

The Contextualization of Archetypes: Clinical Template Governance

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Abstract. This paper is a status report from a large-scale openEHR-based EPR project from the North Norway Regional Health Authority. It concerns the standardization of a regional ICT portfolio and the ongoing development of a new process oriented EPR systems encouraged by the unfolding of a national repository for openEHR archetypes. Subject of interest; the contextualization of clinical templates is governed over multiple national boundaries which is complex due to the dependency of clinical resources. From the outset of this, we are interested in how local, regional, and national organizers maneuver to standardize while applying OpenEHR technology.

Keywords. Electronic patient record, interoperability, semantics, integrated care, OpenEHR

Introduction

Large and complex health care organizations globally fight to achieve seamless integration and standardization across professional, departmental and institutional boundaries. In Norwegian healthcare, existing Electronic Patient Record (EPR) systems provide an inadequate basis for such a workflow, and even quite modern EPRs are still considered systems of documentation rather than systems of process and decision support. Shared care and integrated care has over a decade been a focus area for the health authorities in Norway and more recently, which particularly emphasises the need for EPR systems to be organized in a more structured manner and for such systems to be more interoperable in order to communicate information across heterogeneous practices [1, 2]. The reason for this is an increasing demand for rapid feedback on results, and an urge to compare organizational or clinical data internally, regionally, or nationally. Structured EPR data 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. Structured data elements will also make it possible to organize information that supports process support- and decision support inside an integrated EPR portfolio with focus on patient pathways.

A national initiative to deal with this has gradually gained foothold in Norwegian healthcare. 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 ven-

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dors are building their system portfolio around the OpenEHR technology. Archetypes are information elements of clinical concepts, where observations, options, instructions, and actions form the iterative process of treatment and care [3]. By using OpenEHR, it is possible to make EPR content structured in a multilevel modeling approach that includes templates, archetypes, and a reference model intended to improve semantic interoperability and the reuse of data [4]. Archetypes are re-usable structured models of clinical concepts and knowledge made to standardize the content of EPRs. How do different pieces of software know what the data means, is give an increased opportunity for interoperability. “How to build a patient –centric longitudinal EPR across enterprises” and how to secure sharing of data among stakeholders in different areas of healthcare includes a focus on semantics with a standardized language for EPR variables. For example, a study by Garde et al. [5] concerns the modeling of clinical content of EPR systems that could become available internationally. The study shows how clinical content can be made available using archetypes and templates from OpenEHR and ISO 13606. Through this, the OpenEHR platform could become the foundation for safe sharing of the information the clinicians need as tool for decision support inside the EPR system (ibid). The Clinical Knowledge Manager for archetypes is planned to contain between 1000 and 2000 archetypes, archiving information about how new archetypes are translated, modeled, and shared. A precondition for success is that clinicians agree on the content of each archetype in the consensus process. In turn this will secure a common understanding of the clinical content of EPR systems over regional and national boundaries. Information based on archetypes will in the future form the content of any given EPR system that supports the sharing of OpenEHR technology. Clinical data (archetypes) will be contextualized through the use of templates. In turn, all schemes included reports, clinical processes, and clinical or organizational decision support are planned and organized by using different templates.

This paper concerns the three layers of organization, local, regional, and national that embodies the contextualization of structured data using archetypes. While earlier research on OpenEHR archetypes has demonstrated success on clinical process- and decision support on a local level [3], this paper focuses on the effect a national repository for archetypes has for the interoperability of a local, regional and national organized template production. Based on this we present the following research questions: What advantages does a national repository of consensus made archetypes bring, and what are the pitfalls?

1. Methods

This research use qualitative methods, interpretive, and ethnographically oriented, grounded in the action research tradition through the first and second author participation and contribution in the work accomplished [6].

Analysis of longitudinal research is a continuous and iterative process with an ever-changing intensity. As Klein and Myers [7] suggest, it can be understood as a hermeneutic circle that refers to relating the whole to the part, and the part to the whole. The part is not a fixed unit, but flexible, that is allowing changes to the unit of analysis for a given purpose. However, ethnography may also prove efficient in identifying, analyzing, and evaluating changes in practices that emerge from using the IT system as part of the design and implementation of this system. My background as a clinical nurse, ten years of working with clinical cancer research, and almost six years at NST

as an advisor, PhD student, and project manager has shaped my competence to include action research to the methodology of this research. I will do this by including the results from the national initiatives through the projects, and by inviting board members to participate and bring the regional archetype development into the research as important field experiences. Accordingly, action research is a framework for inquiry that seeks to bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people. Six interviews has been added (first author), and ten interviews (second author) to the numerous of meetings, documents, and texts written for the project lasting for an average of 1 hour.

2. Results

2.1. *The Archetype Governance*

The National Administration Office of Archetypes (NRUA) was established in 2013 by National ICT with the goal to produce high quality archetypes. The NRUA employs three people whereof two in full positions and one in a part-time position. Two new employees are suggested to start working specifically with modeling of archetypes and templates. NRUA further includes representatives from each of the four Regional Health Authorities. There are between two and three members from each of the four health regions. As an example, there were three members from the North Norwegian Health Authority, one physician with special interest in health informatics, one nurse with a PhD in information Systems, and one project manager from the regional ICT development program where the new process oriented EPR is developed.

The overall goal with NRUA is to coordinate the development and use of archetypes on a national level, both handling translations of international archetypes as well as handling local initiatives. It is called "Do-ocracy" where doers make the decisions, but where the reviews are initiated by the Editorial Group which also covers the recruitment of the reviewers to the national Clinical Knowledge Manager. If requirements are met, the further approval is done by the Editorial Group. The requirements are factors such as having the right number of clinical specialists for the right archetype (national level) where all four health regions are included.

Since the beginning in January 2014 NRUA has focused on the translation of already existing observation-archetypes like blood pressure, body weight, nutritional risk, height, and temperature. Clinicians have been invited to participate through the national Clinical Knowledge Manager after coordination between the regional groups and the secretariat at NRUA. Other archetypes are also considered, all based on regional programs or initiatives such as a specific nursing registration scheme in the West Norway Regional Health authority, archetypes for national clinical registers, archetypes ordered by clinical work-groups with focus on the development of the new EPR system, and a number of archetypes ordered by cooperating vendors on a global level. In this face the focus was on the translation of existing archetypes from the global Clinical Knowledge Manager. In CKM the specialist only need to adapt to what is clinically relevant. Specialists from all of Norway discuss the clinical content of variables that are important for clinical processes. An increasing problem has been late coming requests for structural changes which so far have led to several review-rounds that in turn can lead to an increased drop-out rate. However, there have not yet been disagreements of severe

character. Even so, there are always questions and skeptical engagement when it comes to tools like the Clinical Knowledge manager both towards usability and log-in errors: *“In both our experience, and based on feedback from newly recruited users, the CKM has an intuitive user interface making it easy to understand how comments are entered and saved. Some users experience problems with error pop-ups during login, but this seem to be related to older versions of Internet Explorer.”* (Member of NRUA)

On the regional level the project has invited 90 clinicians, nurses, nutrition specialists, and doctors. The clinicians chosen were based on the “have to” and “should” lists, and the most of them had earlier relations to regional ICT projects. In present time the project have 40 activated clinicians and approximately 10 members from the regional NRUA group and National Centre for Telemedicine that also include researchers with technological background. This group has gathered once every fourth week to discuss and coordinate with the national development. For the six archetypes now in the loop of getting consensus (Body-weight, Pulse, Respiration, Boy-Temperature, Height-Length, and MEWS-score which is a modified early warning score to detect the degree of illness) and with several more in the loop, the portfolio has increased to a number possible to start produce template of different character.

2.2. Clinical ICT Governance

Based on the two-layered model of the new EPR it became obvious that the regional health authority needed a new regional administration with focus on the clinical content of EPR systems independent of systems vendors. The production of template based schemes and reports, process- and decision support (contextualization) are processes that include initiative and dedication from a large number of clinical resources that needs to adapt to the process. Based on the ongoing regional project where the new EPR already was tested a clinical governance should be in place: *“Regional decisions have already been effectuated and there is a risk of them dissolving without necessary regional governance in place.”* (Leader of the “standardization-of-practice” project). In the beginning of 2013 the local ICT department at the University hospital started to plan the archetype governance, and the general governance of clinical EPR content on a regional level (modeling of clinical content). The first version of a mandate was planned and written by the local ICT department at the University Hospital as host for the EPR development process in cooperation with the large regional ICT project. The result was a “breakdown” where the focus was “which health trusts became responsible for what”. In more previous time new efforts has been done, and a regional model for radiology governance has been established in one of the health trusts as a pilot project. The project manager was asked where the bottle-neck towards success was situated, with the following answer: *“Except from the fact that there are political issues to the case.....new organizational functions require our department to “grow” into a new role.* As of this the future is uncertain, it is impossible to adapt to new technology that not yet has been installed”. In addition to this, the processes towards national consensus on archetypes have struggled due to the lack of clinicians and specialists needed to gain consensus which also have resulted in less activity with the development of the EPR and the following tests of the product. The interruptions caused by this has been several; 1) The national repository of archetypes is a slow developing process, but an increasing number of archetypes makes it possible for the vendor and clinical environment to start the production of clinical content. 2) The vendor has not yet installed all the tools needed for the clinicians to integrate clinical content. 3) The hospitals and

their ICT administration has not been organized (the regional administration) to agree on a standardized portfolio of schemes, process- and decision support, but has the technical installations and organizational standards in process.

2.3. Regional ICT Administration, Former Clinical and Technical

The existing regional ICT organization has since 2005 supported and managed all the hospitals' ICT systems which include clinical governance (in a cooperative sense), and all technical parts of the ICT portfolio. In 2013, the Health Region decided to reduce the number of ICT installations connected to the EPR from nine to one, creating a more efficient and cost saving centralized ICT portfolio. This was an important step towards a more regionalized and standardized EPR. The regional ICT organized and owned the project that was conducted in close collaboration with the EPR vendor, the regional ICT project and the four health trusts. This centralization is bounded to reduce technical maintenance and the organizational workload on the regional ICT organization, having just one centralized installation. The installation and the backup installation are both situated close to the University hospital. The regional ICT is responsible for governance of a regional system portfolio including the New EPR.

In addition to a centralized ICT portfolio, the actual *use* of the ERP systems has been evaluated. The regional ICT project established in 2012 a sub-project focusing on standardizing work routines for using EPR in the region. More than 500 users from the four Health Trusts participated in the process. The goals of standardizing were to increase quality and safety in patient treatment and establish a basis for sharing patient information across the region and former health trust boundaries. This project was also a required standardization effort needed for using a more process oriented and open EPR portfolio. Since the new EPR is based on structured information, process and decision support, and aims to underline patient pathways from beginning to the end across the region and different levels of healthcare, it is important to use the EPR in a streamlined way. This is a user-controlled system that needs to be founded on already established regional standards and new local/regional/national standards for process and decision support. The contextualization of archetypes depends on a standardized and integrated ICT portfolio where systems with different reference models for structured information needs to be mapped for integration. To achieve this a more nuanced governance is applicable: *"My guess is regional functional governance is placed in the biggest health trust, they already have an established organization for governing both the new and the old EPR, One alternative is that this is run from the health trust, another one is that this organization is moved to a regional level"* (Leader BigProject).

3. Discussion

3.1. The Contextualization of Archetypes

By using OpenEHR the clinicians will be supported with a more open, adaptive, and collaborative system which enables modeling of clinical content owned and made by the clinicians environment on local/regional/national levels. The modeling of clinical content, and the following contextualization into reports, schemes, process- and decision support will consist of variables from different applicable systems such as for

instance the EPR, Radiology (RIS/PACS) and laboratory to mention a few. The answer to succeed with standardization through context based archetypes is to build a “Democracy” of determined clinicians. This “concept of speak” taken from the leader of the secretariat of NRUA pinpoint the challenges for organizers, which theoretically calls for coordination of work to make clinicians proud owners of clinical content. To achieve this, archetypes for structured data and sharing of information has to become more visible for the clinicians through a more targeted information practice. So far, the national consensus processes for archetypes show that dedicated clinicians are hard to obtain because of much pressure in everyday work. Therefore the vision of the project needs a strong anchorage both top- down and bottom- up in the clinical organizations. It is important that the clinicians are presented for some effects of what this new EPR can give them. In particular, the role of the governance structure implicates a shift from an organization that serves clinical practice to an organization that exercises authority over it to ensure that every practice followed the work-standards.

In the bigger perspective, the governance of a new standardized portfolio of structured data in multiple systems is three-folded. The contextualization of clinical variables into meaningful clinical decision support includes the involvement of clinical resources on a local, regional, and national level. Hence, this also includes three layers of organization needed to be involved. NRUA is a national decision maker that organizes the regional groups, vendors, and ICT projects. The regional governance or clinical modeling group place orders, coordinate regional projects, and contributes to national consensus. Both organizations are built on and dependent of clinicians and their contribution which primarily is based on interest and overtime in practice. On the contrary we have the regional ICT which is contributing by standardizing the ICT portfolio, securing the integration, and mapping the reference models. In all, the regional ICT needs to be coordinated with the clinical groups in this complex governance model to be.

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