Paper in progress: The interplay between local and global organizational infrastructure to make an archetype-based EPR system grow

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Abstract. Interoperable Electronic Patient Records (EPRs) are of high priority in all Western Healthcare Authorities, and for this purpose the openEHR approach is promising. The openEHR approach is intended to support "user-driven" standardization processes of clinical information on local/regional/national levels, and addresses a need of a multi-level organizational infrastructure - a mixture of various structures, processes and relational aspects. This requires a well-functioning governance organization that make decisions, monitor results and performances at different healthcare levels. Important questions to ask are how will the clinicians enroll wishes and requirements of new archetypes, how to prioritize the development of required archetypes, and how to govern standardized clinical information on several organizational levels? In this paper, we have followed the development process of a new EPR system based on the openEHR approach, with the aim to give answer to these kind of questions.

1 Introduction

A considerable body of literature has demonstrated, empirically as well as analytically, that information systems need to be situated to the local context of use[4],[10],[16]. This challenges the focus on Electronic Patient Record (EPR) systems as means to support shared - and integrated care, which over a decade has been of high priority for the health authorities in Norway and other western countries [14],[15]. Recently, a national Norwegian initiative has gradually gained foothold using the openEHR approach to establish interoperable Electronic Patient Record (EPR) systems. The national initiative have been established both for the purpose of building a national repository (a so-called Clinical Knowledge Manager) of common semantic data elements for collaborative EPR systems, and large EPR vendors are building their system portfolio around the openEHR technology [8],[15],[20].

Accordingly, for infrastructural information systems that span numerous contexts spread out globally, it is necessary to strike a balance between sensitiveness to local

contexts and a need to standardize across contexts. Standardization by the openEHR approach is intended to be driven by the clinicians' on local/regional/national levels, and addresses a need of a multi-level organizational infrastructure - a mixture of various structures, processes and relational aspects – and require a well-functioning governance organization that make decisions, monitor results and performances at different healthcare levels[20]. Important questions to ask are how will the clinicians enroll wishes and requirements of new archetypes, how to prioritize the development of required archetypes, and how to govern standardized clinical information on several organizational levels?

Accordingly, we ask the following research question: ***What is the interplay between local and global organizational infrastructure to make an archetype-based EPR system grow?***

Empirically, we focus on the development of a new EPR system based on the openEHR approach using archetypes, which allow user communities to define structured data in a very dynamic ways and offers a comprehensive semantic framework combining formal clinical modelling, terminology, and a service infrastructure [22]. The openEHR approach is apparently ensuring the global-local dynamic of organizational infrastructure, as well as clinician driven modelling of standardized clinical information on a theoretical level. While earlier research on OpenEHR archetypes has demonstrated success on conforming to this approach on a local levels [5],[12], this paper focuses on the openEHR approach on local, regional and national level.

This study is positioned within a constructive paradigm and makes use of interpretive methods [11],[21], where we empirically report from a large-scale EPR project, running from 2012 to 2016 in the North Norwegian Regional Health Authority. In 2011, the North Norwegian Regional Health Authority issued a bid for tender, requesting new clinical ICT systems for all 11 hospitals in northern Norway. The Health Authority established a Regional Project with a cost likely to exceed €100 million for the period 2012–2016. The EPR vendor, DIPS ASA, became responsible for developing a completely new regional EPR for the Health Trusts, in close collaboration with The Regional Project.

Data was collected (in progress) through qualitative interpretive methods [11],[21], which included open-ended interviews, document studies and participation in project meetings. We have traced the development process of the new EPR system based on openEHR technology – starting on the local level with user-vendor workshops to ongoing implementation of real working EPR functionality. Through this approach, we emphasize various viewpoints of the process in order to ensure deeper understandings of the ongoing organizational 'infrastructuring' process of an interoperable EPR system and presented as three vignettes in this paper.

2 Background information/ Theory

Within a ward, the medical record mediates and coordinates the work of nurses, secretaries, managers, various medical specialists and other health professions. Within a hospital, the patient records are exchanged and circulated as the patient receives

different kinds of treatments. This kind of cooperation and coordination is increasing as a result of the trend from multidisciplinary treatment approach, "illness complexes"- as well as an increased number of medical specialties cooperating over organizational boarders [2],[3],[19].

The focus on multidisciplinary treatment approaches crossing organizational boarders addresses an increased need of Electronic Patient Record (EPR) systems able to communicate information across heterogeneous practices. Structured clinical information is an answer to this demand, which will make it possible for clinicians to categorize variables in order to build meaningful reports, to extract data for quality registers, and for clinical research [15]. In Norway, initiatives using an openEHR architecture have been established both for the purpose of building a national repository (a so-called Clinical Knowledge Manager) of common semantic data elements for collaborative EPR systems, and large EPR vendors are building their system portfolio around the OpenEHR technology based on an archetype approach. By using OpenEHR, it is possible to make EPR content structured in a multilevel modeling approach, in which archetypes are re-usable structured models of clinical concepts and knowledge made to standardize the content of EPRs [8],[15],[17],[20].

Archetypes are information elements of clinical concepts, where observations, options, instructions, and actions form the iterative clinical process and the specification of clinical content can be authored and amended later [6]. The overall advantage of the openEHR archetype based approach, from the system developer's point of view, is based on the two-level modeling approach where the developers would not need to know all the organizational peculiarities in every different context [1],[5],[7],[9].

The archetype approach can be compared to be the backbone of a large computer-supported cooperative (CSCW) system as well as a large-scale organizational memory and a means for decision-making for the authorities. Moreover, archetypes are the foundation for coordinating activity distributed in time and space. Accordingly, when archetypes are used to coordinate clinical work, influence decision making, and serve as data for research – work that is distributed widely over time and space, a corresponding complex and organizational structure and infrastructure evolves [4]. The notion of infrastructure is increasingly used for describing the networks of information systems to be developed to support cooperation and communication within and across e.g. health care. Despite the distributed coordination of activities, a considerable body of research has demonstrated that successful sociotechnical design of information infrastructure systems in health care starts with a thorough understanding of the practices in which they are planned to function [3],[10].

Information infrastructures in healthcare are characterized by their size and complexity concerning the technological elements as well as the number of developers and users involved. For those actively involved in the design of such networks, specifying the technological standards are undeniably what the design is all about. However, interoperability and standardization require a well-functioning governance organization, and in particular, a national archetype approach addresses a need of a multi-level organizational infrastructure - a mixture of various structures, processes and relational aspects - to ensure the clinicians "voice" thorough the standardization processes. By using OpenEHR, the clinical content is intended to be

standardized by the clinicians' on local/regional/national levels. In this paper, we use the notion of information infrastructure to study the evolving archetype and its organizational consequences [4],[13],[18].

3 Case

3.1 The Regional Project

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 Regional Project was then established with a budget of EUR 90M 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) EPR 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.

DIPS, the principal vendor in the Regional 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 Model-Driven-Development methodology as early as 2006. This culminated in 2011 with the decision to use the openEHR architecture for its future EPR system, which in this paper is referred to as the NewEPR system.

3.2 Vignette 1: Leaving the messy details of clinical practice to the users

As elaborated above, 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 period2008–2011—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).*
>
> *"The profit by using the "archetype approach" is that it allows us (the developers) to live in "our own little developers' world"—though, not the developers who implement the system. (…) the designers don't need so much clinical contextual knowledge, and the domain experts don't need extended technical skills—but we have to know a little bit of each other's domains" (Manager, 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. 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.

More than 150 clinicians from all the 11 hospitals in the northern health region were invited to workshops to define their requests for a new EPR system. In the initial phase of the development project, it was easy "to sell in" to the clinicians the benefit of an archetype approach. In example, the clinicians were enthusiastic to the possibility of gaining flexible structured clinical information, which could be re-used during clinical processes, and serve as a premise for process- and decision support.
A developer from the Vendor explained: *"We are going to build a LEGO® city, but at this stage we are making the description of how to put the single bricks [archetypes] together"*.

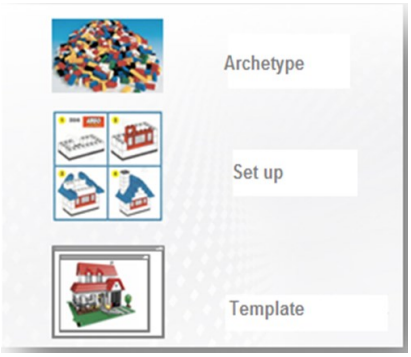

Figure 1.

However, building software according to the openEHR approach is different from traditional software design. Traditionally, the clinicians' requirements are gathered via the well-known "use case" methodology, designs and models are built from the requirements, implementation proceeds from the design, followed by testing and deployment of the software. Through an openEHR approach, the Vendor could concentrate on developing the technical part of the new EPR while the clinicians were expected to model the clinical content of various healthcare domains through archetypes.

At this stage of the development process, the vendor did not have any working software to present to the clinicians, but needed feedback from the clinicians about how the software should process the archetypes dynamically into the prospective user interface. According to the developers, they would not develop a specific local functionality for surgery planning, but rather a generic functionality making surgery planning possible (Figure 1). It was challenging for the clinicians to grasp the potential of a completely new technology. In particular, it was difficult to distinguishing the feedback in 1) how the prospective user interface should look like, 2) which clinical information that should be transformed into archetypes 3) the potential of local configuration of archetypes – in which 2) and 3) actually not was the purpose of the developer/clinician cooperation, but meant to be done by the clinicians themselves.

3.3 Vignette 2: Bureaucratization: Centralization – national governance. The Vendor led initiative.

During the first year of the development process, it became clear to everybody that the new EPR would not be fully operative without the presence of a broad range of archetypes to represent the clinical content of related to the surgery planning process. Accordingly, an increased understanding of the need for a broader national initiative to do this work led to the establishment of an editorial group for building and governing of a national archetype repository (a so-called Clinical Knowledge Manager) in January 2014. The initiative was developed through National ICT and the vendor that holds more than 80 % of the secondary healthcare EPR systems. In February 2014, the editorial group launched a Norwegian CKM, aiming to govern Norwegian archetypes by the same principles as the international CKM. It is important to notice that during 2014 the National Editorial group was of formed with members from each of the four regional health authorities and from the Directorate of Health. Two full time positions had the responsibility to coordinate the work of the Editorial Group (Figure 2).

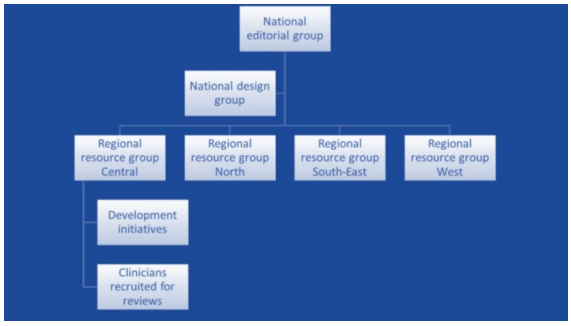

Figure 2

Launching a national repository of archetypes was an important step towards sharing clinical information over organizational boarders. Moreover, building the repository by the principles from the openEHR was a step towards vendor-neutral health data. To get a basic catalogue of archetypes quickly, the archetype governance program saw it as effective to start the process of filling the repository with observation type archetypes already developed and approved internationally. In addition, the development of archetypes is intended to be initiated through a so-called "do-ocracy", where domain experts - clinicians, allied health workers, and other experts – propose which clinical information that has to be defined as archetypes. In Norway the primarily work with archetypes were conducted at a national level, where the National Editorial group coordinated this the work.

During 2013, at the regional level the local ICT department at the University hospital in cooperation with the Regional Project had started to plan the archetype governance. The first version of a mandate had focused on "which health trusts became responsible for what", but the focus evolved into a need of new

organizational functions with new roles. However, it was difficult to plan for new technology that not was developed or installed.

The progress of modelling national approved archetypes went slow, and was increasingly a problem for the Vendor. The surgery-planning module combines structured data from the EPR with logistic data and resource overview data from other systems in order to create a schedule for surgery activities. Accordingly, the surgery-planning module needed working archetypes. In general, an estimated number of 1000-2000 archetypes were necessary to encompass the clinical content of an EPR system. In October 2015, the national repository had 26 approved archetypes, and 100 more were in process, but the absence of completed archetypes complicated and delayed the development of the new archetype-based EPR system.

In this situation, the Vendor started to work with archetypes them-selves in cooperation with international stakeholders and the National Editorial group, to be able to test the functionality they had developed, even if this was far from ideal. The evolving complexity of modelling archetypes made the Vendor reconsidering how much should be expected from the customers. The archetype concept state clearly that it is the clinicians' responsibility to propose and create archetypes, but the vendor could not deliver an empty system requiring the customers to spend years building the archetypes in order to utilize the new EPR system. Consequently, the Vendor took the responsibility of defining and creating the initial archetypes for the surgery planning module, in addition to the national approved archetypes appropriate for the particular functionality.

3.4 Vignette 3: In progress – implementation of archetype-based surgery planning functionality.

In April 2016, the surgery planning module was finally ready to be put into clinical use – though, in a very restricted clinical context; surgery performed on a limited group of outpatients in a University Hospital of Northern Norway. After more than 4 year of development and testing of the new EPR system, the implementation of the surgery planning module into clinical practice was prolonged and welcome by clinicians, project management, and the vendor.

As described in vignette 1 and 2, the archetype development process had not followed the official channels for several reasons. The archetype development process had been handled to reach the goal of a structured and process supporting EPR system, but the intended corresponding organizational structure had not evolved in correlation to the archetype process. The archetype concept was a complex concept to take in – also stated by the national pre-project: "[…] it calls for a degree of maturity to work with archetypes"[23]. In addition, the regional Resource group had been supporting the work from the National Editorial Group, e.g. by recruiting clinicians to join the national archetype consensus processes, and participating in the National Editorial Group's governance meetings and in national inquiry processes. Less focus had been put into the local development process where the new EPR system was to be implemented. Moreover, the vendor has not yet installed all the tools needed for the clinicians/domain experts to integrate archetypes into the EPR system. By time of implementing the surgery planning functionality of the new EPR system, the regional organization intended to fill into the official channel of a do-ocracy was not up running.

Nevertheless, the thorny road of organizational interdependencies to make the archetype-based EPR system reach clinical use raised some interesting questions related to the premature corresponding organizational structure. How will the end users enroll wishes and requirements of new archetypes during implementation and use? Will the clinicians recognized problems or see the opportunities within a process supporting system as a something to be solved by archetypes – especially when it comes to archetypes as actions and instructions that are bound up with local/regional/national standards for process and decision support? Will it be necessary to have special trained personnel, holding both a clinical as well as a technical understanding of the archetype concept, to support the clinicians during implementation and use? How will the interaction between end users, the Regional Resource Groups, the volunteer clinicians of the national consensus process, and the National Editorial Group spell out?

4. Concluding discussion

The vignettes are selected "snapshots" of the evolving and unpredictable process of growing an information infrastructure – and in particular the organizational infrastructure to support the archetype approach.

The evolving archetype approach can be compared as the backbone of a large computer-supported cooperative (CSCW) system. In this paper, we have put focus on the organizational aspect of the infrastructure. Vignette 1 and 2 describe the interplay between the clinician-vendor cooperation and the pressing need of a national archetype repository. Moreover, it is fair to say that the Vendor filled in the "domain expert" role as the development process evolved, even if that not was the initial intention. By following the development process into implementation (Vignette 3), it is timely to ask what the "domain expert level" actually implies?

The archetype based EPR systems are intended to be user-driven systems ("putting the clinicians back into the driver's seat"). Consequently, the domain expert level is very important for the interplay between local and global infrastructuring. During the implementation of the surgery-planning module, the vendor's role as domain expert has been evident. The closing questions of Vignette 3 point to the importance of both technical and clinical knowledge to fill this role – or level of organization. Still, it is not clear how to staff this organizational level because contextualization of archetypes need regional as well as local governance, vendor-dependent tool to integrate contextualized archetypes into the EPR system, and a "receiving set of experts" to organize the enrollment of clinical needs and prioritizing the development of archetypes.

However, by follow the implementation of the surgery-planning module (EPR system situated locally) seems promising in order to give answers to organize the "domain expert level". During the initial implementation, it looks like the Vendor must have a much more integrated role (cf. two-level model approach) than intended. Accordingly, it is tempting to suggest that the Vendor will fill a part of the "domain expert role" when it comes to defining this organizational level. However, the data collection and analyzed are not completed.

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