Evaluating Model-Driven Development for large-scale EHRs through the openEHR approach

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ABSTRACT

Purpose: In healthcare, the openEHR standard is a promising Model-Driven Development (MDD) approach for electronic healthcare records. This paper aims to identify key socio-technical challenges when the openEHR approach is put to use in Norwegian hospitals. More specifically, key fundamental assumptions are investigated empirically. These assumptions promise a clear separation of technical and domain concerns, users being in control of the modelling process, and widespread user commitment. Finally, these assumptions promise an easy way to model and map complex organizations.

Methods: This longitudinal case study is based on an interpretive approach, whereby data were gathered through 440 h of participant observation, 22 semi-structured interviews and extensive document studies over 4 years.

Results: The separation of clinical and technical concerns seemed to be aspirational, because both designing the technical system and modelling the domain required technical and clinical competence. Hence developers and clinicians found themselves working together in both arenas. User control and user commitment seemed not to apply in large-scale projects, as modelling the domain turned out to be too complicated and hence to appeal only to especially interested users worldwide, not the local end-users. Modelling proved to be a complex standardization process that shaped both the actual modelling and healthcare practice itself.

Conclusion: A broad assemblage of contributors seems to be needed for developing an archetype-based system, in which roles, responsibilities and contributions cannot be clearly defined and delimited. The way MDD occurs has implications for medical practice per se in the form of the need to standardize practices to ensure that medical concepts are uniform across practices.

1. Introduction

Developing software for today's organizations is highly challenging due to numerous stakeholders, changing user requirements and an evolving domain [1,2]. As a result, traditional development strategies for information systems hardly fulfil the expectations of the user domains in either the short or the long term. An illustration is the waterfall model where customers specify in advance what they need, and then the designers develop the system according to what is specified [3]. This leaves little flexibility for changing course along the way and therefore limits user involvement as well. In the longer term, introduction of new concepts and functionality may require complex software and database changes followed by

rebuilding, testing and redeployment. This process may therefore be expensive, resource demanding and risky.

One strategy for dealing with these challenges is to increase the level of abstraction in the development process through Model-Driven Development (MDD) methods [4–6]. The primary idea is that the designers should not need to deal with issues and concerns directly in every practice, but should be able to manage organizational concerns at various levels of abstractions and models of the use domain, in which experienced users manage the modelling.

In healthcare, the openEHR[1] standard [7] is a promising MDD approach for electronic healthcare records [8,9]. 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 line with MDD generally, the openEHR approach rests on several key assumptions

[1] http://www.openehr.org.

related to its application. First, it assumes that the level of abstraction can be managed relatively easily, i.e., distinctly separating technical and clinical concerns based on the two-level object model. Second, it assumes that clinicians can generally take control in modelling the electronic health record (EHR) systems themselves, facilitated by the tools provided by openEHR (see, for instance Ref. [10]). Third, it assumes that clinicians will welcome this process enthusiastically and will be highly motivated to contribute in the development process (see, for instance Ref. [11]). Fourth, an inherent assumption in the modelling approach is that this represents a straightforward mapping of a practice where the practice itself is left unchanged in the process.

However, MDD is not straightforward and many efforts have resulted in failure [12,13], which generally suggests that crucial social factors have been ignored in the process [8]. This echoes several core studies in the medical informatics community suggesting that socio-technical issues must be dealt with carefully in the implementation of new ICT systems [14–17]. Moreover, this is particularly valid when the scope and size of an ICT system increase and where organizational politics more readily come into play [1,18]. Accordingly, while there have been many reports from successful pilot studies on openEHR (see, for instance Refs. [19–21]), we do not know much about how openEHR works for large-scale EHRs [22,23]. By large-scale EHRs in this context, we mean EHRs that typically have hospital-wide scope and that cover the hospital's need for clinical documentation across its departments.

Overall, this makes larger initiatives in this domain extremely interesting because it is unclear what specific socio-technical challenges the openEHR methodology will be up against. We explore this further by challenging the four key assumptions associated with MDD in general and with openEHR in particular. We therefore pose the following research question: *What are the major socio-technical challenges of the openEHR approach for large-scale systems?*

Empirically, we draw on a large-scale healthcare project ('FIKS') for developing and implementing a new EHR system, run by the Northern Norwegian Health Authority, lasting from 2012 to 2016 with costs approaching EUR 90 million. The vendor involved ('DIPS') is the largest EHR vendor in Norway, covering 82% of the EHR hospital market and encompassing 80,000 users. In 2006, DIPS started to experiment with an MDD approach, which culminated in 2011 with its decision to use the openEHR framework [24] for developing its new next-generation EHR for the hospital market.

The paper is organized as follows: In Section 2, we present some background on MDD and more specifically the openEHR framework. In Section 3, we present the methodology for our research. Section 4 presents background on the FIKS project and our case, divided into 4 phases. In Section 5, we discuss the case and in Section 6 we conclude the paper.

2. Background on Model-Driven Development and openEHR

A major concern in developing large-scale EHRs for hospitals is that the organizations evolve and change continuously, which in turn requires that vendors respond to a constant flow of new demands. As a part of this, there are growing demands for integrated workflows and interoperability across institutional, departmental and professional boundaries as well as a variety of technological platforms [25]. This makes it difficult for designers to grasp all the peculiarities within the targeted clinical practice, resulting in several rounds back and forth between users and designers to keep the development process on track.

For software companies, one strategy for dealing with these challenges is to increase the level of abstraction in the development process through Model-Driven Development (MDD) [4]. MDD is part of a family of several related concepts, which broadly speaking also includes model-driven engineering, model-driven architecture [5] and domain-specific modelling [26]. The primary idea is that the designers should not need to deal with issues and concerns in each practice directly, but should be able to manage organizational concerns through various levels of abstractions [6,27].

This is expected to separate organizational issues from the underlying technology platforms, in a way that makes change more manageable [28]. The chosen model typically aims at achieving specific goals such as increased automation in program development, improved interoperability, and easy maintenance of software. Generally, the concepts used in MDD operate relatively independently of the implemented technology, and are therefore much closer to the use domain than traditional development methods are. As a result the models may be easier to specify, understand and maintain, which sometimes makes it "possible for domain experts rather than computing technology specialists to produce systems" [4].

Modelling in healthcare has recently been promoted through Detailed Clinical Models (DCMs) [29,30,61]. A DCM is "a relatively small, standalone information model designed to express a clinical concept in a standardized and reusable manner" [30], where the modelling process generally involves structuring and standardization of data elements for clinical use as well as the conceptual modelling of data elements, structures and their relationships [30]. In this way, the DCM is expected to capture and organize the details of the reality of a given healthcare domain [6].

Furthermore, to deal with the healthcare sector's reiterating complexity, a two-level modelling strategy has been promoted for modelling EHRs [24,31,32] where "clinical observation models and the meta- information about the clinical observation models are separated" [30]. The most widespread dual-model standards are ISO 13606, openEHR and HL7CDA [29], which are all global candidates for data structure definitions [29,33].

In this regard, openEHR is of particular interest because a large community of developers are engaged and many open-source tools are available [29]. Several countries have also established EHR strategies that involve openEHR: in the UK, "openEHR archetypes have been selected by the Interoperability Board for the description of data structures" [56]. In Norway, the National ICT Health Trust[2] has recommended a national strategy of building an infrastructure for specialized healthcare based on the openEHR architecture [58,59], and this has been put into action through the procurements of new EHR systems. Initiatives in Brazil use the openEHR approach to model hospital information systems based on a national logical infrastructure [34]. In Australia, the Personally Controlled EHR was launched in 2012, utilizing the openEHR approach [35]

Accordingly, the openEHR standard is a promising MDD approach for EHRs. It is currently promoted by the openEHR foundation[3]—a not-for-profit company. Recently, openEHR has also been incorporated in Microsoft's Connected Health Framework [57]. Like other MDD approaches, the openEHR approach implies that the technical design of the system is separated from detailed organizational issues. OpenEHR is built on a two-level modelling approach where a small and standardized reference model represents the first level while structured models of the use domain—the archetypes—represent the second level. An archetype is a formal definition of a clinical concept, which together with several other archetypes represents a model of the clinical practice or domain. As to the similarities and differences between ISO 13606 and openEHR,

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