Core Archetypes

The Means to Build Confidence Around the Power of Structured EPR Systems?

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Abstract—**This paper reports from three different levels of working with archetypes in Norwegian healthcare. The paper contributes to a qualitative longitudinal interpretive study, connected to the development of a large-scale electronic patient record (EPR) system in the North Norwegian Health Authority. The focus of the paper is on how the notion of core archetypes could contribute to speeding up the process of developing national archetypes in Norway. Also, how core archetypes may increase clinicians understanding of structured EPR systems, based on different user experiences. We discuss when to start using archetypes in clinical practice. Also, whether constructing a prototype of a basis EPR system based on core archetypes, can contribute to a faster development of the new EPR system, and national archetypes in Norway.**

Keywords-archetypes; electronic patient records; semantic interoperability; core archetypes.

I. INTRODUCTION

An increased emphasis on cost savings, patient safety, and efficiency in healthcare, has raised the focus on seamless integration, and standardization across professional, departmental, and institutional boundaries [1]-[3]. Important efforts to achieve such goals, are improving the role of the electronic patient records (EPR), to make it a structured work tool, supporting patient pathways and decision support [4]. Semantic interoperability is a key requirement for improving EPR communication [8], to ensure that senders and recipients have the same understanding of information and standards [9]. An important element for reaching semantic interoperability is standardizing the clinical EPR content. However, standardizing clinical workpractice and routines have been difficult to accomplish [5]-[7].

In Norwegian healthcare, improving the role of the EPR has been part of national strategies and visions since the 1990's [1]-[2], to enable sharing and integrating healthcare, as well as organizing information in a more structured manner [10]. Hence, in 2012 the North Norwegian Health Authority established a large ICT (information and communication technology) project named FIKS (standardization of the regional ICT portfolio), to standardize

the regional ICT portfolio. One of FIKS's most important roles was to collaborate closely with the largest EPR vendor in Norway, on developing a new openEHR based EPR system, using archetypes as core elements for standardizing the clinical content. The openEHR framework built on a two-level modelling. The intention of the first level, the technical reference model, was to increase semantic interoperability, and reuse of data [11]-[13]. The second level, contained archetypes and templates, as standards for the clinical content. The two-level model made it possible to make changes only to the clinical content of the archetypes, without having to alter the underlying open EHR information model.

The openEHR framework allowed for archetype design at different levels of healthcare organizations. In Norway however, the primarily work with archetypes was conducted at a national level, with NRUA (National Editorial group for Archetype development in Norway) as the coordinator of the work. To design optimal archetypes for the clinical content of EPR systems, it was necessary for clinicians to have a key role in both developing and approving the national archetypes. The clinical content of an archetype based EPR system had to contain numerous archetypes, to cover the clinical practice. There were 39 approved archetypes in March 2016, and even if 100, more were in the process, an estimated number of 1000-2000 was necessary, to encompass the clinical content of an EPR system. The absence of completed archetypes complicated and delayed the development of the new archetype-based EPR system. Hence, this raised a question whether to start using unapproved archetypes or not, and the consequences of using them before a national consensus was reached. In addition, it was challenging for the users included in developing the new EPR, to grasp the potential of this system based on a completely new technology. These factors might in part explain why the development process lasted much longer than expected.

We introduce the concept of core archetypes, as a contribution to solving this dilemma. NRUA has claimed it possible to use 30 core archetypes, as a foundation for about

90% of a basic EPR system [14]. The remaining 10 % represent specific archetypes related to clinical specialties, important to include for completing the EPR system. Our questions are therefore: Can a set of core archetypes provide the necessary foundation for understanding the potential of a new open-EHR based EPR system, and can focusing on these core archetypes speed up the archetype design process? Our goal was to evaluate the establishment of this core set of archetypes, through interaction with projects essential to the ongoing process. The rest of the paper is structured as follows; in section two, the method is presented, in section three, the three levels of archetype work in Norway are described. The concluding discussion in the fourth section, focuses on when to start using archetypes, and the use of core archetypes for a prototype of a basic EPR system.

II. METHOD

This paper contributes to a longitudinal interpretive study, connected to the development of a large-scale EPR system by the North Norwegian Health Authority. The methodologically positioning of the study is within a qualitative interpretive paradigm. The focus is on evolving and improving the understanding of a studied phenomenon, by looking at it from different viewpoints, within a context [15]-[16]. An advantage of using a qualitative interpretive approach is enabling complex textual descriptions of how people experience a particular matter, by providing information about the human side of a given process [16].

The fieldwork draws on the first author's role working in FIKS for two years and afterwards continuing to follow activities in the project, by participating in workshops and meetings connected to the development of the new EPR systems. The second author has contributed in the regional and national work with the new EPR and archetypes for the last seven years, participating in meetings, discussions and observations. The personal information protection commissionaire for research in the health region, and the Norwegian social science data service (NSD), approved the data collection for this study. All informants provided written consents for the interviews by e-mail. Both authors have conducted several open-ended interviews, both related to the development of the new EPR, and the national work with archetypes. The purpose of using open-ended interviews is enabling informants to tell their story, without the author's pre-perceptions getting in the way. The interviewers had prepared some questions, to make sure the interviews covered the topics they wanted to focus on. In addition, new interesting issues to include emerged in several interviews. The interviews were transcribed and analyzed separately, and as a part of a whole [Ibid]. Interesting quotes were translated into English (almost all Interviews were in Norwegian). In addition to transcribed and interpreted interviews, observations from several workshops and meetings as well as project documents from FIKS and NRUA were included in the data collection. In table I, an overview of the data collection is presented.

TABLE I.   AN OVERVIEW OF THE DATA COLLECTION

Data source	
Interviews with contributors to the work with archetypes, and the development of new EPR.	30 open ended interviews
Participatory observation	250 hours
Participation in meetings, workshops, and informal discussions.	300 hours
Document studies: Documents from the CKM, concerning archetypes in general, and the problem/diagnosis archetype in particular.	

A document analysis on the consensus process of one particular archetype namely Problem/diagnosis, provided important insights for understanding the national work with archetypes.

III. WORKING WITH ARCHETYPES IN NORWAY

We have focused on three parallel processes important for the Norwegian archetype development between 2012-2016. First, the development of a new openEHR based EPR system, using archetypes as standards for the clinical content, with focus on development of the surgical pre-planning module. Second, the internal process of establishing a well-functioning NRUA organization, including a network of competent healthcare personnel to participate in the consensus process. Third, the development of local archetypes at a specialized hospital clinic, including the first attempts of using archetypes for clinical practice.

A. Development of the new EPR system

In 2012, the North Norwegian Health Authority completed an extensive tender, and decided to regionalize their new ICT portfolio. To carry out these changes, they established a regional project FIKS, to run from 2012-2016. FIKS was considered one of the largest ICT investments in Norwegian healthcare, with a total cost expected to exceed €100 million [17]. The main goals of the project were to establish a regional ICT portfolio, as a foundation for regionally standardized patient pathways, decision support, and integrations between clinical ICT systems.

A regionalization, including standardizing EPR work practice, was a necessary requirement to reach such goals, enabling the Health Authorities to better administrate and compare information from the hospitals in the region. The FIKS project run in close collaboration with system users from the hospitals and the vendors.

The new EPR was designed to improve the user's workdays, providing structured data including predefined content elements, and schemes for documentation, enabling an increased overview and reuse of patient data. In addition, the possibility of including patient pathways was important for improving the EPR. This was enabled by using the international openEHR architecture, standardized by CEN/ISO [18]. The openEHR architecture built on standardized information models, open source components, and highly structured clinical content, with archetypes as core building blocks. Archetypes were structured data elements of

clinical concepts, where observations, evaluations, instructions, and actions, formed the ongoing process of treatment and care [19]. Archetypes were used to define how clinical data was structured, seamlessly stored, and transferred between EPR systems [20]. The intention was for archetypes to contain a maximum dataset, including evidence about knowledge objects, and relevant attributes [21]-[22]. It was possible to design both widely reusable generic archetypes, as well as specialized ones, designed for a distinct local setting [8], [14], [22-24]. The new EPR system required archetypes, as standards for the clinical content. The problem was that there were no archetypes available in Norway, when they started designing this new EPR system in 2012. The idea was for the vendor to design some generic archetypes necessary for the overall structure of the EPR. Further, the system users themselves would continue developing archetypes necessary for clinical practice, for example clinical observations such as blood pressure, body weight, clinical scorings, and schemes for procedures. One member of FIKS stated: *"At first it seemed possible for clinicians to design archetype based schemes on the fly, I don't however think this will be the case."*

The vendor started in 2012 the work with designing generic archetypes for the new EPR system. Since there were several archetypes available in the international CKM, constructed by the openEHR organization, it seemed rather straightforward to import these archetypes, and adjust them to Norwegian conditions. However, after working with archetype design for a year without achieving the desired results, it became obvious that this work was more complex than anticipated. The vendor recommended to establish a Norwegian CKM, and standardized methods for developing and maintaining Norwegian archetypes. Technology for storing and reusing archetypes, as well as defining how archetypes would relate to terminologies, were also important requirements identified.

In addition to the archetype development, a parallel process of designing functionality for the new EPR system took place. More than 100 system users, from all the hospitals in the North Norwegian Health Authority, participated in an attempt of user centered system design, where an agile method - scrum was practiced. The idea was to develop the new EPR module by module, based on user stories from the system users as a foundation for the functionality. It became difficult for the system users to grasp the potential of the forthcoming EPR system, as neither archetypes nor the EPR system functionality was finished. The needs for the new EPR, identified by end-users, mainly built on challenges connected to the existing EPR system. One clinician stated: *"When you ask clinicians today, they will outline needs related to their current work. Their starting point is the EPR they use today, that may be 20 years old. They are more likely to think small steps ahead, rather than focusing on large revolutionary changes, necessary for exploiting the potential of archetypes and openEHR."* Consequently, developing the EPR based on this approach, was time consuming, and

inefficient. Since they did not have any prototype or model of the new system, it was demanding for clinicians to see the potential of it.

As an example, they have worked with the pre-surgical planning module for the new EPR from FIKS started in 2012, still close to the end of 2015, six of the 18 nationally approved archetypes necessary for this module, have reached national consensus. They were prioritized, as a collaboration between NRUA and FIKS. Without the necessary archetypes in place, it was challenging to develop and test functionality for this module, as well as knowing what to prioritize working on. To increase the pace of finishing this module, NRUA has lately been involved closer in working with the necessary archetype requirements for this module.

B. Constructing a national organization for handling archetypes

The EPR vendor, developing the new EPR system, had gained more than 70% of the Norwegian marked, over the last years [25]. Hence, National ICT, the organization responsible for coordinating ICT-related initiatives in the Norwegian specialized health care services, decided to work with Norwegian archetypes at a national level. NRUA was established in 2013, to form a national archetype repository – clinical knowledge manager (CKM). The overall goal of NRUA, was to coordinate the development, and use of archetypes on a national level, both handling the national consensus process of agreeing on archetypes, as well as supporting local initiatives for archetype design and usage. The NRUA organization consisted of five persons responsible for clinical modeling of archetypes, in addition to representatives from all the four Regional Health Authorities in Norway. NRUA established an editorial group to initiate archetype reviews, and form collaboration with clinicians. They also managed the recruitment for the national consensus process. In the consensus process clinicians used the web based CKM to review and approve archetypes, enabling asyncronically communication between participants in the process. The first years NRUA focused primarily on establishing a well-functioning organization, with a network of clinicians and other system users to work with archetypes. They provided training and support for new CKM users, established connections to the international CKM, and translated existing archetypes into Norwegian, for the clinicians to review. One of the archetype reviewers stated: *"NRUA has members with a genuine interest in archetypes and they have worked very hard to get this organization up and running."* Because of establishing the organization, the actual consensus work moved slowly the first years. The first archetype was nationally approved in 2014, five months after NRUA started their work. However, investing this much time on the organization early on, enabled NRUA to increase the pace of archetype development last year. There were 39archetypes approved in Norway in March 2016 and a 100 more was in the process. A goal is to have 200 archetypes approved by the end of 2016. In addition, NRUA had gained

valuable knowledge along the way, both on how to structure archetypes, and on how to run the organization.

The extensive process of reaching archetype consensus was time-consuming for the contributors to participate in. When they first started as reviewers, it took time to get to know the CKM tool, and understand the complex clinical and technical relations of the archetypes. Each archetype had several review iterations. One clinician stated: *"A review iteration takes everything between 15min and 1,5 hour, depending on the complexity of the archetype. In addition, all archetypes go through more than one review iteration."* Recruiting participants to work with national archetypes was challenging, and the time-consuming review process led to several dropouts from the work, especially from clinicians. Since archetypes were used as standards for the clinical content of the EPR, it was important for clinicians to have an essential role in defining and designing them. One clinician said: *"It is crucial to include clinicians in this work; they have the clinical knowledge and know what is important to focus on, for the archetypes to be useful standards for clinical work."* He also commented, *"If others than clinicians design the archetypes, it will be troublesome to get clinicians to accept and use them."* It was however difficult for NRUA and the clinicians to know what archetypes to prioritize working with and how long the consensus process of each archetypes would take, to be able to plan the work with archetypes ahead. It was also problematic to ensure that the archetypes fit the clinical practice of Norwegian healthcare, since they had no way of testing them out in clinical practice.

C. Developing and trying out archetypes in clinical practice

Based on the notion of archetypes being the new standard for communication in Norwegian healthcare, several projects have been eager to start using them. Since the national design of archetypes took years to gain foothold, some local initiatives began to use archetypes for clinical practice, before they had been through the national consensus process, some even started developing local archetypes themselves. One member of NRUA stated: *"Systems that use archetypes today are not designed on nationally approved archetypes, or even international ones. They are mainly constructed by system users themselves."*

One example was a hospital clinic in the Southern and Eastern Norway Regional Health Authority that developed highly specialized archetypes for their clinical practice. This was a clinic working within a very narrow clinical field. Thus, they had a clearly defined focus area, and mainly needed specialized archetypes designed particularly for this field of expertise. When they started working with archetypes in 2014, NRUA was still in the process of establishing national consensus on their first archetype, (even if they had started the consensus process of several other archetypes as well). The clinic used approximately eight archetypes that had started the consensus process in Norway, the rest they assembled from the international CKM, and other existing

repositories or clinical standards worldwide. The ones they did not find in any existing CKM, they developed themselves, in close collaboration with the EPR vendor. When the clinic started using archetypes for clinical practice, this was one of the first attempts to try out archetypes in a Norwegian clinical setting. This provided the clinic, NRUA, and the vendor, retrospective with important insight on the usability of archetypes at different levels, especially compositions, evaluations, and cluster archetypes. Testing archetypes in an actual clinical setting enabled identifying necessary requirements for improving, not only the local, but also the national archetypes, to make them suitable for both small and large-scale clinical usage. The clinic identified some challenges related to conforming these local archetypes to the national standards. First, the versioning of the local and the national archetypes clashed. Second, extensive structural differences between the local and the national archetypes, led to interoperability issues for different versions of the same archetype, with the risk of losing data when switching the local archetypes into national ones. In addition, the users experienced that creating local archetypes based on schemes from the old EPR were unpractical to use. NRUA is assisting the clinic in their further work, to enable the local archetypes to conform to the national ones.

IV. CONCLUDING DISCUSSION

The three examples described; A) the development of the new EPR, B) the process of establishing a national organization for developing and approving archetypes, and C) the process of starting a local initiative with hands on archetypes and solutions, indicates a need for improving and speeding up the archetype development process. In this context, there are two important issues to address. First, the question of consensus and/or the clinical value of archetypes; There is a broad agreement to only use consensus made archetypes in a production environment (use in the EPR), despite this it has been necessary to use "unapproved" archetypes in production, to speed up the processes. Secondly, and based on this, is the use of core archetypes to provide a prototype of a basic EPR system, to enable accelerating the process of archetype consensus, and the development of the new EPR system.

Based on these examples, the work with archetypes in different settings of Norwegian healthcare has raised a number of important issues. In the North Norwegian Health Authority, the strategy was not to start using archetypes before they had reached national consensus. The overall goals were to secure structured high quality archetypes, in line with the national standard, confirming that the archetypes they include in the new EPR system were compatible with other archetypes in Norway. However, since the vendor started developing archetypes for the new EPR themselves, the national consensus work related to these archetypes started too late to support the development process. This strategy contributed to delays in the development strategy. In addition, it was not possible to test the developed

functionality for the modules of the new EPR, like the surgical pre-planning, without any available archetypes to structure the clinical content. They adopted this strategy, due to the unknown consequences of using archetypes that had not reached national consensus. A project leader in FIKS stated: *"Some of the consequences we dread from using unapproved archetypes are the lack of interoperability, the need for converting data, loss of historical data, all leading to increasing cost."* However, they did not want to stop developing the new EPR system completely, due to the lack of archetypes. *"There is a risk that if we are too cautious with starting to use archetypes it will make our development set to provide excessive profit related to reuse of data and clinical parameters fall way behind (project leader FIKS)."*

In the Southern and Eastern Norway Regional Health Authority, the strategy was nearly the opposite. They started to use archetypes that had been included in the consensus process. Thus, some places, as in the small clinic described, they also used archetypes not yet included in the consensus process, and even developed some new ones themselves. Starting to use unapproved archetypes in a clinical production environment, provided important insights for the vendor, the clinicians, and NRUA, on the actual usability of the archetypes that were under development nationally. NRUA has gradually undergone the hospitals very specialized structured schemes and variables. The development that this local initiative started was important for the maturity of NRUA as an organization, the archetype development, as well as for the EPR vendors. If they had waited for the regional EPR project to have all their archetypes approved, for example for the surgical pre-planning module, before testing out archetypes in clinical practice, they would still be missing the knowledge on how the archetypes actually work in a clinical setting. The understandings gained from this project, made it conceivable to improve the structure and content of the national archetypes. It also contributed to NRUA increasing their knowledge on archetypes, and capacity of assisting similar future projects. Clinical involvement, a suitable graphical interface, and integrations, are all interconnected with the development of archetypes and templates.

On the other hand, a clinical environment using archetypes that had not reached national consensus led to several interoperability challenges. The local archetypes were versioned following the same standard used by NRUA. This would consequentially lead to both a local and a national archetype with the same version number. Firstly, if the possibility to create a new version disappears there will be a loss of clinical data when converting to a consensus made archetype. Secondly, mixing up the local and the national archetypes might be a secondary problem, since the two definitely are comparable. Further, since the national archetypes were developed after the local ones were taken into use, there is a risk of a dissimilar structure of the local and national archetypes. If the deviations are too extensive, the local and the national archetypes might not be able to communicate. One of the archetype reviewers with a technological background described this potential problem: *"The local system will continue to work on its own, but if the structure of the archetypes is changed extensively to enable national consensus, they will no longer be able to communicate with the old version of the archetypes. Consequentially a system based on the local archetypes, cannot communicate with systems using national archetypes."* Accordingly, this might lead to losing historical data, or having to spend an extensive amount of time and money on converting all existing data to the new national archetype format.

To solve these complex issues, instead of trying out the archetypes in local projects with potentially complicated and expensive consequences, another approach would be to prioritize finishing the national consensus on the 30 core archetypes, and then use them to create a prototype of a basic EPR system. NRUA has defined the core archetypes as a sufficient basis for an EPR system[14], and they have composed a synthesis stating that: *"90% of the journal functions in the electronic patient record including non-specialized examinations and procedures can be represented by using 30 core archetypes"* [14]. Having a prototype based on the core archetypes for the clinicians to test, would most likely help them better grasp the potential of the new EPR, and how to continue the development process. One clinician stated: *"It is difficult for clinicians to imagine the possibilities of new EPR and not base their requirements on today's needs. Having a prototype would ensure that the archetypes cover then necessary clinical content for the modules of new EPR."* Such prototype might also provide useful information for the vendor on how to include the archetypes technically in their new system, and gain knowledge that is missing today on how to create and import templates into the EPR system based on archetypes. In addition, NRUA could profit on such a prototype, to identify which archetypes to prioritize for the national consensus process for each clinical specialty. This also includes further experience with fitting the archetypes for clinical practice. As time has gone by and NRUA's knowledge on archetype development has increased, they have already started to revise the synthesis. One member of NRUA stated: *"The synthesis was created by NRUA based on a fundamental understanding of essential elements to include in an EPR, and archetypes necessary to cover the fundamentals areas. It will probably be necessary to extend the number of core archetypes to 30-50."*

18 of the core archetypes are nationally approved and five more are in the process. Creating a basis model of an EPR system, based on core archetypes for testing the clinical usability of archetypes, could increase the pace of the national consensus work. The question is however, why these were not prioritized for the consensus processes. One of the members of NRUA said: *"We started out prioritizing the defined core archetypes. However, the work with core archetypes takes time since these are very generic and extensive concepts archetypes."* Establishing generic archetypes within an

immature organization was time consuming, since there were no experienced archetype designers, neither clinicians nor technical personnel in Norway. Hence, trying and failing was part of the process. How many clinicians to include, how to structure the archetypes, whether to translate international archetypes, or establish new ones from scratch, were some of the questions to consider. As a result, the last two years of working with archetypes in Norway on different levels of healthcare, NRUA has gained the necessary level of competence to fulfill their role as an organization that coordinate the national work with archetypes, as well as supporting local initiatives. Consequentially, future local initiatives should include NRUA at an early stage, to avoid the type of challenges that the clinic in the Southeast health region experienced from using local archetypes. Based on this, an important conclusive remark is; yes, the core archetype is a promising tool for future accomplishments of archetypes, and speeding up the development of the new EPR. Still the process described, and the following maturation of the national environment has been a necessary process. Now, NRUA and the national consensus work have reached the required maturity level, to exploit the possibilities that constructing a prototype/model by using core archetypes can provide for the future work with archetypes, and the new EPR system in Norwegian healthcare.

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