and every tiny change to our software had to be done by our developers and that was an overwhelming task (...)"When the user interface can be [automatically] generated based on the archetypes, it will save the developers an enormous amount of work. It implies that domain experts can define the content, and the developers will not have to spend time on designing screen forms for data entry and workflow"(system architect, DIPS).

While focusing heavily on development of the software, DIPS had expected the users—in accordance with the openEHR approach and the national strategy (National ICT - Action 41, 2012), to take charge of modelling archetypes. Hence, DIPS expected the Northern Norway Health Authority to organize relevant user forums for doing this:

> "The process of modelling archetypes is something the FIKS project has not dealt with at all. They [the users] like the idea of archetypes—having structured data and eventually being able to exchange information that different systems can understand—but I don't think they realize what is their responsibility in the process" (developer DIPS)

Hence, the first piloting showed that the new EHR would not be operative without the presence of a broad range of archetypes to represent the clinical content of

different disciplines. Consequently it became difficult for the users to grasp the potential of the new technology and the users where not informed of their role in developing archetypes.

The management of the FIKS project realized that building a repository of archetypes would be a task too huge for Norway's smallest health region. This needed to be done on a national level. An increased understanding of the need for a broader national initiative on this work led to the establishment of an editorial group for national governing of archetypes (NRUA) in January 2014. NRUA was part of the National ICT organization.

Handing the generification over to the user communities

Up and running, NRUA organized the process, aimed to govern the Norwegian archetype repository by the same principles as the international repository. Moreover, the repository was going to evolve through a so-called "do-ocracy" for which clinicians, allied health workers, and other experts propose needs of clinical information defined as archetypes. This denotes that the clinicians had to map and determine which clinical information needed to be modelled, e.g. mapping a patient pathway and the need for clinical information to support the pathway. However, for each and every clinical information concept, e.g. "smoking history" used in the admission note, the work with modelling archetypes started with a mind map where the different aspects of the proposed archetype were listed.

To start out, clinicians took the archetype for "smoking history" from the international CKM, and translated it into Norwegian. However, they discovered that some aspects were missing due to contextual differences: In Norway, use of snuff has been replacing cigarettes, and hence it is just as important to map use of snuff as the number of cigarettes smoked. Thus, the archetype had to be revised to consider this. The clinicians worked in two different project groups, and it turned out they "mind-mapped" different aspects of the archetype on smoking history, resulting in two different suggestions. To align the different suggestions a consensus process was initiated, which turned to be time consuming and cumbersome.

NRUA organized the important consensus process of the requested archetype, which included picking and recruiting relevant clinicians in terms of their specialist background – and issued the approved archetypes when consensus was obtained. The consensus processes were conducted through an online-tool – the openEHR clinical knowledge manager (CKM). Accordingly, the clinicians did not have to meet in person, but could take part in the consensus process from their private computers. However, the review process in the Norwegian CKM depended on the clinicians' willingness to contribute:

"It is not easy to recruit clinicians; we try to get a permanent staff of dedicated people who are willing to spend the time—it is actually volunteering in the first place. Some say no for this reason, they want to do it as part of their working hours. Once enrolled in the CKM, you have to train them in how the system is used, so it takes some time before you have a bunch of people who know what to do when the invitation to evaluate a new archetype pops into their mailbox". (Member, editorial group)

Concluding discussion

There is a complex interplay between the vendor's decision of "business strategy" to fit into the huge and evolving healthcare market, and the necessary generification to make a system work in several different contexts. In this case, the vendor's development strategy influenced the traditional generification because the new strategy changed the customization process. The processes of ordering, prioritizing, and persuading as described by Pollock and Williams (2008) is now moved from the vendor to the clinical communities. Even though the users are "put in the drives' seat" of the customization process, the complexity of customization through the MDD approach presuppose the process to be organized. This addresses a need to formalize the responsibility of the generification process. First, there is a need for an overall decision, on a national and regional level, to allocate appropriate resources to take part in on all levels of this work, both the consensus process and the formalization of archetypes. Second, the must be an organization responsible for tailoring the archetypes into different organizational needs.

Accordingly, the MDD approach of EPR systems change the concept of generification in terms of «handing over» the customization process to the user communities' and their willingness to contribute to the development and maintenance of archetypes. The generification process is no longer "in the hands" of the vendor. The new aspects of the generification processes need to be further explored (Beale, 2000; Christensen and Ellingsen, 2016; Pollock and Williams, 2008).

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