Structuring the EPRs; The National development of Archetypes for Core Functionallity

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***Abstract*—The aim of this paper is to highlight the importance of introducing a set of core archetypes to succeed with the national consensus work on archetypes in Norway. This is illustrated by emphasizing on four important challenges identified through the national work with archetypes in Norway from 2012-2016. First, the process of establishing a well-functioning national archetype organization, including a network of competent healthcare personnel to participate in the consensus process. This comprises how to increase the pace of developing these national archetype. Second, the interdependence between the archetypes and the new electronic patient record system (EPR), focusing on the need for archetypes to enable developing an EPR system, at the same time as an EPR system is required to develop and test out high quality archetypes. Third, the development of local archetypes at a specialized hospital clinic, including the first attempts of using archetypes for clinical practice, and useful lessons learned for the national archetype work. Fourth, the need to define the number of archetypes to plan the future archetype work, including estimating resources for the work, and the challenges of governing archetypes in relation to who is responsible for what aspects of the archetypes. Establishing a prototype of an EPR system based on generic core archetypes may increase clinicians understanding of structured EPR. Our research questions are therefore: What has been the challenges in the national archetype process so far, and how could these challenges be met through developing a set of core archetypes? Empirically the paper focuses on the national archetype work, and the regional archetype organization in the North Norwegian health authority. Our qualitative case also includes other archetype initiatives in Norway like for instance the use of archetypes for clinical practice at the small clinic in the Southern and Eastern Norway Regional Health Authority. Except from being a status report on national archetype development, this paper also contributes to a longitudinal interpretive study, related to the development of a large-scale EPR system by the North Norwegian Health Authority.**

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

I. INTRODUCTION

There has been an increased focus in Norwegian healthcare to improve the role of the electronic patient record system (EPR) [1]. This has been an important part of national strategies and visions for healthcare since the 1990's [2][3], due to the augmented focus to enable sharing and integrating healthcare, as well as organizing information in a more structured manner [4]. The increased emphasis on cost savings, patient safety, and efficiency in healthcare practices, has raised the focus on seamless integration and standardization, both within as well as across professional, departmental, and institutional boundaries [2][3][5]. Considerable amounts of resources have been directed towards establishing fully integrated healthcare infrastructures, both from the government, and healthcare providers [6]. A central element in achieving such goals are interconnected and interoperable EPR systems [6]. Significant improvements of the EPR have been necessary for these systems to evolve from being tools for information storage, into structured work tools supporting patient pathways and decision support [7]. EPR systems have been required to be flexible enough for representing specific medical knowledge, at the same time as ensuring the need for interoperability with other systems [8]. The EPR has been essential for coordinating hospital work processes, and there has been an extensive need for standardizing the EPR content, to facilitate sharing and comparing health data within and across health care practices, to reach semantic interoperability. This has been a key requirement for improving EPR communication [9], to ensure that both senders and recipients understand information and standards the same way [10]. Semantic interoperability: requires that the information system understands both requests information and the information sources. Semantics are defined as the meanings of different terms and expressions [11]. Hence, semantic interoperability is the way information systems exchange information on the terms of shared, pre-established and negotiated meanings of language and expressions [11].

Standards in hospitals are useful both to specify workpractices, and to define how technologies interact [12]. However, standardizing clinical workpractices and routines have been difficult to accomplish [13][14][15]. This paper builds on two important standardization processes in Norwegian healthcare, one regional and one national. In 2012 the North Norwegian Health Authority established a large information and communication technology (ICT) project named standardization of the regional ICT portfolio (FIKS), 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 open Integrated Care Electronic Health Record (EHR) based EPR system, using archetypes as core elements for standardizing the clinical content. Archetypes are structured data elements of clinical concepts, envisioned to ensure technology-independent interoperability, easy reuse of information and efficient decision support [16]. They are clinical information models used to standardize the clinical content of an EPR system. The archetypes contain a maximum dataset, including evidence about knowledge objects, and relevant attributes [8] They also need to include rules, measurement intervals, data types, presentation formats, data representation conditions (codes, terminologies), etc. [8]. It is possible to combine archetypes into templates to create documents, messages, specific forms and reports, including referrals, radiology reports and discharge forms. Templates are often locally made, based on three things: the requirements for the form, available archetypes, and the local use of terminologies.

The openEHR framework built on a two-level modelling approach separating the clinical and technical development of the EPR system. The intention of the first level, the technical reference model, was to increase semantic interoperability, and secure a reuse of data [11][17][18]. The reference model is generic enough to store any type of clinical information, and it is a stable object model to build software and data on. These are used to specify how to organize and group clinical information, capture contextual information, query and update the EPR and so on [19]. The second level, contained archetypes and templates, as standards for the clinical content. This makes it possible for clinicians to be in charge of designing and defining the archetype standards, hence the clinical content of the EPR system. There are some important issues related to allocating the right resources for the national archetype work, recruiting participants for this work and the role clinical competence play in the future archetype development, these are not however addressed in this paper. The two-level model enabled making 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.

The other standardization process we have focused on was the national standardization of archetypes as the clinical content of the EPR system. In Norway the primarily work with archetypes was conducted at a national level, coordinated by NRUA (National Editorial group for Archetype development in Norway) established by National ICT in 2013, National ICT is responsible for coordinating ICT-related initiatives in the Norwegian specialized health care service [20]. To design optimal archetypes to standardize the clinical content of EPR systems, it was necessary for clinicians to have a key role in both developing and approving the national archetypes. Therefore, one of the most important tasks for NRUA was to recruit enough clinicians to participate in standardizing archetypes. The clinical content of an archetype based EPR system had to contain numerous archetypes, to encompass all clinical practice. There were 42 nationally approved archetypes by May 2016, and even if more than 100 were in the process, this was not nearly enough to comprehend the total clinical content of an EPR system. One important question to address was how many archetypes standardizing the clinical content of an EPR system required? The absence of necessary archetypes complicated and delayed the development of the new archetype-based EPR system. Hence, this raised a question of when to start using archetypes for clinical practice, and the consequences of using archetypes before reaching national consensus.

In addition, it was challenging for the users included in developing the new EPR, to grasp the potential of this system based on the close relation between the archetypes and the technology in this entirely new technological solution. These factors might contribute to explain why the development process took much longer than expected. The aim of this paper is to highlight the importance of introducing a set of core archetypes to succeed with the national consensus work on archetypes in Norway. Establishing a prototype of an EPR system, based on generic core archetypes, is a promising way to increase the pace of the national archetype work. In addition, such prototype might provide clinicians with a better understanding of this new way of developing and using the EPR, at the same time as it is possible to test the archetypes in a production like environment. One important dilemma to solve before establishing such prototype is however, how many archetypes would such solution require? Our focus is on how to use a set of core archetypes to keep up and escalation the pace of the national archetype work in Norway, and to evaluate the establishment of this core set of archetypes through interaction with projects essential to the ongoing process. Our research question is therefore: What has been the challenges in the national archetype process so far, and how could these challenges be met through developing a set of core archetypes?

We followed different aspects of the archetype work in Norway describing how the development have progressed over time. In the paper some important experiences with, testing out archetypes and implementing them to clinical practice are addressed, in addition to how this has contributing to speeding up the work with archetypes in Norway. Being able to estimate the number of core

archetypes needed for establishing such prototype would ease planning the future work with archetypes in Norway related to how estimating the number of resources the work requires and predicting when to expect having a complete set of clinical standards for an EPR system. Defining a set of core archetypes would contribute to increased clinical understanding of the archetype concept and the potentials openEHR system have for improving the clinical practice.

The rest of the paper has the following structure: Section two, has a presentation of the method. In section three, there is a description of the four aspects of working with archetypes in Norway. The discussion in the fourth section focuses on when to start using archetypes, the use of core archetypes for a prototype of a basic EPR system and how to plan the future archetype work. The fifth section concludes the paper.

II. METHOD

The work with archetypes in Norway is mainly conducted on a national level, however, also regional archetype organizations has gained increasing foothold over the last two years. Our site of research is therefore both NRUA, and the regional archetype organization in the North Norwegian health authority. Our qualitative case also includes other archetype initiatives in Norway like for instance the use of archetypes for clinical practice at the small clinic in the Southern and Eastern Norway Regional Health Authority (described in section C). Except from being a status report on national archetype development, this paper also contributes to a longitudinal interpretive study, related 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 [21][22]. 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 [22].

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. This author have also been an observer and participant in both the regional and national work with archetypes in Norway, participating in meetings, workshops and discussions. 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. He has represented the North Norwegian health region in NRUA, and been the leader of the regional archetype organization. He has also recently become the leader of NRUA. 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.

The data analysis was accomplished in several stages with data and citations from numerous sources. A document study including different iterations and negotiations of several archetypes like problem/diagnosis, had a key role during the field work, and provided contextual and historical insight into the process of establishing archetypes in Norway. The Norwegian CKM repository consists of nationally approved archetypes including the documents from each review iteration, where clinicians discuss and approve the content of each part of the archetype in what they refer to as "consensus" processes. We have read all the logs several times, both separately and combined with the interview data as a whole, to enable extracting the most important topics. Interesting citations from the different participants, related to each of the topics, were translated into English. Second, we conducted participatory observations in NRUA meetings and workshops as well as vendor meetings and workshops over several years. We also observed a reviewer while he used the CKM to review an archetype, to understand better, how it was for clinicians to use this web-based tool. There was a highlighting of events and milestones from the observations, these became the starting point for questions in the interview guide. This part of the analysis was also an iterative process in, which analysed and transcribed data led to new questions in the next interview, and so on. Third, the authors conducted 30 open-ended interviews with participants in the consensus process, initially while guiding them to become users of the CKM, then after they had used it to work with archetypes for a while, related to the development of the new EPR, and the national work with archetypes. Some participants in the archetype work were interviewed more than once, based on their specific roles in terms of being identified as key informants. 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 still prepared some questions for the interviews, 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 both separately, and as a part of a whole [22]. Information infrastructure and infrastructuring theory were used to transcribe and analyzed the interviews. This was done to put it all together as a whole, to complement different perspectives of the situation.

In addition to interview data from key personnel of the processes and documents from the CKM, we used official reports from organizations such as the National ICT Health Trust, and other websites such as the official site of the openEHR organization. We have aimed at obtaining a historical and contextual understanding of the work involved in the development of archetypes. Table I describes the details of the data collection.

TABLE I. THE DATA COLLECTION

	Number of persons	Duration	Period
Interviews			
Archetype reviewers	17	30-90 min	2014-2016
NRUA members	5	60-90 min	2014-2015
Persons involved in the EPR development	8	60-120 min	2013-2015
Observations			
NRUA/regional resource group		200 hours	2014-2016
Development of EPR system		80 hours	2012-2016
Archetype review and CKM use		5 hours	2014-2015
Discussions		100 hours	2012-2016
Document studies			
		240 hours	2015-2016

III. DIFFERENT ASPECTS OF NORWEGIAN ARCHETYPE WORK

We have focused on four different aspects of working with national archetypes for Norwegian healthcare in the period 2012-2016. First, the process of establishing a well-functioning national archetype organization (NRUA), including a network of competent healthcare personnel to participate in the consensus process. Second, the relation between the archetypes and the new EPR system focusing on development of a new openEHR based EPR system using archetypes as standards for the clinical content. Third, the development of local archetypes at a specialized hospital clinic, including the first attempts of using archetypes for clinical practice and useful lessons learned for the national archetype work. Fourth the need to define the number of archetypes to plan the future archetype work, including estimating resources for the work, and the challenges of governing archetypes in relation to who is responsible for what aspects of the archetypes.

A. *Organizing the National Archetype Work in Norway.*

In Norway, one system vendor had gained more than 70% of the EPR marked [23]. This vendor was developing a new openEHR based EPR system, which three of the four health regions had committed themselves to use. Consequentially it made sense to organize the construction of the archetype standards for the new EPR system at a national level. Hence, National ICT instigated a national organization to work with archetypes in Norway. The established NRUA in 2013, to form a national archetype repository – a clinical knowledge manager (CKM). The overall goal of NRUA was to coordinate development and use of archetypes on a national level, both handling the national consensus process of reviewing and approving archetypes, as well as supporting local initiatives for archetype design and usage in Norway. NRUA had five part-time engaged employees, working with governing and modeling archetypes. In addition, 2-3 representatives from each of the four Regional Health Authorities in Norway, and representatives from the Norwegian directorate of health were members of NRUA.

NRUA established an editorial group to initiate archetype reviews, these reviews were highly depended on clinicians participating in standardizing the clinical content of healthcare practice, and organizing these standards as archetypes. Therefore, recruiting clinicians and activating them as archetype reviewers for the national consensus process, was an essential part of NRUA's work. In the consensus process clinicians used the web based CKM to review and approve archetypes, enabling flexible asynchronous communication between the different contributors. The archetype reviewers only communicated through the online CKM without participating in any face-to-face meetings. The first year NRUA focused primarily on establishing a well-functioning organization prepared to handle coordinating hundreds of participants from different professions, including a large network of clinicians, working with archetypes. They offered training and support for new CKM users, and established relations with the international CKM run by the openEHR foundation. In addition, NRUA imported existing archetypes from the international CKM, and translated them into Norwegian, for 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."* The organizational work also included defining the steps of the consensus process, and forming a priority scheme for how to organize working with the national archetypes. Prioritizing launching a well-functioning organization, the actual consensus work moved slowly the first year.

However, they still managed to approve the first national archetype as early as in June 2014, only six months after NRUA was established. Investing a considerable amount of time on the organizational concerns initially, enabled NRUA to increase the pace of the archetype development the next two years. In May 2016, there were 42 nationally approved archetypes in Norway. The population of archetypes approved was considered complex and essential for EPR functionality. In addition, more than 100 had started the consensus process. The goal was to have 200 archetypes approved by the end of 2016. In addition, NRUA gained

valuable knowledge along the way, both on how to structure archetypes, and on how to run a national organization. Hence, NRUA has gradually become an accomplished organization for supporting and supervising local and regional archetype projects. They have also become competent to arrange information and modelling courses to expand the competence on archetypes within Norwegian healthcare.

It was yet challenging to recruit reviewers for the national consensus process, especially clinicians. This was a rather extensive process to participate in, and the reviewers were not in any way compensated for contributing to the national archetype work. When they first started as reviewers, it was also time consuming to learn how to use the CKM work tool. Several reviewers said that it took quite some time to understand the complex relation between the clinical and technical components of the archetypes, and to get used to the concept of archetypes as clinical standards. In addition, many archetypes went through more than one review iteration before being nationally approved, the average number was 2 iterations, however, one of the archetypes had as many as seven without reaching national consensus. Each review iteration took a considerable amount of time for the clinicians to finish and some reviewers had more than one archetype to review simultaneously. One clinician stated: *"A review iteration can take between 15min and 1,5 hour or even longer to finish, depending on the complexity of the archetype and whether I need to look things up, or consult with colleagues."* The time-consuming review process done at the clinician's free time, and the loosely committed online work process, both led to several dropouts from the archetype work, especially among clinicians. Since National ICT had recommended archetypes as standards for the clinical content of the EPR, it was important for clinicians to have an essential role in defining and designing these standards since they were the main users of the standards in the EPR system. Also the two-level model of openEHR related on domain experts (clinicians) as the main developers of the clinical content of the archetypes. 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 practice."* He also commented, "*If the archetypes are not designed by clinicians it will be very difficult to get clinicians to accept and use them."* Though it was difficult for NRUA to plan the work with archetypes ahead, included estimating the number of clinicians needed for the national work, what archetypes to prioritize working with, and how many archetypes the Norwegian CKM needed. It was also problematic to ensure that the archetypes fit the clinical requirements of Norwegian healthcare, since they did not have any way of testing then out in clinical practice.

B. Relations between Archetype Standards and the EPR System

National ICT gained an interest for archetypes as clinical standards several years, before the vendor started working with the openEHR based EPR system in 2011. In 2008, National ICT run an internal project translating variables for electronic medical charts into archetypes. However, deciding to purchase the new EPR system for most of Norwegian hospitals, the interest for archetypes expanded to several parts of Norwegian healthcare.

The vendor started developing the new EPR system in close collaboration with the North Norwegian Health Authority. After a bid for tender process in 2012, this health region decided to regionalize their new ICT portfolio. To complete this process, they established a regional project, FIKS, to run from 2012-2016. FIKS was one of the largest ICT investments in Norwegian healthcare, with a total cost expected to exceed €100 million [24]. The main goal of FIKS was 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 goal, 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 EPR vendor. One of the most important goals of FIKS was to collaborate with the EPR vendor on developing the openEHR based EPR system for Norwegian healthcare. This new EPR was designed to improve the user's workdays, providing structured data including predefined content elements and schemes for documentation, enabling better overview and reuse of patient information. In addition, the possibilities to include patient pathways and increase the semantic interoperability were important to improving the EPR. This was enabled by using the international openEHR architecture, standardized by CEN/ISO [25]. 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 [16]. Archetypes were used to define how clinical data was structured, seamlessly stored, and transferred between EPR systems [26]. The intention was for archetypes to contain a maximum dataset, including evidence about knowledge objects, and relevant attributes [8][27]. It was possible to design both widely reusable generic archetypes securing interoperability within and across healthcare institutions, as well as specialized ones intended for a distinct local setting [9][27][28][29][30]. In figure 1. the archetype problem/diagnosis is used as an example of an archetype

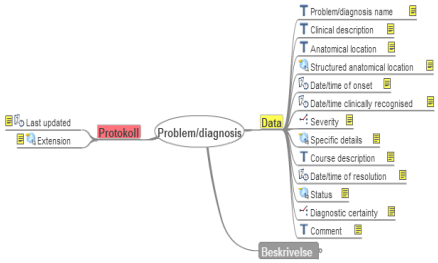

Figure 1. The archetype problem/diagnosis

The new EPR system required archetypes, as standards for structuring the clinical content it was necessary to have a common language to raise the semantic interoperability. According to the two-level model the openEHR architecture built on, it was possible to develop the archetypes standards and the reference model of the EPR system separately [16]. Still, splitting the development processes for the new EPR systems and the archetypes, turned out to be more complex and challenging than expected, due to close interrelations between these two processes. The vendor first became aware of this in 2012, when they started to develop functionality for the openEHR based EPR system. The development of the new EPR system included an extensive process of designing necessary functionality. They also decided to develop the new EPR module by module, to prevent a "big bang" implementation for the healthcare practice. This required including clinicians and other domain experts in the development process. 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. System users participated in workshops suggesting and prioritizing requirements for the new system. The vendor developed functionality based on the needs and requests identified by the end-users and domain experts. The users mainly based their requests on challenges, flaws, and limitations they had identified from using the existing EPR system. It was difficult to understand the potential and possibilities of the new system since it was based on a very different architecture from what they were used to. One clinician stated: *"When you ask clinicians, they will most likely point out the needs for changes based on their current workpractice. Their starting point is the more than 20 years old EPR system they use today. They are more likely to think small steps ahead to improve their current work, rather than focusing on large revolutionary changes, necessary for exploiting the potential of archetypes and openEHR."* It was very difficult for the system users to grasp the potential of the forthcoming EPR system, and the new type of clinical standards, as neither the archetypes nor the EPR system functionality was finished. Consequently, developing the EPR based on this approach was time consuming, and inefficient with a risk of ending up with a system unable to exploit the potential of openEHR based EPR systems. The original strategy was for the vendor to import a set of generic archetypes from the international CKM to have some basic ones to start working with. Then the system users themselves would continue developing archetypes necessary for their clinical practice, for example clinical observations such as blood pressure, body weight, clinical scorings, and schemes for procedures. One member of FIKS said: *"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."*

It seemed rather straightforward to import already existing archetypes, and adjust them to Norwegian conditions. According to the openEHR organization, the archetypes were system independent and could be downloaded and used freely for any purpose. However, after trying to implement archetypes for a year, without achieving the desired results, it became evident that this work was more complex than anticipated. Thus, developing and testing functionality for the EPR system became unmanageable without being able to include the necessary archetypes related to the modules of the EPR system developed.

Based on both the archetype initiative and the vendors experiences it was decided to establish one technological solutions for storing and reusing archetypes a Norwegian clinical knowledge manager (CKM) containing archetypes designed to fit Norwegian conditions, the CKM also including standardized methods for developing and maintaining national archetypes.

One example illustrating the relation between system development and the archetypes is the ongoing work with the pre-surgical planning module. FIKS started working with this module in 2012, yet, in May 2016, this module still was not implemented in clinical practice. One of the reasons was the lack of necessary archetypes to support the functionality. They started working with this module before the national archetype work had even started, and the definitions of the requirements for working with archetypes at a national level were not yet made. After including NRUA in the work with the necessary archetype requirements for this module it was possible to gradually increase the pace of the development process of the pre surgical planning module. The project defined together with NRUA the need for 18 national archetypes for this module. There is an ongoing process of finishing the necessary archetypes, six of them had reached national consensus in May 2016, and more of them had started the consensus process. The North Norwegian Health Authority had defined a principle of only using nationally approved archetypes. However, as time went by, this principle was severely challenges by the need to complete the pre surgical planning module. There was a dilemma whether to wait for the rest of the archetypes to reach national consensus, and further delay the implementation of the new EPR, or begin to use archetypes not yet nationally approved,

enabling implementing the pre surgical planning module at the hospital, however risking the need for changing the archetypes later on.

In addition to defining when to start using the archetypes, another important question to address was if all archetypes had to be national. When they worked with the pre surgical planning module defining the necessary archetypes, they defined some national ones. Others were more system specific for this particular EPR system, and were possible for the vendors to develop themselves. It seemed unnecessary to approve archetypes only useful for this particular EPR system at a national level. Another issue might be how much of the EPR system to structure as archetypes. Was it only possible to use the archetypes to standardize the clinical content, or could they also be used for structuring other parts of the EPR system, like workflows and administrative routines. It was important to include NRUA in assessing archetype requests, due to the extensive competence on archetypes they had gained over the years. These questions might have been easier to answer if there were a way of testing out archetypes for clinical practice. Accordingly, some local projects have lately been trying out archetypes for real time use, for very small and restricted parts of clinical practice. The following section describes one such example.

C. Using the Archetypes for Clinical Practice

Based on the notion of archetypes being the currently used standards for communication within Norwegian healthcare, many projects eager to start using them. Since the national archetype design of archetypes used several years to gain foothold, some local initiatives began to develop and implement archetypes for clinical practice, before they had reached national consensus. 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 were they developed a "self-check" registration form for patients to fill out when entering the clinic. This form built on the new openEHR based EPR system, and needed a number of highly specialized archetypes to meet the clinical requirements. The clinic worked with this registration form as a project between February and November 2015. When the clinic started working with structuring their EPR content, the Norwegian CKM only contained a few nationally approved archetypes (even if they had started the consensus process of several other archetypes as well), and NRUA was still a rather immature organization. Therefore, the project had to develop most of the necessary archetypes themselves, in close collaboration with the system vendor, and Ocean informatics (the international CKM community). They searched the international CKM and CKM's from other countries to find relevant archetypes for their practice, without any luck. They identified a need for 58 archetypes, in total, and they ended up with using six nationally approved archetypes in addition to developing 52 themselves. However, due to NRUA being a newly established organization they had not yet defined the final modelling patterns for national archetypes. The project had to start using an immature modelling pattern, which consequentially led to needs for structural changes to the archetypes after implemented them to the EPR system, generating extra work and interoperability problems for the project and the clinic using the archetypes.

This clinic had a clearly defined focus area, working within a very narrow clinical field, and thought they mainly needed specialized archetypes designed especially for their field of expertise. Still, while developing and implementing the archetypes, they became more and more aware that some of the archetypes they thought were suitable only for this particular practice, also were applicable for other specialties. Having to include the needs of other potential users made the development of the archetypes, more complex than first expected. After implementing the archetypes, they also identified a need for some of the locally developed archetypes to be included into already existing national archetypes instead of being stand-alone archetypes.

Developing archetypes locally became a time-consuming and challenging process for the project, in addition to the lack of modelling patterns, there were no national guidelines for developing national archetypes in Norway. It was very challenging for the system vendor to create high quality archetypes without having national procedures to follow, since the archetypes were complex data elements that could be potentially structure in numbers of different ways. One member from NRUA said: *"It is not difficult to create an archetype, though it is very demanding to construct high quality archetypes."* Comprehending the complexity of archetypes and the interrelation between different archetypes is a maturity process that takes time to grasp. Another challenge potentially leading to interoperability issues, were the problems related to versioning the archetypes. The local and the national archetypes were versioned the same way creating a risk of mixing up the different sorts of archetypes. IT was necessary to convert the locally designed archetypes to national ones at some point. By doing this there was a risk of changing the local archetypes so much that the two versions (local and national) were no longer compatible, hence there were a risk of losing historical data and having to spend lots of money to convert data to the national archetype.

Another challenge identified in this project related to the involved clinical resources. They had two clinicians working 20%, one nurse working 80% and one mercantile resource working 20 % in the project, this turned out to not be enough clinical resources for developing the 52 archetypes within the deadline of the project. This consequentially compromised the quality of the archetypes they developed, and representatives from the project underlined the importance of including enough clinicians to enable making them the main developers of archetype standards for the EPR system. In addition, the project experienced that creating local

archetypes based on schemes from the old EPR were unpractical to use. There was a need for a new way of thinking to utilize the potential of the openEHR architecture. It took time to adjust the clinician's way of thinking to fit the openEHR and archetype based systems. The clinic still, six months after implementing the archetypes in the registration form, use a lot of time and resources on adjusting the archetypes and including them in the national consensus processes.

When this clinic started using the new EPR system including archetypes for clinical practice, this was one of the first attempts in Norway to try out archetypes in a clinical setting, and one of the first times using the new EPR, including archetypes, for a clinical setting. This provided the clinic, NRUA, system users, and the vendor, with important insight on the usability of archetypes at different levels of the system, 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 useful for both small and large-scale clinical usage. Gaining this important experience further underlined the need for NRUA to assist in similar future projects better enabling the local archetypes to conform to the national ones, and prevent projects from ending up with the extensive challenges this clinic experienced related to both developing the archetypes using them and adjusting them to the national ones after they were implemented.

This clinic creating a "self-check" registration form ended up needing 58 archetypes, and even if some of them were included as parts of existing archetypes and others were expanded to cover other specialties, this was a quite high number. It became important to try estimating the total number of archetypes needed for an EPR system.

D. Coordination and Distribution of Consensus Based Archetypes

Establishing NRUA for coordinating the national work with archetypes in Norway was an important step towards archetypes being a successful way of standardizing the clinical content of an EPR system. Defining the interrelation between the archetypes and the openEHR based EPR system, and trying out archetypes for clinical practice, also contributed to moving this process forward. However, there were still some important question to address in order for this work to continue expanding. One of them was to try estimating how many archetypes this standardization process required. This directly related to defining the number of resources needed to standardize all necessary clinical content. Another issue was governing the archetypes in relation to distributing the responsibilities and different aspects of archetypes and the CKM, including defining the borders between NRUA – developing archetypes, and system vendors – using the archetypes for openEHR based EPR systems.

Defining how many archetypes to develop and estimating the need for resources, turned out to be difficult, since the archetype work in Norway were quite immature and still mainly conducted at a theoretical level. To estimate the forthcoming work, what archetypes to prioritize, and estimate the number and specialties of necessary reviewers, it was important to try to predict the total archetype number. NRUA partially addressed this by defined a synthesis of using core archetypes. This was an attempt of defining what archetypes to prioritize working with [28]: *"90% of the journal functions in the electronic patient record including non-specialized examinations and procedures can be represented by using 30 core archetypes* [28]*."* The synthesis underlined that the core archetypes did not include data from any clinical specialties, just the basic structured data of an EPR system. An even though one member of NRUA made some modifications to the synthesis, expanding it to include between 30-50 archetypes, due to extended experience with establishing and modelling archetypes, this number was quite low, and should be possible to accomplish if the national work was structured around these archetypes. Prioritizing archetypes for the national consensus process, to get an overview of the basic structure of an openEHR base EPR system, seemed like a clever strategy for the archetype development. If NRUA had prioritized finishing the national consensus work on the core archetypes, it would have been possible to design a prototype of an EPR system including the necessary archetypes. This prototype would have enabled testing the clinical usability of the archetypes, and the relation between the clinical archetype standards and the reference model of the EPR system. Consequentially such prototype would contribute to increase the pace also of the national consensus work. One clinician stated: *"Having a prototype would ensure that the archetypes cover the necessary clinical content for the modules of the new EPR."* Another reviewer said: *"It is difficult for clinicians to imagine the possibilities of new EPR and not base their requirements on today's needs."* Moving the development from a theoretical to a practical level were the clinicians were able to test out archetypes in relation with functionality, would potentially make it easier to detect the possibilities and advantages of using a structured archetype base EPR system. Thus, we had to question why they did not prioritize the core archetypes for the national consensus process, enabling designing such prototype. Until May 2016, 20 of the original 30 core archetypes were nationally approved, and 4 more were in the consensus process, the last 6 had not yet started the process. One member 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 concept archetypes."* NRUA also had a policy to start the consensus work on an archetype only on request from the healthcare organization. This was partly bases on the lack of available resources to work with archetypes. The requested archetypes are often specialized ones covering specific areas of the EPR, there are rarely requests for generic archetypes, covering basic

elements of the EPR system. Another reason why they did not prioritize the core archetypes was probably the uncertainty about the validity of the core archetype synthesis, since NRUA had already started to modify it by including more archetypes than originally intended. The reason for this was the fact that archetype development was very complex process due to both the archetypes themselves being complicated standards demanding extensive technical and clinical knowledge. In addition, there was a closer interrelation between the archetypes and the reference model established than first expected. As a result, in a national forum in May 2016 the leader of NRUA stated that it would most likely be necessary to include about 200 archetypes to cover 80% of the clinical content of an EPR system. This was extensively more than the original core archetype synthesis from 2013. This indicated that a successive awareness and increased knowledge about archetype standards have required the hypothesis of core archetypes to change over time. Standardizing an EPR system by using archetypes was more complex than firs expected, by both NRUA and the system vendor. The further the work with archetypes in Norway evolved, and the more experienced NRUS got, the more archetypes seems necessary to include, even for covering the basics of an EPR system. Another statement underlining the assumption that increased knowledge raises the number of archetypes required for standardizing the clinical content, was made by one of the members of Ocean informatics, a partner in the international openEHR community working with archetypes since 1999 [31]. The international CKM is a repository including about 500 archetypes. She said that between 1000-2000 archetypes were necessary for covering all the content of the EPR system. These diverging numbers made estimating resources and a timeline for the future work with archetypes very demanding.

In addition, it was important to outline some borders between the archetypes and the systems they were included in. It was a fine balance since the system vendor was included in the consensus work, (which is open for all vendors to participate in). In addition, this new EPR system was the only one conforming to openEHR and archetype standards, meaning that if the standards developed were not useful for this system, it was no other large-scale system in Norway to use them in. One dilemma was therefore how to get system independent standards that still were useful for the only EPR system using archetypes. The Western Norway Regional Health Authority recently brought a request to NRUA for changing the nationally approved archetype Observation.nutritional_risk_screening. After implementing the archetype to the EPR system, the health region realized that the modelling pattern was not optimal for clinical use. The request included altering some of the variables in the archetypes. The 15 members of NRUA discussed this request by email and members from all health regions were involved in the discussion. One of NRUA's main concerns was whether this change request really related to the quality of the archetype itself, or to limitations in the EPR system were the archetype was implemented. In the following discussion, members of NRUA underlined the need to address the dilemma of altering archetypes to fit systems requirements. Making such adjustments to fit system requests increase the risk of archetypes becoming too system specific. Several NRUA members advised against this, since it was against the intention of creating flexible and system independent archetypes useful for different purposes. Members from three of the four health regions participated in this discussion, in addition to NRUA's editorial board, indicating that the archetype work was a national initiative were the health regions were included in all important decision-making. It was important to conduct the important dependency discussion concerning the national archetypes and that all health regions agreed before making such requested changes. Another important issue to address was how to define governance standards based on archetypes (such as schemes, scorings, clinical processes) and how to distribute these between system vendors using different clinical Information Models (CIM). NRUA and the regional archetype organizations contributes to this, but the government, the regional health authorities have to be active decision makers

IV. DISCUSSION

The four examples described in part III, all indicates a need for improving and speeding up the national archetype process in Norway. The main issues to discuss are 1) the question of consensus and/or the clinical value of archetypes: When to start using the archetypes? The balance between only using nationally approved archetypes and the need for speeding up the process by using unapproved archetypes to test the archetypes in a production environment (the EPR). 2) The importance of testing the archetypes for clinical practice.

A. The Temporal Evolvement of the Archetype Work

The archetype strategy of the North Norwegian Health Authority is to use only nationally consensus made archetypes. The overall goals are to secure high quality structured archetypes, in line with the national standard, confirming that the archetypes they include in the new EPR system are compatible with other archetypes in Norway. They adopted this strategy, due to the unknown consequences of using archetypes that has 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)."*

One problem is that they started working with the EPR system functionality in 2012 and the national archetype work

did not start until 2014. The reason for this was the notion the vendor had of importing a basic set of archetypes, and letting the system users develop the specific ones themselves. When the vendor defined a need for working nationally with the archetypes due to both their complexity and the extensive use of the same openEHR based EPR system in Norway the process of developing functionality had already reached a stage where they needed archetypes for the system. One example is the pre surgical planning module, the vendor started working on this in collaboration with system users in 2012, and still in May 2016, only six of the necessary archetypes were approved nationally. Thus, the strategy of waiting for nationally approved archetypes led to delays in the development process. At this point, the health region had to assess their strategy and consider using unapproved archetypes to prevent further delays. However, it is decided that all archetypes have to go through the national consensus process at some point, and before this has been complete, it is always a risk of having to change the archetype both technically and clinically after they are implemented, potentially costing the health region a lot of money.

In the Southern and Eastern Norway Regional Health Authority, they have nearly the opposite archetype strategy. Their criteria for using archetypes is that the archetype have started the consensus process. Thus, occasionally, (as in the small clinic described in section C)), they use archetypes not yet included in the consensus process, and even developed new ones themselves. Starting to use unapproved archetypes in a clinical production environment provides the vendor, the clinicians, and NRUA with important insights on the actual usability of the national archetypes, as well as for how to implement them in and use them for an EPR system. The development initiated in the local clinic 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 not have this valuable knowledge gained on how the archetypes actually work in a clinical setting. The experiences achieved from this project, made it conceivable to improve the structure and content of the national archetypes.

On the other hand, using archetypes for clinical practice before nationally approving them, leads to several challenges as described in section C) related to e.g., the structure of the archetypes and the interoperability of local and national archetypes. As an example, the local archetypes were versioned following the same standard NRUA used. This consequentially led to both local and a national archetype with the same version number. Firstly, if the possibility to create a new version disappears there is a risk of losing historical 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 are developed after the local ones are implemented, there is a risk of a dissimilar structure of the local and national archetypes modelling patterns. If the deviations are too extensive, the local and the national archetypes might not be compatible. 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 data, or having to spend an extensive amount of time and money on converting all existing data to the new national archetype format. This indicates a need for an improved overall structure for the national archetypes including a guiding manual for developing such, if there should be any local archetype development in the future.

When to start using the archetypes and the consequences of using them before the consensus process is complete are not questions that are only relevant for this health region. This question is important to address at a national level of Norwegian healthcare. If the archetypes needed for a project or a system are not available nationally, is it better to wait for the potentially time consuming consensus process or is it necessary to develop some archetypes locally e.g., in collaboration with the vendor of the EPR? In addition, if local archetypes are developed, how is it possible to ensure the quality of these compared to national ones? 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 create a test version, or a prototype of the new EPR system to test archetypes for clinical practice.

B. Future Development of the National Archetype Work

As the example in section D from the Western Norway Regional Health Authority describes, there is a need for emphasizing the interrelation between the archetypes and the systems using them. In addition, some of the lessons learned from the archetypes so far, and the need for defining the extent of the future work includes estimating how many archetypes to make, how much resources this work requires and how long establishing archetype standards for an EPR system will take.

First, the work with developing archetypes has over the last years enabled the system vendor and NRUA to approach each other, since they both have experienced that this are two interrelated processes that cannot fully be separated the way the two level model of openEHR describes. Testing out archetypes for clinical practice and working with developing the EPR system have enabled both organizations to gain evidence based knowledge and experience of this work. However, these two development processes have been unsynchronized from the start. Establishing a national

archetype organization and the work with national archetypes started almost two years after the development of the new EPR system. The reason for this was mainly the original notion that archetypes was easy both to implement from other CKM's, and to develop by the system users themselves. After both National ICT and the vendor had worked with archetypes for a while, it became clear that establishing a Norwegian CKM was necessary to develop archetypes that fit the conditions of Norwegian healthcare. Since nobody had experience from working with archetype standards and openEHR based EPR systems in Norway, a maturity process where necessary for both organizations, before establishing an organized way of working with these issues. Working with archetypes and the system as separate processes provided a risk for challenges when trying to combine them. That brought on the question of how close the archetypes and the system needed to be. There was an example in Norway described in section D were the Western Norway Regional Health Authority requested a change in one archetype after trying to implement it to the EPR system. When discussing the need for changing the archetype the main question was how to relate to such changes, and if the archetypes should be adjusted to fit specific systems vendor's requirements, or if the vendors should rather adjust their systems to fit the archetype standards. OpenEHR archetypes are systems independent, which is one of the great advantages of using archetypes as standards for the clinical content of EPR systems. Therefore, it is not expedient to change the structure or content of the archetypes to fit one particular vendor's needs. Adjusting to the requirements of one vendor risk compromise the archetype and there is a possibility that they end up as system dependent standards that just fits with the needs and requirements of one particular vendor. The previous leader of NRUA stated *"National archetypes should not be modelled from limitations in the software of the vendor using them"* However, the archetypes in the Norwegian CKM are very new, and have mostly not been used for clinical settings. Implementing them to clinical environments might therefore require some changes due to the structure and content of the archetypes. In addition, if the Norwegian archetypes do not fit the requirements of the only large-scale EPR system conforming to openEHR architecture in Norway, who will then use them? In addition, in the national consensus work with archetypes, the EPR vendor is strongly involved in establishing the national standards influencing both their content and structure. It is however possible for all vendors to join the national archetype work and it might even be positive that the vendors participates of this process. This way they can follow and participate in the national discussions related to archetypes and contribute to detect challenges related to archetypes. They may also understand the concept and construction of archetypes better, and how to create their EPR system to fit the requirements of these standards.

Due to the archetypes and the EPR system being closely interrelated, there is a need for defining some borders between them and what part of archetype governance NRUA, and what part the vendor are responsible for related to establishing and changing archetypes. For example if one nationally approved archetype is changed after it has been implemented in the EPR system who is responsible for ensuring that all relevant data is interoperable, and all relevant systems, schemes and templates using this archetype gets updated? There are different degrees of changing archetypes. Minor problems related to for instance data storage only requires a new version of the archetype without compromising the interoperability between the new and the old version. A major change in the data structure will require a new archetype and this may not be compatible with the old one.

Another important question for planning the future work with archetypes is how to define the number of archetypes needed for the EPR system and how many would be necessary for creating a prototype of a basic EPR system? Are the 30-50 core archetypes defined by NRUA [28] a sufficient basis for covering 90% of the clinical content of an EPR system, and thereby create a general prototype of the system, or does this require a more extensive set of clinical standards? It seems to be diverging opinions related to this matter. This was illustrated on the national forum in May 2016 the leader of NRUA said that it is likely that 200 archetypes are enough to cover 80% of the EPR systems clinical content. This might be why NRUA has set a goal of nationally approving 200 archetypes by the end of 2016. The question is however if the archetypes approved by then are generic enough to actually cover 80% of the EPR content, or if the practice of working only with archetypes requested by the healthcare practice leads to ending up with working with less generic archetypes more specified for one particular use like the core journal or "the patient security program." It might be necessary for NRUA to adjust the current strategy, if the goal is to develop archetypes to cover as much of an EPR system as quickly as possible. At the same forum, a representative from Ocean informatics stated that between 1000-2000 archetypes are necessary to have a complete set of standards for an EPR system. Is there a need for 30-50 archetypes to cover 90% of the EPR, 200 to cover 80% of the EPR or 2000 to cover all of the EPR that is correct? There is a vast different between these estimates, and it seems rather uncertain at this moment what the total requirements of archetypes really are. The difference in the estimates makes planning the future work, and assessing the necessary resources for participating in the work very challenging. One of the reasons why this is difficult is probably the absence of archetypes used in clinical practice. According to this, establishing a prototype of a basic EPR system based on the core archetypes would be a good way of testing how much of the EPR content the core archetypes really cover. This way it may be easier to estimate the total number of archetypes required and plan the future work with archetypes in more detail due to the time and resources needed. The progress in the national archetype work have increased the competence

of all the involved actors, this has been necessary for increasing the pace of this work. As the national archetype work progress, the hypothesis of core archetypes also evolves including more archetypes than first predicted covering less of the EPR system that expected. Realizing this is a result of the clinical and technical development processes approaching each other, NRUA being an important part of the vendor's development projects, and the vendor being a significant contributor to the archetype work and national consensus process. They have both gained experience and competence from trying out the archetypes for clinical practice. In the project in the Southern and Eastern Norway Regional Health Authority the vendor got to experience the challenges related to developing archetypes and they were able to test how well the system was equipped to implement archetypes. NRUA gained experience on how the archetypes fit clinical practice moving the development of archetypes from a theoretical to a practical level. The system users also experienced archetypes for real clinical use, helping them better understand the potential of archetypes and the new structured EPR system.

In addition to presenting how much of the clinical content the core archetypes cover, creating a prototype would be very useful for the clinicians, enabling them to see and try out archetypes in a practice like environment. This could enable them to better grasp the potential of the new EPR, and identify what the necessary requirements for continuing the development process are. 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. However, this would require reaching national consensus on the defined core archetypes. The reason for not having prioritized the core archetypes for the consensus process were many: 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. In addition, the requests for archetypes from different parts of the healthcare sector like the core journal project and the "patient security program" led to down prioritizing the more general core archetypes. NRUA was an organization with few persons, set to do most of this national archetype work and several issues like prioritizing their time, how many clinicians to include, how to structure the archetypes, whether to translate international archetypes, or establish new ones from scratch, what type of archetypes to prioritize, had to be considered. As a result of more and more focus on archetypes in the healthcare sector, 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. On the other hand, the lack of organizational and clinical resources in the governance organization is slowing down a positive development. Having such competent organization to coordinate the archetype work might necessitate reconsidering how to work with archetypes in Norway. In the example of implementing archetypes for clinical use described in part C, this project developed in collaboration with the system vendor 52 archetypes in 9 months. This illustrates that intensifying the archetype work by defining a set of archetypes requested for a smaller part of the health care service, and work systematically with these in a project is a way of speeding up the archetype development. Maybe a similar approach would have been beneficial for the pre surgical planning project, to complete the necessary archetypes for this module, or for completing the core archetypes, to enable developing a prototype of a basic EPR system. There is of course a difference in developing archetypes locally in collaboration with a system vendor and establishing nationally approved archetypes, however it do not necessarily need to be impossible to establish projects to work with national archetypes as well. This way there would be a set of clinicians and other necessary reviewers working with a particular set of archetypes as a part of their workday. This way reviewing archetypes could be included in the project preventing the reviewers from having to do this at their free time. Consequentially the group of clinicians involved would have been more dependable, however, including all of them in the project would either require a very large project or review processes with fewer participants with the risk of compromising the notion of a maximum dataset for the archetypes. NRUA is however currently working towards the goal of having 200 consensus made archetypes by the end of 2016. The question is however, if the archetypes they are working with are the core archetypes requested to fulfill the basics of an EPR system or if the development of archetypes so far includes too many specialized archetypes requested by part of the healthcare service.

V. CONCLUSION

Working with archetypes in Norway has been a gradually expanding process starting with a project in National ICT in 2008. The work gained national focus when the largest EPR vendor decided to develop an openEHR based EPR system based on archetypes as clinical standards. Since then, three of four health regions in Norway conformed to this system vendor, hence they decided to work with the OpenEHR standards to standardize clinical information at a national level. It has been challenging to increase the pace of the national archetype work in Norway due to several factors. It is however essential for the progress of the archetype work and the new EPR system that the development of archetypes continues to gain momentum. One important factor to accomplish this, is to develop a set of core archetypes to cover the basics of the clinical information in the EPR system. These archetypes are set to cover 80-90% of the EPR content leaving only the most specific ones out. To accomplish this there are several issues to address

First, how to organize the national archetype work in Norway, and the need for a solid organization to coordinate this work including hundreds of system users participating in the review process. Second, the relations between the archetype standards and the EPR system. There turned out to be a closer interconnection between the two levels of the openEHR model than first expected. It was difficult to develop the system before the archetypes were finished, as well as it was challenging to develop high standard archetypes without having a system to test them in, leaving the development at a theoretical level. Third, using the archetypes for clinical practice, and the balance between establishing national archetypes and developing local ones. To have some practical experience related to archetypes in clinical use is important for NRUA, the system vendor and for the system users to get an impression of how the new archetype based openEHR EPR system will be, and the potential of this new way of structuring clinical information. There also have to be a balance between only using nationally approved archetypes and the need for speeding up the process by using unapproved archetypes to test the archetypes in a production environment (use in the EPR). Fourth, how to coordinate and distribute the consensus based archetypes. This relates to versioning the archetypes, how to relate them to the existing national archetypes and the general complexity of developing archetypes.

A need for defining a set of core archetypes to develop a prototype of a basic EPR to solve some of these challenges have been addressed including the difficulties related to define the number of archetypes required for such prototype. Planning the future work with archetypes including defining how many archetypes an EPR system need for standardizing the clinical content, in relation to how many resources the work requires, and when it can be possible to have a complete set of archetypes, covering the necessary clinical content of the EPR system. Another important issue is how to distribute the governance of the archetypes between NRUA and system vendors using them in relation to establishing and changing archetypes to ensure that the archetypes keeps as high quality as possible.

Using the core archetype as a basis is a promising tool for future accomplishments in standardization, 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. Establishing archetypes as standards for the clinical content of an EPR system is a way of establishing a national governance of clinical standards in Norway. It is important to share the responsibility for maintaining this between the 4 health authorities, since they all have to contribute to this work to reach the goal of archetypes being reusable standards enabling process and decision support as well as interoperability between the EPR systems and the rest of the ICT portfolio.

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