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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.
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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

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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,

[2] The National ICT Health Trust is responsible for coordinating ICT-related initiatives in the specialized health care services. It is a central agent in bringing about and realizing national efforts and strategies for ICT. The mandate is given by the Regional Health Authorities.

[3] http://www.openehr.org/about/foundation.

they were both a result of the EU GEHR (Good Electronic Health Record) project [27]. While ISO 13606 and openEHR share the same archetype definition language (ADL), they are different: ISO 13606 is a specification for the *communication* of EHR data while openEHR is a specification of an EHR system, i.e. the management, storage and retrieval of health data.

Consistent use of archetypes is supposed to ensure a high degree of interoperability between various EHRs adhering to the openEHR approach. Examples of archetypes may be weight measurement, blood pressure or microbiology results. An archetype represents a description of all the information a clinician might need about, for instance, a body temperature measurement [37]. The body temperature value is accompanied by data describing the context of the temperature measurement: who (who measured the temperature, how (which type of equipment was used, if the patients' body was covered/clothed), when (related to date and time of day), and where on the body the temperature is measured. The menstrual cycle also affects body temperature, so information about this is included in describing the state of the patient (Fig 1).

The archetypes can be tailored to different local clinical situations using templates. This may imply composing archetypes into larger structures corresponding to screen forms, documents or reports [7] or imposing local constraints on archetypes by removing or mandating optional sections [24].

While openEHR is a standard that provides guidelines on how to model medical concepts (see above on DCM), it does not provide a list of medical concepts as part of the standard. The key feature is rather that it informs domain experts or experienced clinicians *how* to model their healthcare practice through archetypes. Users can do this either by applying internationally agreed-upon archetypes or by defining their own local archetypes. This is supposed to empower users and domain experts:

> "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" [37].

For developers in software companies, the anticipated effect is that this will ensure an easier development process because it separates the technical design from clinical concerns. Hence, it is expected that a system's developer would not need to know all the organizational peculiarities in every different context.

> "Technical models are developed by software engineers, whilst knowledge concept definitions are developed by the people who know about them—domain specialists. The two development processes are disengaged, and domain specialists are empowered to directly produce artefacts which will control how their information systems function" [24].

While stakeholders in both the technical and the clinical domain may find such a promise significant, Blobel et al. [6] have taken a more careful position. Based on their Generic Component Model, they argue that there needs to be a gradual move from the clinical to the technical domain through careful considerations on several viewpoints of the system (such as business, enterprise, information, computational, engineering, and technology).

Regardless, in order to support users in developing archetypes, the openEHR community has provided an online tool—an international repository—called the Clinical Knowledge Manager (CKM), where clinicians can develop, manage, publish and use archetypes, freely available under a Creative Commons licence. More than 300 archetypes are available in the international CKM and can be downloaded and specialized to suit different national, regional and local contexts.

There is also a possibility for exploiting knowledge developed in medical vocabularies. In this regard, openEHR archetypes offer the option to bind terms used in the model definition to existing medical terminologies such as SNOMED-CT and LOINC [8], although it is recognized that "the effort needed to bind archetype fragments to a standard terminology will be considerable" [33].

OpenEHR has been tested in many medical informatics pilot and research projects with considerable success (see, for instance, Refs. [19,21,38,39]). By pilot studies, we refer to small, experimental and prototype-based projects of limited scope and duration. They are often limited to specific medical disciplines, such as neonatal care [38] or obstetrics [34], conducted to evaluate and adjust aspects of technology or design before implementation throughout the hospital, or even larger scale in the healthcare sector. In comparison, there has been limited experience with real large-scale implementations [23,40–42] in hospitals and at national level.

Scaling things up implies that complex socio-technical issues may emerge in ways that are overlooked in smaller pilot projects [43,44]. For instance, coordinating users at different levels that are supposed to take part in developing, adapting and using archetypes on a national scale may prove to be both a complicated and unpredictable process [45]. This echoes a strand of research in the medical informatics community that has focused on socio-technical issues. For instance, Gremy and Bonnin [14] state that medical informatics applications aiming at supporting medical work and aiding the running of large organizations interact with the individual and intrude on his or her professional activity:

> "The contribution of computer machinery is not exterior but intermingles narrowly with human intellectual and social activities. . . one must keep in mind that the main component of the information processing system is the human being: that is, the user(s)" [14].

Along these lines, Berg [17] points out that getting such technologies to work in concrete healthcare practices appears to rely on politically textured processes of organizational change. Aarts et al. [16] focus on how the implementation of a Computerized Physician Order Entry System (CPOE) affects the roles and responsibilities of healthcare workers and that it must fit the workflow in hospitals to enhance quality of care. If socio-technical aspects of the use of such systems are not understood, there is a danger that they may lead to adverse events instead of mitigating them. Ash et al.

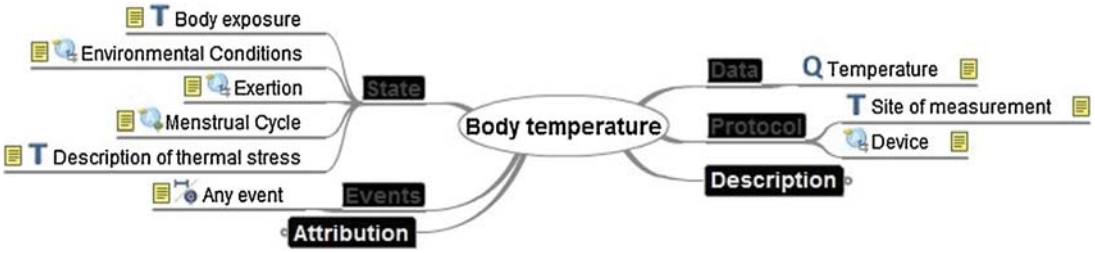

Fig. 1. The archetype for body temperature.

[46] find that implementing health ICT systems may have serious undesirable and unintended consequences such as errors, security concerns and issues related to alerts, workflow and interpersonal relations. A key lesson learned from these studies is that one needs a thorough understanding of the clinical practices involved in order to understand why and how health personnel act the way they do when new ICT is implemented [47].

3. Method

Empirically, this paper focuses on the effort of DIPS, Norway's largest EHR systems vendor, to realize an openEHR approach—initially in the Northern Norway health region, progressing through the national level and then on the international level. We have traced this scaling process from the perspective of DIPS and its interaction with the key user base in the process.

Methodologically, the study is an interpretive case study [48,49] where the aim of inquiry is to identify the perspectives of the different stakeholders in order to gain a thorough understanding of the phenomenon. As stated by Gremy and Bonnin [14], this implies "to assess not only the machinery (hard and soft), but above all to assess what medical informatics really do for people". In line with this, conducting interpretive research means getting access to the meaning that people assign to what is going on in their context [48].

Our data have been collected over four years (2012–2015), through engaging with a broad range of stakeholders in the FIKS project. The first author has conducted intensive participatory observations, spanning from observing healthcare personnel and developers at work at DIPS to participation in workshops between the vendor and users in the design of the new EHR system, module testing and participating in meetings and seminars on archetype strategy. During the project period so far, the first author has conducted 540 h of observation. The field notes from the observations fill three notebooks, each with 160 pages of A4 size.

In total, 22 semi-structured interviews (9 developers and representatives from DIPS, 1 archetype editor, 2 project managers, 10 healthcare staff members (surgeons, nurses, and secretaries)) were conducted and lasted for 45–90 min each. A digital voice recorder was used in the interviews, and the interviews were transcribed immediately after recording.

Informal talks were also an important source of data. Themes emerging from the observations and the interviews were brought up in the informal talks, and these became very important to validate the interpretations we made during the process.

Besides document studies of the ongoing project, the reports from National ICT on ICT architecture and archetype strategy have been especially important to enable us to understand the actions and the shifts in actions that we observed along the process.

The analysis of the data is based on a hermeneutic approach, where a complex whole is understood "from preconceptions about the meanings of its parts and their interrelationships" [48]. This implies an iterative process back and forth between the viewpoint of the different stakeholders and our increasing understanding of the project as a whole. This also prevented us from giving undue weight to specific stakeholders' viewpoints, as we strived to get as complete a picture as possible of what was happening. Right from the process of transcription of the field notes and the interviews, we looked for reiterating themes and patterns, which in turn were explored further in the following interviews and informal talks.

An important principle in interpretive field research is the interaction between the researcher and the subject [14,48]. This principle acknowledges that the researchers' preconceptions play a part in how the material is interpreted. Hence, critical reflection on how the material is socially constructed is needed. The first author, who collected the data, is a surgical nurse and has been working in health care for several years. She has thorough experience on how EHRs have been used in clinical work as well as for management purposes. Accordingly, the initial data gathering was largely from an "inside perspective", based on knowledge of how things work in health care. Combined with the intensive engagement with the empirical field, and the analytic tool provided by the theoretical lens, this may be described as an insider's knowledge with an outsider's view [50].

The field notes from the observations and the transcriptions of interviews are available in the Norwegian language.

4. Case

4.1. Background

Following an invitation to tender, the Northern Norway Regional Health Authority decided in 2011 to invest in new clinical ICT systems for all the 11 hospitals in Northern Norway. The FIKS project was then established with a budget of EUR 90 m for the period 2012–2016, and it is currently one of the most ambitious healthcare-related ICT projects in Norway. A key aim of this project was to replace an existing, largely free-text-based EHR with a new archetype-based (i.e., highly structured) EHR offering extensive decision support, interoperability capabilities and easy reuse of data for clinical research. The procurement conformed to the national Norwegian strategy of building an infrastructure for specialized healthcare based on the openEHR architecture [58]. In 2012, the National ICT Health Trust conducted a project to gain experience in using archetypes from openEHR to define clinical variables, which resulted in a recommendation to build an infrastructure for specialized healthcare based on this approach [59].

DIPS, the principal vendor in the FIKS project, currently holds approximately 86% of the hospital-based EHR market in Norway. During the last 25 years, it had accumulated high-level expertise in developing ICT systems in this domain. Due to the complexity of the domain, DIPS had started to experiment with an MDD methodology as early as 2006. This culminated in 2011 with the decision to use the openEHR architecture for its EHR for the future, a product we refer to here as NewArena. Consequently, DIPS was well positioned to respond to both local clinical needs and national strategic expectations when developing the next generation EHR. But most importantly, DIPS regarded the openEHR architecture as the perfect strategy to handle an increasingly complex healthcare 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 (. . .) [in comparison] openEHR is a very good domain model of the healthcare sector (. . .) and building a system where it is possible to model things and change structure afterwards would be very efficient for us" (system architect, DIPS).*

Through this adherence to the openEHR framework, DIPS could concentrate its efforts on developing the technical part of the new EHR while the users were expected to model the clinical content of various healthcare domains through archetypes in accordance with the national strategy [58]. In turn, the vendor's running software would process and interpret the archetype library in order to generate user interfaces, workflow and process support. Everything would thus be in accordance with a model-driven design approach that enabled DIPS's designers to operate on a more abstract level than traditional development methods would have allowed.

4.2. Phase 1—preparing for local archetype design

When the FIKS project started in January 2012, DIPS invited a broad range of future users into different development tracks.

More than 150 clinicians from all the 11 hospitals in the northern health region were invited to workshops to define their wishes and needs for a new EHR. At the same time, DIPS wanted to lay the groundwork for clinical modelling that would raise the level of abstraction in the specification phase, which in turn would increase automation of DIPS's development process. As a result of the workshops, five main themes for the user interface for the new EHR were identified: display of data, workflow, use of clinical pathway templates, communication capabilities, and implementation of/access to guidelines. An overall aim was to develop NewArena in such a way that it constituted a software framework for dynamically handling the defined archetypes. This was illustrated when the developers presented ideas for a new surgery-planning module to the users. According to the developers, they would not develop a specific local functionality for surgery planning, but rather a generic functionality that made surgery planning possible. DIPS thus aimed at building the framework that allowed the archetypes to be dynamically amended later on. This also represented a different approach than other comparable vendors had applied:

> "Perhaps you have heard of the Slovenian vendor Marand, which is serving a hospital in Moscow. They use archetypes, but they are doing it differently than we plan to. They start out with defining the archetypes that they need, after which they develop software based on the archetypes. This means that the software is to a great extent directly connected to just these archetypes (. . .) In contrast, we want to write the software first, then we import archetypes that auto-generate screens and a lot of other things (. . .) thus, it is the step of not writing more code which we aim for. NewArena is therefore foremost in the world . . . no one else is trying to do what we do" (developer 4, DIPS).

The idea was that this would make an extremely flexible, efficient and sustainable system, as it would reduce the work of the developers considerably:

> "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).

This was in accordance with the principles in the openEHR architecture; the separation of concerns would allow stable—and at the same time evolving—EHR systems to be built without specific knowledge about the clinical content. The flexibility made possible by separating clinical and technical concerns would enable the clinicians to take control of the content without technical insight and understanding of the systems. This flexibility would represent a totally new situation:

> "It used to be like 'you tell me what you want and we will make it' . . . but now you decide what you want, and then you create it yourself. We have in a way made the tools that can process the archetypes which then give you a user interface" (developer 4, DIPS).

The first demonstrations for the users of what the new software could do were very impressive. To enhance the users' understanding of the new system, DIPS made a presentation of the two-level model concept by using LEGO® as an analogy. The archetypes were pictured as LEGO® bricks in the hand of the users, who build any construction (document) following a template. The demonstrations showed how the clinicians could design archetypes "on the fly" as they were documenting their work. If they needed a variable, they could just open the smart editor and define it immediately, after which it could be easily reused—for instance in the patient's medication chart. Archetypes were also demonstrated as making it possible for the clinicians to design their own set-up of documents by reuse and combination of data. The clinicians embraced the flexibility to register what suited their discipline best and the possibilities of reusing the data for research and reporting.

In October 2013, an early version of the new EHR was ready to be piloted and tested at the university hospital. It demonstrated the user interface, some basic functions on how to set up a document, how to search for content in the EHR and how to make lists of patients for different purposes. The users were happy with the prospects of these functionalities. However, many end-users thought that they were getting a structured EHR ready to be used, but this was not the case. DIPS had only defined a small number of archetypes to exemplify how these would work in the EHR. Now, it became clear to everybody that the new EHR would not be fully operative without the presence of a broad range of archetypes to represent the clinical content of different disciplines.

4.3. Phase 2—scaling archetypes to the national level

The lack of archetypes to exploit the functionality of NewArena became a pressing concern for DIPS. While focusing heavily on development of the software, DIPS had expected the users—in accordance with the openEHR approach—to take charge of modelling archetypes. Along these lines, DIPS expected the Northern Norway Regional 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 2, DIPS)

The management of the FIKS project for their part 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. DIPS had also expected a stronger initiative from the National ICT Health Trust, which had recommended the development of an openEHR-based architecture. Hence, an increased understanding of the need for a broader national initiative on this work led the National ICT to establish an editorial group for national governing of archetypes in January 2014. The group was located in the western health region, because they had gained experience in modelling archetypes through a project in 2012 [59]. In February 2014, the editorial group launched a Norwegian CKM, aiming to govern Norwegian archetypes by the same principles as the international CKM. The secretariat in the editorial group would be responsible for the editing of archetypes, i.e., if there were a request for a given archetype, it would be their responsibility to find out whether the archetype was already available in other repositories and to organize the consultative process among clinicians. The editorial group would ensure the quality of the process by ensuring that all perspectives were taken into account. For the hearings on archetypes, the quality criteria included picking and recruiting the clinicians who were most relevant in terms of their specialist background as well as geographic distribution of the clinicians throughout Norway.

If the clinicians consented to the archetype and the editorial group found the quality of the process acceptable, the archetype would be approved. The clinicians' role was to participate in defining the archetypes and to attend the hearings. This was not expected to take very much time. If some clinicians had a request for a given set of data or functionality in terms of archetypes, they had to participate in the process of defining the exact content. Still, the clinicians were not expected to learn how to model the

archetypes—that was too complicated. The editorial group would design and map the archetypes after local initiatives had defined requirements. The group would also issue the final approval of archetypes after a review process among clinicians. However, the recruitment of clinicians for the review process in the Norwegian CKM progressed slowly:

> "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)

In addition to the slow recruitment of clinicians for the review process, the modelling of archetypes proved to be a cumbersome process. In the project ACT 41, the report stated "It takes a great deal of maturity to work with archetypes". Although the competence in the project group was fairly high, the task was not easy from either the technical or the clinical perspective. Archetypes are defined as maximum data sets and hence they should encompass all possible use cases. As Norwegians started to work on the archetype "smoking history" from the international CKM, 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. The archetype thus had to be revised to take this into consideration.

At the start of work on a mind map, the different aspects of an archetype on smoking history were listed. For a maximum data set, the strategy is "if you can think of it, include it". But the different fields could be populated in very different ways, as became clear when two different groups were to model the same clinical content for "smoking history". The groups came up with totally different results, and the aligning of the different suggestions depended on negotiations that could sometimes be time consuming and cumbersome (Figs. 2 and 3).

By November 2014, only one archetype had been approved in the Norwegian CKM, the widely used example of blood pressure. It had been translated into Norwegian from the International CKM and modified for Norwegian healthcare. So far, no locally initiated archetypes had been approved.

4.4. Phase 3—DIPS undertakes the archetype design job

The slow progress in the national initiative of modelling archetypes was increasingly a problem for DIPS. The vendor was running behind schedule for delivery of NewArena, and the surgery-planning module in particular needed working archetypes. The surgery-planning module combines structured data from the EHR with logistic data and resource overview data from other systems in order to create a schedule for surgery activities. Hence, integration and interoperability are important features of such a module. The module was supposed to be released in October 2012, but in November 2014 it was still not available:

> "When you look at how far the national editorial group has come, they are still talking about blood pressure and weight... that's not good enough for us. We can't wait for the national editorial group to finish before we deliver our product to the customers" (developer 2, DIPS).

In this situation, DIPS staff started to work on archetypes themselves, to be able to test the functionality they had developed. However, this was far from ideal, because they did not have the clinical knowledge to do so. An illustration of the emerging problems came to the fore when the developers tried to model an archetype for an involuntary psychiatric commitment. Because they did not know the criteria for such a decision, the archetype turned out to be inadequate. What was more surprising, however, was that the ideal separation between the domain and the technical concerns was not as clear as they believed it to be. Rather, modelling the archetypes required a certain degree of technical insight as well:

> "You cannot just delegate this to a clinician. One must have knowledge about archetypes, about modelling and data structures, how things actually work within the technical domain" (developer 3, DIPS).

This seemed something that also clinicians experienced, from their point of view. They were only supposed to define clinical content of the archetypes, but this turned out to be difficult because content depended so much upon context. So only listing content without relating it to how it should be used and reused turned out to be difficult:

> "When I first logged on to the CKM I felt totally lost. The whole thing appeared too technical to me—I did not understand what my contribution would be" (clinician).

The members of the national editorial group, for their part, were not happy with DIPS experimenting with modelling archetypes. An important goal for the dual modelling approach was to have vendor-independent systems using national archetypes to ensure interoperability.

> "We've been a little concerned that DIPS has initiated and created their own archetypes in their back yard, so to speak. We have looked into some of these archetypes, and in our opinion most of them are not reusable at all. So it is a bit worrisome, we know they've got time pressure for delivery of a product, and we are lagging behind in approving the archetypes that they can use" (member of editorial group).

However, this problem was also recognized by DIPS staff, and they were worried about the developers' lack of the clinical knowledge required for the modelling. They invited users to workshops for modelling archetypes, but were still not sure that the result conformed to the OpenEHR standard. Still, because DIPS needed approved archetypes, they felt obliged to contribute to building the repository. Trying to speed up the process of defining archetypes, DIPS took the initiative to gather 25 delegates to agree upon the content of basic documents in the EHR: the admission note, the outpatient clinic assessment and the discharge note. These notes were regarded as particularly important when it came to reuse of data to facilitate the clinicians' working routines when documenting their work. Also, these kinds of notes are widely used in hospitals, adjusted to the individual medical discipline. The delegates met for three working days, but there were long discussions on what would be proper content, and they only reached agreement upon the content of the admission note. The process of deciding which elements could be structured was context-dependent and based on the experience of the individuals participating in the workshop. The discussions were characterized by strong opinions on specific needs for the diverse medical disciplines. Hence, it became difficult to widen the scope from what was specific to a single department to what would apply in general.

The meetings resulted in agreement upon a list of archetypes that could make up a basis of "most needed" archetypes for the admission note. Having tried to model archetypes by themselves, DIPS had encountered the complexity of adhering to the openEHR standard to make them interoperable, and the lack of clinical knowledge to actually define the content. Thus, they intended to submit the list of archetypes to the national editorial group where

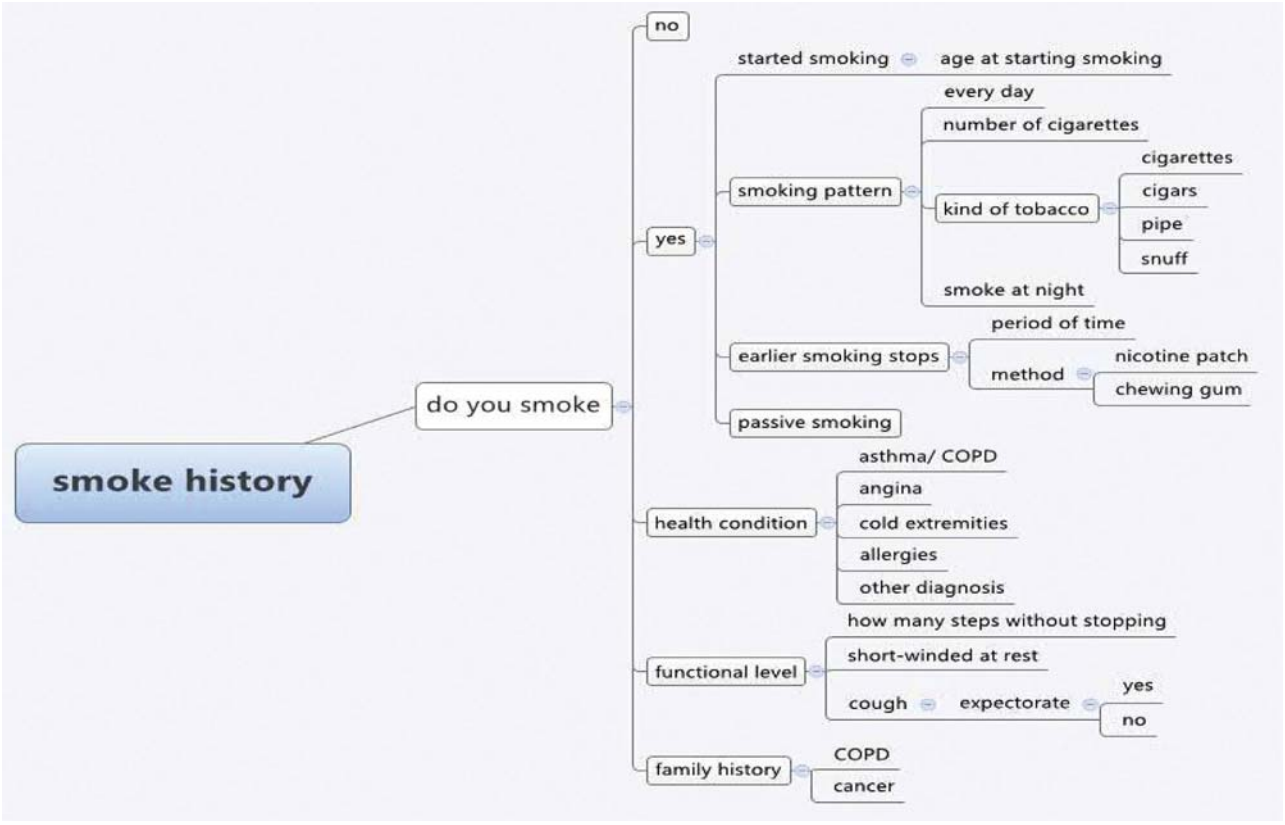

Fig. 2. Mind maps of smoking history archetypes reflecting different perspectives.

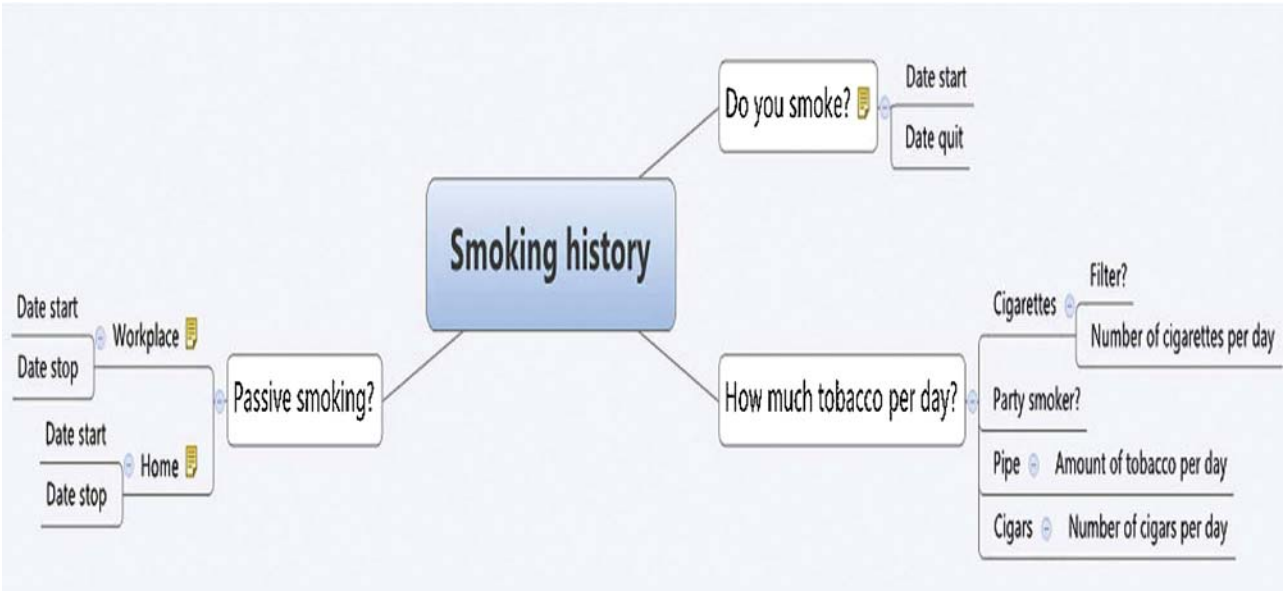

Fig. 3. Mind maps of smoking history archetypes reflecting different perspectives.

the archetypes could undergo the quality assessment needed for incorporation in the Norwegian CKM. However, taking the slow progress of the national CKM into consideration, they also decided to turn to international expertise to ensure archetypes according to the openEHR standard.

4.5. Phase 4—going global

In order to deliver NewArena, DIPS depended on working archetypes. This was clearly a lesson learned from the initial testing of the system. The key problem was that modelling Norwegian

archetypes was progressing too slowly for their needs. Also, their internal efforts to model archetypes had fallen short of the expectations. Although the international CKM holds more than 300 archetypes, only a small number have passed through the formal governance processes in Norway, which allow vendors to implement them with confidence that they have been clinically assured. Accordingly, it became increasingly clear to DIPS that time might be running out:

> "Selling the idea [of an openEHR-based EHR] without the archetypes is only going to hold for just so long. It's like selling tinned air. Unless we get a repository of archetypes that we can reuse between countries and between vendors, this is nothing but a good idea" (manager, DIPS)

Given this precarious situation, DIPS felt it was time to "go global" and took steps to improve its international collaboration with other international vendors using the openEHR architecture. The openEHR industrial group consisted of seven associated vendors from around the world (Cambio Healthcare systems, Code 24, Critical Software, DIPS, Infinnity Solutions, Marand and Ocean Informatics). In May 2014, DIPS decided to take on a technical solution developed by one of the other vendors in the openEHR industrial group, the Think!EHR Platform, as a building block for NewArena. The Think!EHR Platform is designed for real-time transactional health data storage, query, retrieval and exchange based on vendor-neutral open data standards including openEHR.

DIPS also addressed Ocean Informatics, the academic expertise behind openEHR, at a joint workshop in the northern health region of Norway. DIPS encouraged Ocean Informatics to engage more closely with the industry:

> "I am in no doubt that openEHR is the best alternative there is, but it is hard to do and requires a lot of work. No single actor is going to be able to do this alone (. . .) We see that there is need for a much stronger and more focused collaboration in the openEHR community (. . .) also about academic activities: how do we [the openEHR community] choose our fields of interests when it comes to academic activities—can we cooperate in ways that make us all feel relevant to each other?" (manager, DIPS).

Being in urgent need of archetypes in order to deliver the contracted product, they had been looking for some time at what other essential vendors in the openEHR area had done:

> "We see that Marand for their systems in Slovenia and Moscow had a need for 1000 archetypes. They commissioned Ocean Informatics to help them with the modelling. 1000 archetypes is quite a lot. But modelling without necessary skills, you do not know if you get it right,—and you may run into trouble if you later on want to integrate two systems" (Developer3, DIPS).

In September 2014, DIPS hosted a "Road-Map meeting" for the openEHR community. Amongst other issues on the agenda, the industrial group in openEHR commissioned 69 international key archetypes to be published in the international CKM. Over a four-month period, the archetypes were to be authored, clinically reviewed and published. The list encompassed the archetypes resulting from the meeting that DIPS had initiated nationally to agree on content for the admission note (see phase 3). The editorial process is normally extensive with repeated review rounds on each archetype, following the same process as described for the Norwegian CKM. Therefore, the industrial group asked Ocean Informatics to adopt a rapid development methodology, so that publication could be achieved quickly. This implies shorter and fewer review rounds; i.e., only one or two review rounds per archetype were planned. It was recognized that this might result in occasional missteps and that a published archetype might need future substantial revision. However, balanced against the advantages for the implementers of a rapid development cycle and publication, the risk was accepted.

As a result of the complexity of modelling archetypes, DIPS is reconsidering how much should be expected from its customers, even if the same customers are generally positive to archetypes:

> "We don't plan to just deliver an empty system requiring you (the customers) to spend three years to build it in order to utilize it . . . I assume that we (DIPS) will offer packages containing archetypes, sets of rules and user interfaces, for instance surgery planning" (developer 1, DIPS).

The customers for their part had acknowledged the importance of approved archetypes for ensuring the possibility of reuse, research and reporting of identical data. Thus, in the process of defining the acceptance criteria for the surgery-planning module in NewArena, the users required the national editorial group's approval of all archetypes that were included in the module, even though the user communities themselves were supposed to be responsible for developing the necessary archetypes.

5. Discussion

From the outset of this openEHR project, the key stakeholders were well-aligned on the overall goal, although with varying motivation: DIPS wanted to improve efficiency in its development process by applying a MDD approach, the health authorities found great promise in interoperability on the national level, and the users saw potential for taking charge of their own design. This joint commitment allows us to more narrowly zoom in on the four fundamental assumptions embedded in MDD methods and to provide a critical analysis of these.

5.1. The assumption of separation of clinical and technical concerns

A key concern in MDD is to exploit several levels of abstractions in the development process, which for openEHR is expressed through a two-level modelling approach. The essential idea is then to draw a line between the clinical and technical domains, where users take responsibility for the clinical domain and designers take responsibility for the technical domain, hence placing responsibility for the different areas according to competence [24].

Despite the good intentions, our case unfortunately shows that there is not such a clear separation of technical and clinical concerns. The boundary between the technical and the clinical was rather blurry, where key actors on both sides were dependent on each other and each other's competence. This was clearly expressed in the view of one of the DIPS's experienced developers: *"You cannot just delegate this to a clinician. One must have knowledge about archetypes, about modelling and data structures. . . the general users will not know about archetypes, it is the user-interface and the usability they will relate to, and that will determine their comprehension of the system"*.

Based on a socio-technical perspective [14,16,17,46], we argue instead that the clear separation between the clinical and the technical domain is illusory and echoes a technology-deterministic idea where "technical change is in some sense autonomous, 'outside of society" [51], i.e., not embedded in the organization it is supposed to change. To continue the argumentation, from such a perspective designers typically configure users into predefined roles [52] on how they *should* behave and hence fail to acknowledge how they *actually* behave. This is also illustrated by our data, where the developers are surprised that the users do not act according to the rules outlined in the modelling regime. An essential point from the exist-

ing studies on socio-technical issues (see above) is that technical systems become embedded in practice; it becomes nearly impossible to separate the one from the other because the technical aspects shape the organizational ones and vice versa.

Not taking socio-technical issues into consideration increases the risk of unsuccessful or even abortive implementations [15,16,43]. Both designing the technical system and modelling the domain required technical and clinical competence; as our study illustrates, developers and clinicians thus found themselves working together in both arenas where they could exploit and challenge each other's competence. Developing archetypes is in reality a complex issue that needs to involve many stakeholders. In our case, DIPS had to deal with this challenge by sharing the responsibility for promoting and developing archetypes with the user domain. This also became increasingly clear to the participants in the project who were seeking to establish broader international collaboration among users, vendors and policymakers (see phase 4). This further confirms that there are overlapping boundaries between the social and the technical aspects [53] where many stakeholders need to be involved to develop the new system.

5.2. The assumption of a wide-spread user commitment

MMD in general and openEHR in particular rest on the foundation that clinicians will be attracted to the process of modelling their own systems and will take part in developing archetypes for this reason. However, our study illustrates that while the users were committed to the existing EHR portfolio and NewArena, which would give them new functionality in the short run, they were not particularly committed to the archetype development. This is underscored by the slow and difficult process of recruiting clinicians to participate in the audits in the Norwegian CKM. Eighteen months after the launch, only 60 active users were registered [60]. Moreover, the slow process of developing and negotiating the archetypes was time-consuming and proved to be demotivating for ordinary users.

Overall, it was not very clear who should participate in this and on what grounds. As a result, an essential problem emerging from our data was that developing a repository of archetypes for the national CKM was geared towards a collective and abstract benefit in the future rather than a concrete software product that could swiftly be put into use [54] with immediate benefits for the users. While NewArena benefited from hospital management assigning local users to the design process, the modelling of archetypes suffered from a totally different situation because it was based on personal interest and voluntary contribution to the openEHR community. Hence, the archetypes were supposed to evolve, shaped by a new group of voluntary "global" users beyond the support of hospital management. The clinicians who contribute to the audits of the archetypes may be located anywhere, as our case shows, when the international openEHR community is commissioned to model archetypes for NewArena. Thus, participating in the development of a new system does not necessarily mean being assigned by the health trust to work with the vendor on developing the software; it may also involve participating in the hearings and audits regarding the archetypes for the national editorial board, or for the openEHR community. Such participation is based on individual interests by the principle of "do-ocracy"—i.e., the one who does also decides. In the process of moving from the initial picturing of modelling archetypes "on the fly" to building a tightly governed national repository, the possibility for immediate use was lost. Building for future use was not something that clinicians would prioritize at the expense of pressing day-to-day clinical work.

5.3. The assumption of user control

As we have pointed out in the theory section, experienced users are supposed to take charge in modelling their domain and in this way they control how the EHR should evolve. However, this is no easy matter. For instance, although defining the archetypes is not supposed to require technical skills [10], these turned out to be indispensable. Even if clinicians who take part in the hearing processes in the governance of archetypes are only supposed to define the clinical content, they are later supposed to approve the data model that has been constructed from the definitions. Hence, they need to understand the logic in the way the model is built, as the developer pointed out: "*. . . You need to understand how things actually work within the technical domain*". As the project proceeded, it became obvious that modelling archetypes was not something that every clinician should or would do, as it proved to be both complex and time consuming. Additionally, because interoperability and reuse of data were of greatest interest in the new EHR, as the project progressed it became painfully clear that to achieve this, the archetypes would need to be tightly governed; 'undisciplined creation and application of archetypes threatens the goal of semantic interoperability' [37] p. 337. To ensure interoperability on the national level, the definitions also had to be national or, ideally, international (see more on this in the next sub-section). Thus, the strategy of broad user participation in local archetype modelling was abandoned. It seems that contributing to modelling archetypes is only for especially interested clinicians, and in order to recruit sufficient numbers for the process, one needs to search worldwide.

Another crucial point in our study is that the decisions took place outside the formal organizational structure encompassing end-users. This resulted in an unintended scaling of the openEHR approach from a relatively local scope to an international context in which the local users lost virtually all control. Further, the placing of the responsibility for modelling and approving archetypes in a national editorial group distant to the traditional healthcare hierarchy undermined the promised influence of local users in the hospitals. Hence, in our study, the notion that the "openEHR archetypes are putting the clinician back in the drivers' seat" [11] does not seem to apply for the local clinicians.

The globalization in archetype modelling also represents a change from the traditional role of end-users in the design of IT tools. While global users may contribute to modelling the archetypes, the design of the user interfaces and local peculiarities still relies on close relations between developers and users. But, because power to define the archetypes is assigned to voluntarily participating domain experts, local users may experience that the global users are the ones shaping their practices, as that level takes charge in the modelling of the domain.

5.4. The assumption of modelling the domain

MDD certainly sounds appealing when there is an up-and-running archetype repository that various vendors and users can apply freely. The openEHR community estimates that approximately 2000 archetypes should be sufficient for covering the essential part of hospital-based EHRs. However, the key question is how to reach the stage at which the archetype repository may serve as a working library.

In MDD, the modelling process is frequently portrayed as a task conducted by users in which they depict and map the current domain, i.e. the domain is something that the user communities need to "uncover" and categorize into archetype elements. Rather than adhering to such a simplistic view, we see a different picture. The healthcare domain is inherently heterogeneous, and creating a domain model presupposes negotiation, compromise and agreements. In short, it is a complex standardization process that

influences both the actual modelling and healthcare practice itself: "*Archetypes attempt to harmonize, unify and guide clinical practice by containing consensus knowledge, so containing universally valid content*" [8]. Hence, the process of mapping a practice also implies changing and standardizing the practice.

Our case shows how the process of defining the standards turned out to be a cumbersome and time-consuming process. The negotiations on different levels were comprehensive and the process of reaching consensus was demanding. Even the "simple" example of smoking history shows that clinicians interpret their practices differently [48,49] depending on how they perceive the practice or how they want it to be. They come up with different suggestions that require considerable negotiation in order to reach agreement. These differences reflect the practices and disciplines of each clinician, and hence, standardizing how they record smoking history in a medical history also means changing their way of reasoning and working [14]. Even if semantic interoperability is desirable for the users as well, it can be painful the moment it touches upon the heart of their work practice [55]. It is reasonable to believe that such challenges may escalate when clinicians from different fields are supposed to agree on the same phenomenon.

Additionally, one always has to consider the level at which the archetypes will be used and shared [39]. For instance, at the clinical level, clinicians need to negotiate and compromise on how an archetype at this level should look. This is far from easy, as our example of smoking history illustrates. Several of the chosen international archetypes had to be adjusted when designed for a Norwegian context. This echoes the findings of Pahl et al. [34], who found that although a major part of demographic and clinical patient data for their needs in obstetric care was already represented by existing archetypes, a significant part required major modifications. This leaves one wondering how the challenge of agreeing on national archetypes for specific areas in the healthcare sector might work out. For instance, in Norway, the unions of health care workers such as the Norwegian Nurses Organization and the Norwegian Medical Association have a formal role in suggesting clinical guidelines and care standards for the health authorities. Various specialist unions will typically give priority to specific needs, partly diverging from other specialist unions. This will also complicate the picture of agreeing on one unified standard.

5.5. Lessons learned

Based on our analysis, we would like to highlight some socio-technical aspects that should be addressed in applying MDD following the openEHR method in large-scale EHR projects.

*We suggest that a broad assemblage of contributors must be engaged for developing an archetype-based system. Making models of a domain calls for actors with new competencies—domain experts—who besides being familiar with the unique characteristics of the domain also need to understand data modelling. This "cross-competence" must be achieved in a multidisciplinary collegium, in which it is difficult to differentiate the roles and responsibilities. This contrasts with the assumption embedded in MDD that separating the technical concerns and the domain allows developers to concentrate only on the technical aspect while the users themselves model the domain.

*Further, the widespread user commitment seems to rely on especially interested clinicians worldwide, hence making the promise of user control rather empty as far as end-users are concerned. Local users will need to apply globally defined concepts of the domain rather than defining their own, unless they volunteer to the openEHR community to contribute to the archetype modelling process. In any case, this calls for new strategies for mobilizing a broader range of users to take part in the modelling process, and we suggest formalizing this work within the hospital organization. In a large-scale project such as our case, modelling archetypes should be part of the project's activities.

*Finally, while internationally semantic interoperability through coherent archetypes is an appealing objective, omnipresent questions in each case will be whether the costs outweigh the benefits, what we are doing this for, by which means, and what the consequences are. The modelling of the domain may turn out to be a cumbersome and complicated manoeuvre, as it comes down to defining and standardizing work practices for local clinicians. Local needs and jurisdictional requirements must be addressed or else the models will not be developed and deployed. However, because modelling archetypes is complicated and international (as well as local) cooperation is needed, one needs to find a way where international and local initiatives can successfully function together.

Summary points

Already known:

- Model Driven Development (MDD) rests upon the key assumptions that separation of technical and clinical concerns enables clinicians to engage actively in building an EHR system, leads to widespread user commitment, and that clinicians modelling the domain themselves is a straight forward mapping of—or uncovering of—practice.
- OpenEHR is a promising MDD approach for Health Care in many countries worldwide, but not yet proven in large-scale implementations.

What this study has added:

- Empirical insight from a large scale openEHR implementation, illustrating the complexity of key assumptions embedded in MDD.
- The separation of clinical and technical concerns seemed to be rather aspirational as both designing the technical system and modelling the domain required technical and clinical competence.
- Modelling proved to be a complex standardization process that influenced both the actual modelling and healthcare practice itself.
- User commitment and user control does not to apply to local end-users in large-scale projects, as modelling the domain turned out to be too complicated and hence appeal more to especially interested users worldwide.

5.6. Limitations of the study

Our study is based on an in-depth study of an ongoing large-scale openEHR project (2012–2016). Although we have studied this project over this whole period, we do not know the final outcome of this project, which we believe would have enriched our conclusions. In addition, while we have strived to give the different stakeholders a voice, it has not been possible to include each and every stakeholder's perspective on a detailed level. Our choices of what to include and what to exclude have been motivated by our focus on modelling and designing a new EHR. As a result, the vendor's perspective is emphasized more strongly than the view of different kinds of clinical professionals.

6. Conclusion

By focusing on the assumptions regarding users in MDD, we have identified several socio-technical challenges that emerge—and that must be handled when applying MDD on a large scale for complex domains. MDD is more complex than just sepa-

ration of tasks. Maybe the translation of "separation of the domain issues from the technical issues" into "clinicians are responsible for making archetypes—as the artifact to describe the domain issues; developers deal with technical issues—such as database design and screen generators, independent of content" has been too simple. For the user domain, we find that describing and modelling the domain calls for new competencies. Further, these activities introduce standardization reaching far into work practice that necessarily will scale up and increase complexity in large-scale projects.

Author contribution

Bente Christensen has contributed by acquisition of data, analysis and interpretation of data, drafting the article and approval of submitted version. Gunnar Ellingsen has contributed by analysis and interpretation of data, drafting the article and approval of submitted version.

Conflict of interests

There is no conflict of interests.

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