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Users' role in the making and scaling of an Information Infrastructure for Health Care based on the openEHR specification

A socio-technical perspective on the introduction of a new standard for Electronic Health Records

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Abstract

Norwegian Government has high expectations for quality and efficiency improvement through use of more advanced ICT in Health Care. Electronic Patient Record (EPR) systems in use in Norway are considered to be in Generation 2 with a long development cycle ahead of it to reach Generation 3. This thesis is based on a development project to reach a Generation 3 system, conceptualized as the making and scaling of an Information Infrastructure for Health Care. The technology chosen is based on openEHR architecture, which is very different from the EPR system currently in use in 80% of the Norwegian Hospital Health Care

In this thesis, I discuss the socio-technical challenges in growing and information infrastructure for Health Care based on the openEHR specification, particularly focusing users' role and contribution. Conceptualizing the emerging EPR system as the growing of an Information Infrastructure, the different happenings and activities in the development project have been interpreted as infrastructuring work on the different aspects of an emerging infrastructure.

The dual level modeling approach in openEHR, which aims to separate technical and clinical concerns leaves the configuration of the system to the users by the way they are meant to define and model archetypes that will control how their information systems function. This poses a different role and different tasks for users contributing in the development of the new EPR system. I see this as a new user domain arising, and a new user role that has been named domain-expert.

Given that decision and process support are governments' most prominent ambitions for the next generation EPR system, this work focuses how these features will affect work, as literature describe the effect on work as a potential challenge for adoption and use of such systems. To understand the inertia of the installed base, work practice and the users' efforts in describing and modelling work processes have been given much attention. I find that because process and decision supportive features presuppose models of work embedded in the system, they will affect work. The interdisciplinary work is affected by workflow systems in the way that the systems can "order" responsibility and sequential dependency of tasks. The collective responsibility was affected by the sequential ordering and user role constraints inherent to the system. Moreover, there was a redistribution of tasks as a consequence of the formalization and the accountability mechanism.

Standardization is also discussed as infrastruturing, as clinical pathway templates embedded as models of work will take considerable efforts from users to negotiate, describe, model and implement.

This research is based on a study that has been ongoing for 5 years, which has allowed us to expand the focus of research longitudinally and across different social settings and scales, addressing multiple moments and sites of innovation. This apply to Pollock and Williams'(2010) Biography of Artefacts perspective, particularly suited to study the emergence of large-scale information systems intended for long-term use. Methodologically, the study adheres to interpretive research and makes use of semi-structured interviews, participatory observation and document studies as methods.

Acknowledgements

While working on this thesis I often felt like an explorer. Being allowed to dive into literature, climb onto new acknowledges, ride a Roller coaster between "yes – I've got it" and "I don' understand anything". Literarily, I have travelled to places I would not else have gone to- for conferences where I met people that have enriched my mind. The warm and including atmosphere of this research community has really amazed me.

While research can sometimes be a lonely journey, I have mostly travelled with my fellow Phd student Line Silsand and my supervisor Professor Gunnar Ellingsen. Lately, also Camilla Bjørnstad and Gro Hilde Ulrichsen joined the expedition. Line has had the patience to listen to my ideas and discuss for long lunches. I hope we will continue to write together. I have many times heard of students that could not finish their thesis. Often, a crucial reason was lack of response from their supervisor. Well, it soon became clear to me that if I failed my work, I could not put the blame on Gunnar. Working late hours and weekends as deadlines were coming up Gunnar was always only a few clicks away.

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When setting off for an expedition, ground support is needed. And that is what you are to me, dearest Arild. Your patience with me is unbelievable, particularly because you are not a very patient person. Still, you have been there, tidying the mess I have made because things have been forgotten. That includes taking care of our animals because I am far off in my thoughts or travelling somewhere. Luckily for you, my children Dina, Trygve and Knut Gaute – you are so grown up that you are no longer dependent on my daily care. Instead, I have the pleasure of your support and faith in me - thank you. I hope my work can be an inspiration for you to pursue whatever goal you set for yourself.

Lastly, I feel an urge to express a deep gratitude to all the people that I have encountered as informants in my work with this thesis. I hear of researchers trying to get access to "the field" for months without success, whereas I have met an incredibly openness from the very first day. All you people in FIKS, in the hospitals in Northern Norway, in DIPS ASA – I thank you humbly. You made this work possible.

PAPERS

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1. Introduction

Motivation

I used to work as a nurse in a hospital. Newly educated, I was struck by how the quality of patient care actually depended on my ability to memorize. It was not enough to write note to self, because in many situations it was no room for such doings, I had to memorize. At the end of the day, I would go through all my notes and my recollection to find if any doings were forgotten. Somethings, I was not even aware that I should have done in the first place. Later, working as a managing nurse, I acknowledged the same problem, only now my concern was more often patients waiting for treatment. I was troubled by how often their services depended by my ability to remember what was decided about their treatment. Further, on my knowledge of what was going to happen during their stay, and which surgeon had the right profile for their condition in planning for their stay. All of this was knowledge that I had learnt as a part of a membership, it was not written anywhere and accessible for others. I sincerely felt the need for support to do my work, and as an electronic surgery planning module was introduced as part of the Electronic Patient Record, I was enthusiastic. This was it! So when the possibility to do research on the development of the "next generation" of EPRs, offering process and decision support came up, I was on it. This is my personal motivation for this thesis. As I started out and got into reading, I soon understood that my experiences came from a fundamental need in the sector, which is why, I presume, the project got funding.

The potential quality achievements from EPRs:

Electronic Patient Record (EPR) is gradually becoming an indispensable tool for planning, providing and improving clinical work. So far, the data generated from the different systems and devices have been combined, interpreted applied manually at points of decision in clinical work. However, the emerging complexity of clinical work pleads for more advanced ICT support, assisting health care personnel in keeping track of patients. The situation may be compared with the traffic evolution: There used to be few cars, the roads did not allow high speed and security was hardly an issue. Today, this picture is very different, and cars are able to assist the drivers in reading and coping with all the traffic. Caring for patients has evolved along similar tracks: There are hundreds of professions involved, many handovers of patients

and information, lots of parallel treatment and assessments and higher turnover of patients. Additionally, medicine itself has become extremely advanced, exposing health care personnel to loads of knowledge that should be processed and applied. Thus, there is a need for, and an expectation that ICT would assist health care personnel in keeping an overview of their patients and the updated treatment regimes.

The benefits of EPRs have been increasingly recognized in healthcare. Electronic prescribing, a component of EPRs, may reduce medication prescribing errors (Duplaga et al., 2004; Franklin et al., 2007; Schiff and Rucker, 1998; Shortliffe, 2005) through increased legibility, warnings against drug interactions and previous allergic reactions and possibly automated dose calculation. EPRs have the potential to coordinate distributed care processes and communications among multiple specialists and the patient (Hillestad et al., 2005).
They are also more easily aggregated from different geographic locations to support large clinical research studies compared to their paper counterparts. If Clinical Decision Support (CDS) is provided within EPRs based on practice guidelines, care can be provide based on evidence and best practice in order to achieve better quality and efficiency (Barretto et al., 2003; Kawamoto et al., 2005a; Sim et al., 2001). Still, perhaps the most promising potential of EPRs is its ability to close the loop between clinical practice, research and education (Van der Lei et al., 2002). Recent research has shown that health care delivered in industrialized nations often falls short of optimal, evidence based care. A nationwide audit assessing 439 quality indicators found that US adults receive only about half of recommended care, and the US Institute of Medicine has estimated that up to 98 000 US residents die each year as the result of preventable medical errors (McGlynn et al., 2003). Similarly, a retrospective analysis at two London hospitals found that 11% of admitted patients experienced adverse events, of which 48% were judged to be preventable and of which 8% led to death (Vincent et al., 2001). Many of those events are expected to be prevented by use of ICT support. In Norway, figures from 2013 tells that 2700 patients died as a result of adverse events in hospital, and further 65 400 cases in which adverse events lead to prolonged hospital stay or more serious consequences. Roughly 60-70% of these happenings could be avoided by the use of improved ICT systems (omsorgsdepartementet, 2014) (Ministry of Health and Care Services).

For EPRs to be able to improve quality of care, they should be supported by clinical decision support services (Sittig et al., 2008) , those services that aid clinicians in the process of

decision making. Nonetheless, not all CDS developments have led to improving the clinical practice (Kawamoto et al., 2005a). Hunt et al. (Hunt DL et al., 1998) indicate that 66% of the CDS implementations have led to significant improvement in health care while the remaining 34% did not. Various efforts have been made in order to identify barriers to low adoption, acceptability and ineffectiveness of CDS. Efforts have also been made to identify success factors in developing them (Bennett and Glasziou, 2003; Greenes, 2007a; Kawamoto et al., 2005a; Osheroff et al., 2007) Some of those success factors are the level of integration with clinicians' workflow (Greenes, 2007b; Kawamoto et al., 2005a; Osheroff et al., 2007), the degree of patient-specificity (Greenes, 2007b; Kawamoto et al., 2005a; Osheroff et al., 2007) the availability at the point of care and timely access (Greenes, 2007b; Kawamoto et al., 2005a)

There are few professional fields that pose as great a challenge to the use of computers as clinical medicine. Many safety-critical domains have been relying heavily on automation and computing for decades. Comparisons of healthcare and aviation often point out how information technology successfully transformed an entire industry and increased passenger safety (Kohn et al., 2000). The decision-making processes of a clinician, however, are perhaps more akin to those of a firefighter brigade commander than to the pilot of an airliner. In these domains, decisions are sometimes made with little or unreliable evidence and changing circumstances dictate quick adjustments in the planning of actions (Horsky et al., 2005). In a typical hospital setting, task flow may be context-dependent, users may follow non-linear completion strategies due to interruptions, uncertainties permeate many decisions, and the highly collaborative nature of assessment and treatment is critically dependent on clear and speedy communication. The need to make adjustments in the planning of care is why Clinical Workflows are named *" The Killer Application for Process-oriented Information Systems"* (Dadam et al., 2000).

Research Theme

Paramount, the research studies how a decision and process supportive EPR based on openEHR archetypes is being realized. Initially, the system was to be implemented during the project time, but like many other large-scale ICT projects, there have been delays. Implementation as described in the research protocol is therefore not a theme. Given the shortcomings of todays´ tool related to the expectations in the field, and to the political ambitions for the service, the development of the EPR has been an exigent process in which the most fundamental abilities of the future system had to be defined. Thus, even if there is

already an electronic system in use, the technology base in the new system is so different that it poses new questions and challenges both in the making, and in the scaling. I am particularly interested in the users' roles and efforts in this process. Because the scope and the scale of this system takes infrastructural proportions, applying theory on Information Infrastructure (II) has provided an analytical capability to see the data as aspects of growing an II (Monteiro et al., 2013). A key characteristic of infrastructures is that the different elements are integrated through various standards (Hanseth and Lundberg, 2001). These comprise technical standards in terms of communication protocols and coordinating artefacts (Schmidt and Simonee, 1996) and standard work practices. This implies that designing infrastructures means defining standards. Infrastructure design is an activity distributed in both time and space that involves a large number of actors of various kinds. IIs are not designed from scratch—they are normally designed by modifying and extending what already exists. Hence, the current infrastructure—the installed base—wields a strong influence on what it may become in the future (Hanseth and Lundberg, 2001). An important aspect of the Installed base is that it represents not only various technologies, but also social factors, such as human work tasks and various sets of work procedures. This thesis applies a socio-technical perspective to how a new technology is designed to fit the installed base as well as enable future needs, and to the users' efforts of making it evolve into an extended infrastructure of what is already there.

Research questions

The making and scaling of IIs is a long-lasting process (Ribes and Finholt, 2009) that involves many phases and a broad assemblage of contributors. Given openEHR is a dual modelling approach, redistributing responsibility and tasks unlike traditional development methods, identifying the novel landscape becomes necessary to understand the socio-technical challenges such approaches are up to. Hence, the main aim of this thesis is to identify the efforts and roles it takes to build an Information Infrastructure for Health Care based on the openEHR architecture. Although building II takes an assemblage of contributors, this work particularly focus the user role and efforts. Accordingly, the first research question posed is

RQ 1: How to best organize user participation in large-scale IT development projects in healthcare?

A key characteristic of infrastructures is that the different elements are integrated through various standards (Hanseth and Lundberg 2001). Standards specify how we work and how technologies interact, they hold our sociotechnical societies together (Timmermans and Berg, 2003). Additionally, they are the backbone of western health care infrastructures (Bowker and Star, 2000; Timmermans and Berg, 1997). They are supposed to ensure quality of care through best practices development (Timmermans and Berg 2003), increased efficiency as well as ensuring seamless patient trajectories over organizational boundaries. Standardization has, however, proven extremely difficult to achieve (Ellingsen, 2004; Hepsø et al., 2009; Timmermans and Berg, 1997), particularly when work practices are involved. In this project of study, there are different mechanisms of standardization and standards in play. Being a specification for modelling clinical concepts, openEHR archetypes is promising for bringing semantic and technological interoperability to EPRs to support process orientation (Chen et al., 2009). Hence, openEHR is considered an interesting new strategy of standardization, as it promises great impact to clinicians themselves (Leslie et al., 2009). However, newly introduced standards of technology in health care are not objective, they make a dynamic interplay between the introduced technology and work practice (Bowker and Star, 1999; Timmermans and Berg, 2003; Ellingsen, 2004), holding the capability to transform work practice. Being particularly interested in the users perspectives, the second research question posed is ***RQ 2: What are the challenges in user-controlled standardization, and how do this pan out in heterogeneous health care practices?***

Medical knowledge is becoming more and more subspecialized, leading to more and smaller units in even larger organizations. At the same time, demographic changes like rise in chronic diseases and more elderly people with co- morbidity put pressure on services from multiple providers. Higher turnover of patients also plead for better coordination and cooperation of services. Hence, care is more often organized into Clinical pathways. These are structured multidisciplinary care plans used by health services to detail essential steps in the care of patients with a specific clinical problem. They aim to link evidence to practice and optimize clinical outcomes whilst maximizing clinical efficiency (Rotter et al., 2010). This takes coordination of series of acts distributed among physicians, nurses and secretaries, across geographical locations and organizational units, temporally distributed and across different artefacts. An important strategy to cope with this challenge is to ask the "next generation" of Electronic Patient Records to have inherent cooperation and coordination

abilities, by offering specialized modules for planning. The emergent EPR promises to facilitate planning and implementation of treatment, particularly within surgery as this is one of the most costly and resource demanding activities in hospitals. Based hereon, this thesis poses the third research question, ***RQ3: How can planning of Clinical Pathways including surgery be facilitated by ICT?***

Important features in future EPR systems is decision and process supportive abilities, as this gives promises of enhanced quality of care and efficiency to Health Care (Berg, 2005). Despite the great expectations, such systems have shown difficult to implement, and the adoption is rather low (Kawamoto et al., 2005a). It is therefore of interest to take a closer look at why this can be so, and the perspective I have chosen is to apply the Computer Supported Cooperative Work (CSCW) perspective grounded in work practice studies. Accordingly, the fourth research question posed is ***RQ 4: How is health care work affected by introduction of clinical decision and process supportive systems?***

Main aim	To provide detailed empirical insight into what is users' contribution in the making and scaling of an information infrastructure for Health Care based on the openEHR architecture.
Research question 1	How to best organize user participation in large-scale IT development projects in healthcare?
Research question *2*	What are the challenges in user- controlled standardization, and how do this pan out in heterogeneous health care practices?
Research question 3	How can planning of Clinical Pathways including surgery be facilitated by ICT?
Research question *4*	How is health care work affected by introduction of clinical decision and process supportive systems?

Table 1: Main aim and research questions

Paper	RQ 1	RQ 2	RQ 3	RQ4
Standardizing Clinical Pathways for surgery patients through ICT				
The Biography of Participation				
User-Controlled Standardization Of Health Care Practices				
Evaluating Model-Driven Development for large-scale EHRs through the openEHR approach				
Formalization and Accountability in Surgery Planning				

Table 2: Correspondence between papers and research questions: Dark grey indicate full match, light grey indicates partly match and white indicates no match.

As the table show, the papers contribute to different aspects of the overall aim of the thesis, and the intensity of the gray color indicates to which degree each paper answer the research questions.

Research setting

FIKS

The Norwegian specialized Health Care (Hospital Care) is divided into four regions. The North Norwegian region is the smallest in population (11% of the Norwegian population / 500 0000 inhabitants) whereas it is the largest regarding area (35% / 112.945m2). The North Norwegian Health Authority is responsible for specialized Health Care services for the inhabitants in its area, and runs 4 Health Trusts to do so: The University Hospital in North Norway (comprises 3 hospitals in different towns), Nordlandsykehuset (comprises 3 hospitals in different towns), Helgelandssykehuset (comprises 3 hospitals in different towns) and Finnmarksykehuset (comprises 2 hospitals in different towns). In 2009, the North Norwegian Health Authority issued a call for tender to replace its portfolio of clinical systems in all the 11 hospitals in the region. The portfolio include Electronic Patient Record (EPR) patient administrative system (PAS), Laboratory Information Systems (LAB), Electronic requisition of laboratory services (ERL) Pathology, X-ray information (RIS) and storage and display system for diagnostic images (PACS). Practicing a "best of breed-strategy, four different suppliers were chosen for the systems in this acquisition. The EPR is the largest part of this portfolio, and has most users. In accordance to national strategies for more advanced ICT in health care, the invitation to tender asked for functionality not yet present in any EPR system in Norway. Hence, the EPR should be developed in close collaboration between the

users and the vendor. The development and implementation of the "next generation" EPR were arranged as a regional project for all the 11 hospitals run by the Northern Norway Regional Health Authority. The FIKS project was amounting to 56 million EURO[1], making it an ambitious ICT project for healthcare in Norway.

The Regional Health Authority employs about 12 500 man years, which means the clinical systems will have many users. As responsible for specialized health care and the trader of the new ICT tools, Northern Norway Regional Health Authority had outlined some objectives for this big investment, based on national strategies for the domain. Firstly, they wanted it to contribute to more standardized patient treatment in the region. In Norway, there has been outlined National Guidelines for treatment for various conditions to standardize treatment and the Authority see ICT as a tool for implementing these guidelines in their hospitals. Furthermore, to overcome the problems of poor information flow between hospitals, and to reduce the complexity in maintaining the ICT systems, all the 11 EPRs (one for each hospital) were to be merged into one installation. Working in a regional EPR would necessitate:

- Agreement upon clinical pathways
- Agreements upon standardized templates in the EPR
- Agreement upon coding and configuration in EPR
- Shared structure in EPR.
- Agreement upon data entry practice

Hence, the FIKS project spanned multiple activities that were organized into different sub-project. There were implementation projects for Pathology, Laboratory system and radiology services, as these were products ready to implement. Regarding the EPR, preparatory activities were needed, and a separate project was established to standardize how the current EPR was used, and merge all the 11 installations into one EPR for the region. This was necessary to establish a platform for the new system to work according to the ambitions for the acquisition. The standardization sub-project turned out to be the most comprehensive, as it involved 120 end-users from all the hospitals in the region. To propose a set of uniform guidelines for the definitions and use of EPR content, as well as templates in which the data could be recorded, the sub-project established 18 working groups to address standardisation. The personnel were selected from different hospitals and from different professions to ensure

[1] The papers refer differing amounts, as this has been adjusted during the project due to delays, new activities etc.

that the local perspectives on standards were addressed. The working groups were to map current practices in order to suggest standards or best practices on their areas of expertise. The projects' result was implementation of the regional routines, and a "standardization manual" in 156 pages with the new routines that were to be followed by all the hospitals.

Additionally, there was a development project, where the requested functionality not yet present was to be designed in close collaboration between the vendor and end-users from the hospitals. In this track, 70 clinicians participated. The development project focused initially on the surgery planning module in the EPR, as this was identified as functionality with great impact for the hospitals due to poor resource utilization in this costly service. However, as part of the EPR, this module would also need process and decision supportive abilities, and hence much of the fundamental functionality for the upcoming technology had to be designed as part of this project. Thus, the users were divided into sub-tracks for decision support, process support, surgery planning and also psychiatric documentation. Initially, they were end-users from all the hospitals, but as the process proceeded, user-participation was concentrated on the University Hospital, and the different tracks were merged as it was acknowledged considerable overlap in what they were working on.

From the outset, the timeframe for the FIKS project was due 2016. By then, the whole portfolio should be implemented. However, the development of the EPR took much longer than anticipated, and by now (August 2017) the system is not yet put into use.

The EPR supplier DIPS ASA

As the leading vendor in the Norwegian market, DIPS ASA holds 86% of the hospital market, including the 11 hospitals in the North Norwegian region. Their product DIPS Classic has currently 80 000 health care workers as users. DIPS started out as an "in-house IT service" at Nordlandssykehuset Bodø in 1987, and two years later other hospitals took on the product. At this time, it was merely a patient administrative system (PAS), but a free-text based EPR, radiology and laboratory functionality, also for transferring to primary health care were developed and added subsequently. Since 1997, DIPS has been a Public Limited Company (PLC). However, hospitals and medicine evolve and change continuously, which in turn requires that vendors respond to evolving demands while still maintaining the old software. To meet the changing needs, DIPS ASA started in 2006 to experiment with a Model Driven Development (MDD) approach, which culminated in 2011 with the decision of using the OpenEHR framework (Beale 2002) for their next generation EPR for hospital marked, DIPS

Arena. The introduction of DIPS Arena implicates moving to a novel, service based platform. Hence, all the functionality hardcoded in Classic would have to be migrated and re-coded according to a dual–level modelling approach. Holding such a large share of the hospital market, DIPS ASA decided to apply a stepwise migration to the new platform. The modularity of DIPS Arena would allow for implementing it bit by bit, while still working in their present system, DIPS Classic. This was considered to reduce customers risk compared to migrate in a "big bang" overnight.

Structure of the thesis

The reminder of the thesis is organized as follows: Section 2 provides an overview of the Norwegian Health Care policies and ambitions for the sector when it comes to deployment and use of technology. Section 3 describes the theoretical framework and the perspectives that were adopted during the research. Section 4 elaborates on research approach and methodology as well as an outline of the method applied in this study. Section 5 presents a summary of the papers in this thesis. Following, section 6 provides implications of the research, and finally, section 7 outlines the conclusion and suggestions for future research.

2. The Norwegian health care

Political ambitions for the ICT development in the sector

Through national and regional strategies, guidelines, and status reports, a clear direction for the Norwegian health services emerges: There is a need for technically more advanced and more functional mature ICT-based clinical support systems. The degree of digitization in the specialized health care (hospital sector) is high, but individual specialist systems are acting mainly as isolated silos which at best can copy selected data between systems and actors, using technical integrations and message-based exchanges.

Specialized health care also falls short compared to national goals on closely interacting systems with primary care, which should support and facilitate continuity of patient care. Care provision should be on the patient's terms and with strong and informed patient participation. The systems should hold good and evidence-based knowledge, process, and decision support for health professionals in all specialties and professions. Furthermore, have the monitoring and management capabilities that create opportunity for better and more long-term planning and optimal resource utilization. In addition, they should provide access to necessary data for continuous quality improvement and research.

National Strategies

Since the late nineties, Norway has had a series of national ICT policy strategies that have resulted in guidelines for making use of IT-based tools in health care, including specialist services. The strategies "More health for each bIT" in the period from 1997 to "Teamwork 2.0" in 2013, has largely focused on employing basic IT-based documentation tools (EPR) and specialist systems, and message-based electronic exchange of information between actors at different levels of care.

The latest Policy Strategy is White Paper No 9: "One Citizen- one Health Record" from 2012 which gives three overarching goals for ICT development in health and care services:

• Health professionals should have easy and secure access to patient and user information

• Citizens should have access to secure digital services

• Data should be available for quality improvement, health monitoring, management and research

The White paper describes the following requirements for future EPRs:

• Updated knowledge, process and decision support to health professionals should be included in the records system.

• Secondary use of data like reporting of structured data for National Quality Improvement Registers should be automatic, without duplication, and should be an integral part of the regular documentation processes.

• Compilation of high quality data will make it possible to monitor the health status of the population, make systematic assessments of services, and make the basis for management, quality improvement and research.

• Increased use of structured data will help improve the quality of reporting and easier interaction by enabling information to be shared and reused in different contexts. Degree of structuring must be reconciled with clinicians' demand for simplicity, and the desired data reuse.

Status Report on ICT in the health care sector

As part of the research for the white paper "One citizen – one Health Record", the Directorate of Health prepared three reports; an overall summary, a comparative analysis of the regional health authorities in the ICT field, and an analysis of the Norwegian supplier market for

electronic medical records. Together they describe a “state of the art” on ICT in the health care sector in Norway at the time of 2014. Alarmingly, the work presents data telling that in 2013, 2700 patients died as a result of adverse events in hospital, a further 65 400 cases in which adverse events associated with inpatient stays lead to prolonged hospital stay or more serious consequences. Roughly 60-70% of these happenings could be avoided by the use of improved ICT systems.

Overall, the following challenges in today’s ICT system use in Health care were identified:

• Today's information structures and IT systems do not support workflow and continuity of patient care (particularly across organizational boundaries). Data is largely unstructured and lacks common terminology and concepts that enable semantic interoperability.

• Today's ICT systems lack functionality for decision support and quality improvement. These capacities are necessary to strengthen patient safety and improve the quality of health and care services.

• Today's electronic medical records are not authoritative when it comes to storing generated patient data. Significant amounts of data are generated in medical devices, then they are processed locally in separate specialist systems not integrated with the main record, or they are summarized unstructured in text documents stored in the EPR. Either way, the data are not available for decision support or secondary use like quality improvement.

Analysis of supplier market for EMR

The report "Analysis of the Norwegian supplier market for Electronic Medical Records (EMR) and patient administration systems (PAS)" focuses primarily on the supplier market and evaluates vendors and products (EPR / PAS systems) against factors such as functionality, viability, and market position. This perspective is interesting because it presents tools for the assessment of products and suppliers that can also be used to evaluate the region's maturity in the field of clinical ICT, hence pointing out the direction for future development.

One of these tools is the Gartner Group "generation model 'for EPR / PAS systems.

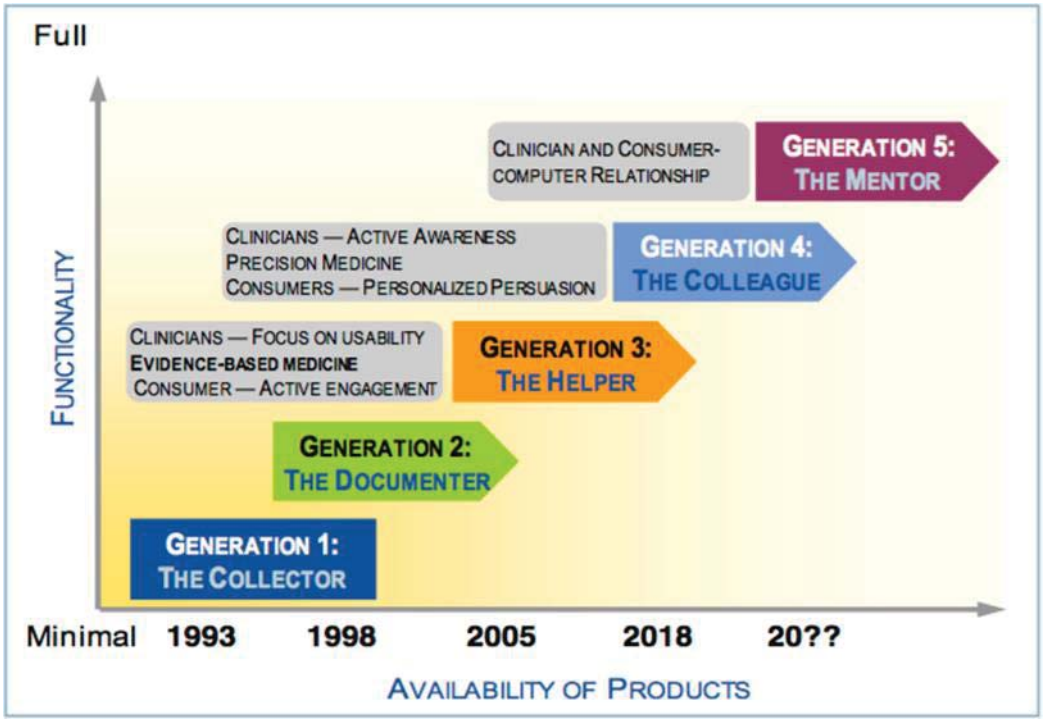

Figure 1: Five Generations of EHRs (source Gartner)

Gartner has developed a model in which EHR solutions are categorized as generation one to five, indicating the maturity of the solution and the richness of the functionality provided[2].

Generation 1 systems are simple systems that are essentially results-reporting tools that enable multiple users to access clinical data that previously may have been scattered among several systems or available only in a paper chart for one individual at a time.

Generation 2 systems are basic systems that clinicians can use at the point of care to begin to document, rather than merely access, clinical data.

Generation 3 systems are more advanced and support clinical episodes and encounter clinicians. These systems include integrated pharmacy functionality and cover both ambulatory and acute-care setting. The systems have the technical capability to bring evidence-based medicine to the point of care. Generation 3 products have been available since 2005.

Generation 4 products "The Colleague," are more advanced systems that provide more sophisticated, clinically relevant data synthesis, presentation and navigation options along with richer and more complex clinical decision support capabilities. The requirements this generation must support represent the natural evolution that all workflow/rules-driven

[2] *Gartner research report; Gartner's 2007 Criteria for the Enterprise CPR (G00149693)*

applications will traverse. Next generation EHRs will be compelled to deal with data and decision support differently because of the explosion of new medical knowledge in areas such as predictive and prescriptive analytics, evidence-based practice research, and new realms of enhanced diagnosis and treatment decision support stemming from areas such as genomics and patient behavioral risk research.

The requirements for Generation 5 have not yet been described.

EPR systems in use in Norway are considered to be in Generation 2 with a long development cycle ahead of it to reach Generation 3, while the leading "State of the Art" internationally used EPR systems are moving towards Generation 4. No system has yet reached Generation 5.

3. Theory

In this chapter I present the theoretical frame used to gain an understanding of the object of study, and the challenges faced during the project time. First, I present some of the trends in health care that makes advanced ICT an overall issue. Then I turn to the technology and how it might answer to the anticipations. At last, I look into the interplay of technology and work.

Quality improvement and efficiency through reorganizing delivery of care into Clinical Pathways.

Health care has always been made up of multidisciplinary services. Still, medical knowledge is becoming more and more subspecialized, leading to more, and smaller, units in ever larger organizations. At the same time, demographic changes like a rise in chronic diseases and increasing numbers of elderly people with co-morbidity put pressure on services from multiple providers. A higher turnover of patients also calls for better coordination of and cooperation between providers. Hence, care is more often reorganized into clinical pathways, stretching across departments, hospitals and also primary care services. Clinical pathways are structured multidisciplinary care plans used by health services to detail essential steps in the care of patients with a specific clinical problem. They aim to link evidence to practice and optimize clinical outcomes whilst maximizing clinical efficiency (Rotter et al., 2010). This takes coordination of series of acts distributed among physicians, nurses and secretaries, across geographical locations and organizational units, which are temporally distributed and across different artefacts.

The benefits of clinical pathways are known as care delivery becomes more evidence based, colleagues and patients know better what care to expect (Rotter et al., 2010). Besides, Clinical pathways also afford a reduction of coordination work because the sequence of activities to pursue and professionals to see is already established. Rather than establishing this anew every time a patient comes in with a given condition, the clinical pathway is made beforehand. This makes care more effective and efficient; ensuring smooth coordination, continuity, and less variation between the individual steps of a patient's trajectory as well as affords safer and more patient-centered care (Allen et al., 2009). However, it is difficult to document their impact (Scheuerlein et al., 2012), partly because of the lack of ICT support to provide data for evaluating effects.

Process and decision support

The organizing of care into clinical pathways causes a growing interest in health care to move towards information systems (EPRs) that behave "process-oriented". In Health Care, this means to offer the right tasks, at the right point in time, to the right persons along with the information needed to perform these tasks. As a consequence, sematic interoperability between systems is a prerequisite in order for providers from different organizational units using different systems to "have easy and secure access to patient and user information" in accordance with the White Paper no9 (see p.13).

ICT is regarded crucial to deliver heath care by clinical pathway templates. Process-supporting information technology is similarly dependent on clinical pathways to succeed (Berg, 2004), as embedded computerized (i.e. formal) representation of work procedures that controls the order in which a sequence of tasks are to be performed, and by whom is a prerequisite for such systems. Information technology can only fulfill its potential in a workplace when decision criteria, terminologies, and work processes in that workplace are standardized. Modeling business processes in hospitals is hence spreading in order to assure better utilization of EPRs (Morquin et al., 2017; Ruiz et al., 2012; Scheuerlein et al., 2012). To have a useful electronic patient record, professionals need to use that record in similar ways; to work with order-entry, they have to heed the agreements assumed by the application (Berg, 2005). Clinical pathways bring the standardization that information technology requires, and, in its turn, information technology can further improve the cooperation, data management, and planning possibilities brought by the clinical pathway. I will elaborate on the need for standardization in the following section.

An important feature of process support is to deliver decision support at the right time, at the right place, to the right person. Process and decision support is hence close connected. Clinical decision support (CDS) systems are Computer based systems that combine medical, health professional and other knowledge with individual patient information to support decisions, assessment, care and treatment of patients. Hence, Clinical decision support depends on good quality clinical data repository and reinforces the need for standardized data representation and storage. Lack of good clinical data warehouse will have significant impact on the quality of advices emanating from CDS systems. Data mining algorithms require good quality clinical data repositories to be able to extract knowledge to support clinical decision-making (Bonney, 2011), hence depending profoundly on large volumes of readily-

accessible, existing clinical datasets usually extracted from the repository content of EPRs. Lack of standardized data in the repository may lead to datasets not representative of the patient population (ibid). It is therefore essential that standardized data representation are used for leveraging the knowledge base repositories to facilitate the generation of patient-specific care recommendations for physicians (ibid).

Decision support comprises a variety of tools and interventions such as computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools (Osheroff et al., 2007). CDS may be categorized according to their level of complexity. The following outline is referring to a report from an expert group commissioned by the Norwegian Heath Directorate[3] : One form of support that for practical reasons are perceived as decision support, is providing access to guidelines and other evidence based knowledge. However, such functionality does not combine the information to the specific patient, and hence does not provide prompts or suggestions for how to treat this patient. Consequently, it takes that the user actively looks up the suggestions, it will not be trigged by any characteristics of the patient. A more accurate term for such functionality would be knowledge support for promoting Evidence Based services.

The next level of complexity would be to tell whether characteristics of the patient are as expected, or normal, like presenting the patients lab results together with the reference values, marking the results that are outside the reference area. It can also be to present relevant information from the EPR, based on present entries. An example would be if the physician enters cerebral insult as tentative diagnosis, the EPR presents data entered previously that can help making this evaluation: Blood pressure, blood glucose, temperature, picturing like CT, score results telling about consciousness level, paresis etc. The entered tentative diagnosis is triggering what information is presented; still, the system does not provide any suggestions for treatment.

Next category goes a step further by providing a detailed suggestion for what the clinician should do. The simplest form is to provide an isolated recommendation based on a simple rule or limits for a given variable. Such recommendations are often well documented, but they do not take into account any contraindications or conflicting considerations. The clinician must therefore put the recommendation into a context and manually evaluate the accuracy of the

[3]Beslutningsstøtte. Rapport fra ekspertgruppe. Helsedirektoratet 2014

recommendation. An example of this would be a physician entering that a patient has chronic atrial fibrillation. In the system, a rule is defined which states that all patients with this diagnosis should be considered for anticoagulant therapy. The system looks up in the patient's list of medications, and find no such medication, hence suggesting that the doctor consider starting such treatment.

The following category is also based on isolated recommendations, but it offers suggestions for a packet of simultaneous or serial actions, i.e. following a protocol. The functionality is based on simple rules or defined limits, but the suggestions that follows can be complex. This poses higher requirements for documentation, and maintenance of such decision support becomes more demanding. Contraindications are still not taken into account.

While the foregoing categories described recommendations isolated from other considerations than the one trigging, this category is integrating the recommendation into the patients situation, meaning that more than one premise is taken into consideration, for instance the patient's other conditions, treatments plans, and the context for the health care to be provided in. There is still a need for critical thinking by health workers, but the recommendation is better adapted to the patient's situation than other categories of decision support.

The most advanced level of decision support is based on generating new hypotheses and appropriate knowledge using known algorithms on existing patient information. Unlike the other categories, it is no limit to what kind of information that can go into algorithms. The purpose may be to suggest the most probable explanation of the patient's condition based on the available information, or it can be to identify factors affecting treatment outcomes for a patient group.

Despite high expectations of quality achievements, decision supportive systems have shown difficult to bring into routine use (Wendt et al., 2000). Kawamoto et al. (2005) have described what features of such systems have the highest success rate: "*On a practical level, our findings imply that clinicians and other healthcare stakeholders should implement clinical decision support systems that (a) provide decision support automatically as part of clinician workflow, (b) deliver decision support at the time and location of decision making, (c) provide actionable recommendations, and (d) use a computer to generate the decision support. In particular, given the close correlation between automatic provision and successful*

outcomes (P < 0.00001), we believe that this feature should be implemented if at all possible."

At first glance, these features looks separate, however automatic provision of decision support as part of workflow and support at the time and location of decision making both presupposes that the one targeted for the support must be the one entering the data. In the multidisciplinary nature of heath care, this is often not the case, as for instance nurses and secretaries make data entry on behalf of the physician. Hence, changing working routines is often necessary to achieve CDS, one of the reasons why CDS has shown difficult to implement (Silsand and Ellingsen, 2016).

The urge for standardisation

For a 3rd generation EPR system to be a "helper" according to Gartners generation model (see fig 1 p. 14), there are two main characteristics: It must offer process and decision support for clinicians. The previous section showed that to do so, it must be able to reuse data in different contexts, hence be based on structured data. The expectations of offering the right tasks, at the right point in time, to the right persons along with the information needed to perform these tasks, makes sematic interoperability between systems a prerequisite in order for providers from different organizational units using different systems to "have easy and secure access to patient and user information" in accordance with the White Paper no9 (see p.11). Also, there is a need to standardize how professionals use the EPR, to work with order-entry, and that they heed the agreements assumed by the application (Berg, 2005). In addition, we have seen that standardizing care for process supportive systems to embed models of clinical pathways also is required.

Timmermans and Berg (2003) define different categories of standards:

Design standards which set structural specifications, like size of syringe needles, size of bed etc.

Terminological standards ensure stability of meaning over different sites and time, and are essential to the aggregation of individual health care data into larger wholes. Examples of these would be the International Classification of Diseases (ICD) and Systematized Nomenclature of Medicine -Clinical Terms (SNOMED-CT). In our object of study, the openEHR archetypes make up terminological standards, see the following section.

Performance standards set outcome specifications. They are often used to regulate professional work, because they do not regulate how things should be done, but only what the outcome of the action should be. Example of what this standard may measure is performance on efficiency, e.g. the number of patients with a given diagnosis treated, or patient outcome from a given treatment.

Procedural standards specify processes. Such standards delineate a number of steps to be taken when specified conditions are met. Example would be clinical guidelines for given diagnosis, or procedure for changing wound dressing on a burn. These standards may be more or less detailed and more or less wide in scope. They may be restricted to indicate what should be done or describe in detail how each step should be performed. Procedural standards are the most difficult to achieve and the most contested as they bring people together from a variety of professional background: "Such standards attempt to achieve the seemingly impossible: prescribe the behavior of professionals….. Practice standards raise issues about human autonomy, flexibility, creativity, collaboration, rationality and objectivity. " (Timmermans and Berg 2003,p.26).

These standards will inevitable intertwine, and in our object of study, certainly all of them are in play. Still, it is procedural standards that are most noticeable as clinical pathway templates are inscriptions of procedural standards, hence inscription of behavior in the EPR (Hanseth and Monteiro 1997).

Despite the urge, standardization within health care has proven difficult to achieve. Although heavy investment and considerable efforts, standardization of health care practices has proven cumbersome processes (Ellingsen, 2004; Meum and Ellingsen, 2011; Timmermans and Berg, 1997) and, at times, an outright failure (Larsen and Ellingsen, 2010). In the United Kingdom, the NHS spent more than £12bn on a 'one size fits all' EPR system that was eventually scrapped and replaced by an innovative new system driven by local decision-making (Mail Online, 2011[4]). An example from Norway is also illustrative: After major delays, the portal system project at the Oslo University Hospital proved a resounding failure, and was terminated in May 2011 having wasted approximately EUR 23 million, which was probably

[4] Mail Online (2011). NHS IT project failure: Labour's £12bn computer scheme scrapped.(cited sept 1, 2013) Available from: http://www.dailymail.co.uk/news/article-2040259/NHS-IT-project-failure-Labours-12bn-scheme-scrapped.html

just the tip of the iceberg (Computerworld, 2011[5]). Meum and Ellingsen (2011) have shown that terminology standards in nursing plans are constantly challenged by workarounds, trade-offs, and negotiations between different perspectives on nursing practice. Hanseth et al. (2012) have described how standard EDIFACT messages for health care were implemented in a top-down strategy of standardisation and less attention was paid to users' work practices. The result of such strategy was a very slow diffusion of the standards.

Responding to some of these challenges is the emerging international openEHR architecture, which offers users the technical capability to conduct standardization and structuration of EPR content themselves (Garde et al., 2007). The openEHR framework is founded on a two-level modelling approach in which the technical design of the health-related information system is separate from clinical concerns. Clinical concerns become wholly the clinicians' responsibilities, for which they can easily define and implement structured/standardized information elements in the EPR. The openEHR approach is presumably a step in the right direction as the users naturally have first-hand insight into how standardization of the EPR content implicates standardization of the users' practice. The users role in the modeling process (hence standardization) is elaborated in the below section.

OpenEHR

In the Healthcare sector, the openEHR standard is a promising approach for electronic healthcare records. It was developed by the openEHR foundation[6] – a not-for-profit company – and standardized by CEN and ISO in the EN/ISO 13606 standard series. Recently openEHR has also been incorporated in Microsoft's Connected Health Framework (Microsoft, 2013, pp. 43-44). Like other model driven approaches, the openEHR approach implies that the technical design of the system is separated from detailed organizational issues. OpenEHR is built on a two-level modelling approach where a small and standardized reference model represents the first level while structured models of the use domain – the archetypes – represent the second level. An archetype is a formal definition of a clinical concept, which together with several other archetypes represents a model of a healthcare domain. Consistent use of archetypes is supposed to ensure a high degree of interoperability between various healthcare systems. This means that the openEHR framework is not only a modelling approach for a specific

[5] Computerworld (2011). M.I. Lyse, Stopper it-prosjekt til 160 millioner (Terminates 21 Million EUR ICT Project) (cited November 10, 2011). Available from: http://www.idg.no/computerworld/article207882.ece
[6] http://www.openehr.org/about/foundation

delopment project; it may also be regarded as a vendor-independent infrastructure for EPR content throughout the healthcare sector (Chen and Klein, 2007).

Examples of archetypes may be weight measurement, blood pressure or microbiology results. A "blood pressure archetype, for example, represents a description of all the information a clinician might need (…) about a blood pressure measurement" (Garde et al., 2007a, p. 333). The blood pressure value is accompanied by data describing the context of the blood pressure measurement: who (who measured the BP), how (which type of equipment was used, if the patient was sitting/bed resting), when (related to datum and time of day), and where (refers to "where" on the patient's body; for example, intra-arteria BP, right/left arm or leg).

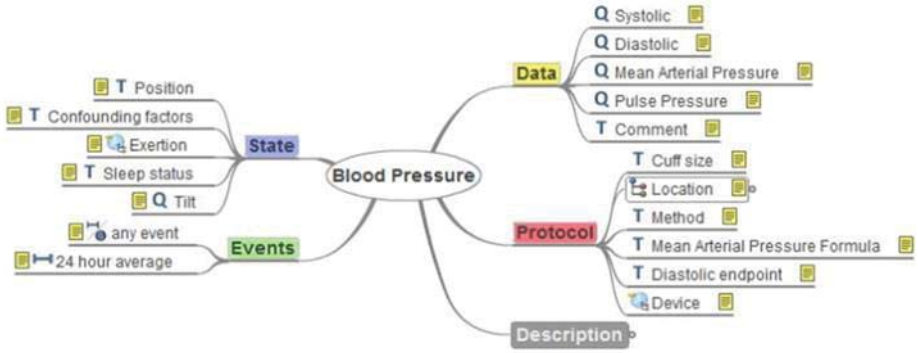

Figure 2. The archetype for blood pressure

The archetypes can be tailored to different local clinical situations using templates. This may imply composing archetypes into larger structures corresponding to screen forms, documents or reports (Beale, T and S Heard, 2007) or imposing local constraints on archetypes by removing or mandating optional sections (Beale, 2002).

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

> "A fundamental aim of the archetype approach … is to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way EHRs are built up using designed structures to express the required clinical data" (Garde et al. 2007, 336).

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

"*Technical models are developed by software engineers, whilst knowledge concept definitions are developed by the people who know about them – domain specialists. The two development processes are disengaged, and domain specialists are empowered to directly produce artefacts which will control how their information systems function*" (Beale, 2002, p. 6). In order to support users in developing archetypes, the openEHR community has provided an online tool – an international repository – called the Clinical Knowledge Manager (CKM) where clinicians can develop, manage, publish and use archetypes, freely available under a Creative Commons license. More than 300 archetypes are available in the international CKM and can be downloaded and specialized to different national, regional and local contexts.

In traditional development strategies, users are expected to provide designers with valuable insight into the users work practice, and give feed-back on functionality designed based on specifications from customers (Johannessen and Ellingsen, 2012). Following the dual-level approach, the user-or customer side has been given new tasks and roles in fitting the technology into use: *" DIPS ARENA can be characterized as a new "do-it-yourself" technology where the expert users (domain experts in the figure below) are able to produce their own applications through toolkits developed in the first phase, and thereby extend the design process into use.*" (Silsand et al., 2012).

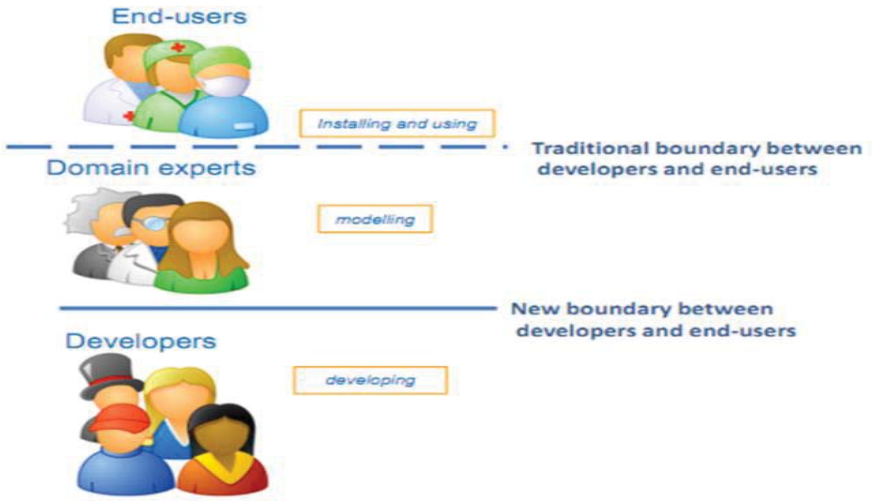

Figure 3 The different roles in ICT design

Because of the increased abstraction level in dual level modelling, the users are presented functionality to define clinical content by modelling archetypes, set up templates, schemes, and models of workflow themselves. The system is not a readily working tools as in technology deployed so far. However, this "fitting" is not something that can be done by each and every end-user himself in order to obtain standardized documentation of clinical work and interoperability of data (Garde et al., 2007b). It is also too complicated to be spread on many hands. Hence, there is a need to build a new kind of competence, and a new kind of user group emerges. Domain experts are the ones describing and modelling the domain by modelling archetypes, and they must do so based on suggestions and needs defined by clinicians.

While the benefits of engaging users in standardization processes seems promising, simply handing over a technical customization capability to the users may not solve all the critical issues implicated in the standardization processes, as advocated through the openEHR architecture. There is still a fundamental tension between the need to standardize on the one hand and the need for local flexibility on the other, which any strategy, method or technology has to deal with (Hanseth et al., 1996). Along these lines, Timmermans and Berg (1997) investigate global-local tension and introduce the notion of 'local universality' to pinpoint how a standard always retains local variants, both shaping and being shaped by local practice. They argue that universality is always local universality and that local universality depends on how standards manage the tension involved in transforming work practices while simultaneously being grounded in those practices.

Moving towards the CSCW perspective.

Starting out my literature reviews, I used the search term "process-support" but few of the hits turned out relevant. Then I found that in computer supported cooperative work (CSCW) literature, the term used was "workflow support", and suddenly there was an ocean of knowledge to swim in.

Workflow systems of various kinds have been around for decades, especially within office and business related domains. They have emerged as a solution to the problem of coordinating events, artifacts, and people (Dourish, 2001). Development of workflow technology has been an important part of the research endeavor within the field of CSCW (Bardram et al. 2006; Bossen, 2006a; Christensen and Ellingsen, 2013). Workflow systems for the coordination of activities in organizations have been subject to much controversy and

criticism for their rigid representation of work in process models (Bossen, 2006b; Ellingsen and Monteiro, 2003; Ren et al., 2008; Schmidt and Wagner, 2004). A process model is typically understood as a computerized (i.e. formal) representation of work procedures that controls the order in which a sequence of tasks are to be performed, and by whom. A potential danger with workflow systems is that their design is pre-dictated entirely by formal procedures ignoring (and even damaging) the informal practice (Schmidt, 1997). Hence, much of the research on workflow systems in CSCW has been directed towards design of systems allowing flexibility (Aalst et al., 2009; Bardram, 2000; Bowers et al., 1995; Christensen and Ellingsen, 2013).

Within the field of CSCW, several studies have noted the dynamic, contingent, and complex features of health care, as well as the multiplicity of coordinative artefacts and technologies needed to accomplish work (Bardram, 2000; Cardoen et al., 2010; Dourish et al., 1996), defying standardization and inscriptions of workflow. In a typical hospital setting, task flow may be context-dependent, users may follow non-linear completion strategies due to interruptions, uncertainties permeate many decisions, and the highly collaborative nature of assessment and treatment is critically dependent on clear and speedy communication. The need to make adjustments in the planning of care is why Clinical Workflows are named "The Killer Application for Process-oriented Information Systems" (Dadam et al., 2000). Nevertheless, workflow technology has been introduced to support different phases or activities of the healthcare process (Bardram et al., 2006). The question is more of what form the workflow support may take. Dourish (2001) describe workflow supportive systems as having two different roles; as organizational accounting devices, and as coordination technologies. Workflow systems, as technical artifacts, have largely been understood in terms of their coordination function, and their aim to relieve the user of the "burden" of coordination. As such, their design, deployment and evaluation have largely been conducted in those terms (Dourish, 2001, p. 54). As to the organizational accounting function, it renders the work processes visible:

" It regularises and describes the work of "being" that organisation, so that the multifold activities of the organisation can be described as contributing to that organisation's function (Dourish, 2001, p. 55). Accoring to Dourish, workflow systems are successes, despite the critiques mostly directed towards their function as coordinative devices, and the success is because of their accountive abilities. He also stresses that the accountive ability simultaneously helps coordinating in that it makes steps visible to the cooperating personnel.

Opening the black box of technology

As mentioned before, the vendor in our research case has chosen dual level modeling based on openEHR as technology for its 3rd generation EPR. OpenEHR represents a new technology and a new standard within Health Care, and thus we expected it to pose new and other issues in the socio-technology interplay. It is to be introduced as a large-scale EPR, but built on a two-level modeling approach, it is different from the packaged systems (ERP)s studied by Pollock and Williams (Pollock et al., 2003; Pollock and Williams, 2008).

Just as our study moved on, trouble, questions and problems turned up that I did not understand what was about. Hence, to understand, I had to open "the black box of technology".

Over the last two decades, it has been quite common to assume that technological systems are substantially renegotiated and reshaped in situ e.g.(Orlikowski, 2000; Suchman, 2007). According to this view, the ways technologies are involved in particular settings are heavily contingent on the social practices and the organizational arrangements that prevail in these settings as well as the skills and proclivities of situated agents (Nardi and Kallinikos, 2007). Orlikowski and Iacono (2001), drawing on a review of the full set of articles published in Information systems Research(ISR) argue that the field has not deeply engaged its core subject matter—the information technology (IT) artifact. Instead, they find that IS researchers tend to give central theoretical significance to the context (within which some usually unspecified technology is seen to operate), the discrete processing capabilities of the artifact (as separable from its context or use), or the dependent variable (that which is posited to be affected or changed as technology is developed, implemented, and used). The IT artifact itself tends to disappear from view, be taken for granted, or is presumed to be unproblematic once it is built and installed. According to Orlikowski (2000), there is an analytically distinction between technology as artifacts and the use of such artifacts. Accordingly, Hanseth et al. (2004) argue that if we want to understand technology in a social context, it is exactly the relationship between what Orlikowski calls the technological artifact and the technology-in-practice we need to understand. *"Such a project cannot fruitfully be pursued by neglecting the ensemble of conditions or constraints established by technologies. It can only be accomplished by thinking about, discovering or envisaging the interstices of choice and creativity left open or enabled by technologies and the distinctive forms by which they invite human participation"* (Nardi and Kallinikos, 2007).

Conceptualizing the Electronic Patient Record as Information Infrastructure

While the CSCW field has proved to be a strong framework for conducting and analyzing workplace studies and single site implementation in a specific department by providing the tools for focusing on the micro-mechanisms of collaboration in a given system, it has somehow lacked the broader picture of users collaborating using multiple systems (Monteiro et al. 2013). The "local sensibility" of smaller scale interactions for design has been important to the historical research agenda of CSCW, for good reasons, but this stands in contrast to today's need for integrated ICT systems that may support cross-organizational workflows. Additionally, researchers point to how important influences from other levels and moments of technological design and implementation may be ignored when one focuses on one specific local or time period (Pollock and Williams, 2010; Hyysalo 2010). Hence, in this work, I have supplied the CSCW perspective with the notion of information infra structure, which has been used to study the design, implementation, and use of large -scale information systems (Monteiro et al., 2013; Hanseth and Lyytinen, 2010; Star and Ruhleder,1996; Pipek and Wulf, 2009) as an alternative to the privileged "local sensibility". This perspective emerges from a disciplinary diverge background; stemming from Information Systems studies, Science Technology and Society studies and innovation studies. That is, disciplinary domains that has a dual focus which covers both technology and human/societal aspects (Monteiro and Hanseth,1996). Although the theory is not explicit in the papers, it is the theoretical lens through which the data have been analyzed.

Accordingly, in our research, we have interpreted DIPS Arena as an evolving Information Infrastructure because we recognize the salient features of such (Star and Ruhleder,1996) in what we have studied:

The enabling function: An II is designed to support a wide range of activities, it is not tailored only for one function. The technology is intended to open a field of new activities, not just improve or automate something that already exists. The enabling feature of IIs plays an important role in policy documents (Ciborra et al., 2000). We find the enabling features described in detail in the white paper "One Citizen, one Health Record" which is the National ambitions that DIPS Arena is supposed to meet.

The scope: Following the general IS trend, IS in Heath care is increasing in scope and complexity: "*In many IS projects today, it is difficult to differentiate the system from the other aspects of an IT-based business intervention, such as process redesign, physical layouts*

of the work place, changes in job design and compensation, or development of IT-infrastructure" (Markus and Mao, 2004). The reach is far beyond a single event or a single event or single-sight practice, accordingly is has a heterogeneous array of users. DIPS Arena will take over the 80 000 users that currently use DIPS Classic. Hospitals all over Norway deploy the system, hence it is geographically spread with thousands of heterogeneous users, still within a specific domain and can hence be classified as a business sector infrastructure (Hanseth and Lyytinen, 2004).

Built on standards: Standards are constitutive elements of infrastructure design. Standards enable the evolution in scope and functionality, and they are a key means by which the infrastructure is architected and who is inscribed in its development. Standards offer means for organic growth of infrastructures in multiple ways (Hanseth and Monteiro, 1997). An important aspect of II is the heterogeneity of standards, and the fact that one standard includes, encompasses or is intertwined with a number of others. Standards specify how we work and how technologies interact, they hold our sociotechnical societies together (Timmermans and Berg, 2003). According to Bowker and Star, (2000) and Timmermans and Berg (1997), they are the backbone of western health care infrastructures. They are supposed to ensure quality of care through best practices development (Timmermans and Berg 2003), increased efficiency as well as ensuring seamless patient trajectories across organizational boundaries. Clearly, both promoting Evidence Based Medicine through providing decision support and introducing workflow supportive information systems imply standardization of services and of work. So do the terminology standards in that they are models of clinical concepts.

Standards will inevitable intertwine, and in our object of study, certainly all of them are in play. Still, it is procedural standards that are most noticeable as clinical decision support and process support are more or less inscriptions of procedural standards, hence inscription of behavior in the EPR (Hanseth and Monteiro 1997). For DIPS Arena, the archetypes that make up the structured information elements are internationally or nationally defined and constitute the backbone of this infrastructure. Consistent use of archetypes is supposed to ensure a high degree of interoperability between different openEHR-based EPRs, as well as efficient reuse of data across different contexts (Kalra, 2006). Moreover, modelling of archetypes poses standardized documentation of work, and as a consequence, standardization of work.

Installed base: “Infrastructures are never built “de novo” – they develop amidst a stream of technical antecedents, social conventions and professional rules and have to be adaptive to the developments of work practice. As these elements are changing, the information infrastructures are continuously evolving” (Aanestad et al., 2017). Yet at the same time, they have to be stable enough to reliably support activities that make use of them: “*only a stable installed base allows new connections to be created*” (Tilson et al., 2010). DIPS Arena is to be implemented in large organizations where already practices are working, these routines are partly resulting from the existing DIPS Classic. Moving to DIPS Arena represents a shift in technology and platform, hence technical backwards compatibility with the installed base becomes a crucial issue. In addition, DIPS Arena will pose (and are expected to, due to its enabling function) new work routines and new ways of utilizing information technology that will have to merge with existing practices.

Connectedness: Systems in an information infrastructure never act as standalone entities; they are rather integrated – typically through standards – with other information systems and communication technologies, as well as with non-technical elements (Aanestad and Jensen, 2011). DIPS Arena will have to work with systems for radiology, laboratory, medication system and other clinical applications, as well as the other elements in the installed base.

Oposing logics: Edwards et al. (2007) point out that because information infrastructures are incremental and modular, they are always constructed in many places, combined and recombined, and they take on new meaning in time and space. The lack of distinctiveness and clear boundaries is reflected in what Tilson et al. (2010) refer to as the paradoxical nature of digital infrastructure. Ribes & Finholt (2009) point to the seemingly paradoxical nature of long-term plans for information technology. They emphasize that designing an information infrastructure is a visionary process, which demands sustainability as a consideration of today. Balancing the needs of today’s users versus future users is an inherently delicate problem. Karasti et al. (2010) identify two distinct temporal orientations in information infrastructures, namely “project time” and “infrastructure time”. The tension is manifested in the need both to produce short-term products and to demonstrate long-term viability, and participants must distribute their time between short-term products that can be cast as “deliverables” and, at the same time, the sustained development of stable and extensible information infrastructures. In our study on the development of DIPS Arena, we soon recognized the conflicting time spans between short term project deliveries and the long-term infrastructure building, also the conflict between todays’ and future users’ needs.

Infrastructuring

Information Infrastructures are always in the process of design (Star and Ruhleder, 1996). By introducing the verb "to infrastructure", (Bowker and Star, 2000) denote the efforts and processes of integrating methods, tools, materials and practices that it takes to grow and change an infrastructure. According to Karasti at al. (2010), these processes are incremental, iterative and long term. This implies that an infrastructure always grow out of something already existing, and new components or changes have to be integrated into these already existing systems and work practices. This perspective has been prominent in the work on this thesis, as the users' efforts in infrastructuring the new EPR system have been focused.

4. Method

Research approach

The study adheres to interpretive research which is an important strand in information system research, that can help IS researchers to understand human thoughts and actions in social and organizational contexts. Interpretive research in IS are "*aimed at producing an understanding of the context of the information system, and the process whereby the information system influence and is influenced by the context*" (Klein and Myers, 1999, p. 69; Walsham, 1995, pp. 4–5). Orlikowski and Baroudi (1991) describe interpretive research as assuming "*that people create and associate their own subjective and inter-subjective meanings as they interact with the world around them. The interpretive researcher thus attempts to understand through accessing the meanings participants assign to them*". The essential objective is not to identify causes of behavior, but rather the meanings people assign to actions and events (Walsham 1995). Grounded in relativism ontologically, interpretive research denies the existence of an objective reality that can be discovered by researchers and replicated by others (Klein and Myers 1999), as there are many interpretations that can be made in an inquiry, none of which is superior. Following the relativism, the researcher's role in inquiry is participatory.

This is much inspired from ethnography. (Blomberg and Karasti, 2013) put this forward as follows: "*The field site is not out there waiting to be visited; instead it is reflexively constructed by every choice the ethnographer makes in selecting, connecting, and bounding the site and via the interactions through which s/he engages with the material artefacts and the people who define the field. Ethnographers define the objects and subjects of their research during fieldwork, informed by their interests and motivations*".

The ambition of interpretive research is to get a grasp on human thought and action in social and organizational contexts (Klein and Myers, 1999). The toolkit to obtain this understanding is mainly observational participation, semi-structured interviews and document studies. The combination of presence in the field and document studies helps to enlighten how the ongoing action and meanings are shaped by the larger social and material contexts in which scientific inquiries take place (Latour, 1987; Latour and Woolgar, 1986). Politics and strategies are hence continually related to the ongoing local actions. Hyysalo (2010) refers to this as "combining the frog's eye-view with the bird's eye-view".

The Biography of Artefacts perspective (BoA)

Pollock and Williams (2010) criticize that much of the research into technology and work organization is about single-site implementations of artefacts with limited numbers of users, while in health care, we see the emergence of large-scale information systems intended for long-term use with multiple use and users. The emergence of a regional EPR encompassing multiple systems, aiming at becoming a National infrastructure in our case is an example of this. Pollock and Williams (2010) argue instead to expand the focus of research longitudinally and across different social settings and scales, addressing multiple moments and sites of innovation, and encompassing different phases of what has been described as the systems development cycle (design, selection/ procurement, implementation and use), and the multiple such cycles that constitute the product cycle for a particular artefact.

A key issue is not to regard the different time spans as somehow ontologically distinct even though studying those means employing an array of different materials and various foci of closer inquiry. An event is not pinned down to a place in a preordered scheme of things, but seen as simultaneously constituting and being constituted by broader patterns. Various events can be examined as evidence of these patterns, while the patterns can be constructed from a range of evidence beyond the foci and granularity of a single site under analysis (Hyysalo, 2010).

It is a key element in this approach to pay attention to the context of the actions studied. Not only context at a micro level, but also the macro level. The need for taking context more into consideration in IS research is also pointed out by Fitzpatrick and Ellingsen (2012).

Studying several sites related to the same technology- e.g. Vendor strategy, developers, user organizations and various intermediaries depends on skill and gaining access, being able to document the events and research funding. This research had the very best conditions regarding access to the different sites, which made certain ethical considerations necessary, see the below section.

It is this longitudinal character of study, the focus on the nexuses rather than “snap-shots” of events that allows us to open new perspectives. This research approach is evident in paper 2 in that we have been able to identify what we call “moments” and in paper 4 in what we call phases.

The Biography of artefacts is hence not a method, more an strategic research approach that presuppose the data to be analyzed in a broader perspective, and that the different methods and data sources that goes into interpretive research applies.

Data collection

Data have been collected over five years (2011-2016). During this period, I participated in numerous activities with the different parties in the project. All of these activities have led to the "construction of the site" (Blomberg and Karasti, 2013), and the actual object of study. Being a large-scale infrastructure, the object of study is "*not within a single site or multi-sited field per se; it is understood to be constituted by mobility, intersection, and flow, with a focus on connections, associations, and relationships across space and time* "(ibid).

Interviews

In total, 43 semi-structured interviews have been conducted. 4 of these were groups of 3 people, and 1 with 2 people. See table for interviewees, note that they are grouped and not named detailed to ensure anonymity. In accordance with hermeneutic interviews, the semi-structured interviews had much of the character of dialogues, where the theme brought up was jointly explored and led to the following theme. Basically, this meant that the interview guide was used as a checklist to ensure the questions of interest were touched upon. A digital voice recorder was used in the interviews, and I immediately transcribed the material. During the transcription, themes that emerged that I wanted to follow up on were noted. In two cases, this led to new interviews with the same informants, else I followed up questions in informal talks.

Interviewees	**No**
Physicians, nurses, secretaries	20
Project members FIKS and Regional Health Authorities	8
Developers and Managers at DIPS ASA	15

Table 2: Semi structured interviews. Each interview lasted for 45-90 minutes.

Participatory observation

Following the Biography of Artefact' approach, participatory observations were conducted in many different settings. I followed nurses and secretaries in planning for surgery in a hospital, and surgeon in out-patient consultation planning for surgery. I took part in workshops with developers from the vendor, the FIKS project and users from the hospitals in design activities regarding the new EPR. I took part in project meetings in FIKS. I spent days with the developers in their office, watching and listening to their discussions in their

work. I took part in testing and piloting of functionality for surgery planning. I aimed at taking part in as much activity as possible at different arenas in the FIKS project, as this enhanced my understanding and eased the analytical process when looking at the data retrospectively. All in all, I was around activities connected to the design process corresponding 2 years of work. Field notes from this work take 5 notebooks, each of 160 pages of A4 size.

Document studies

Besides documents on the FIKS project (minutes from meetings and reports), document studies encompasses governmental policy and strategies both on national and regional level. Also reports and minutes from The National ICT Health Trust, OpenEHR architecture and archetype strategy were included.

Data analysis

As already stated, in interpretive research, prior knowledge and preconceptions are not considered bias, but are the necessary starting point of our understanding (Klein and Myers 1999, p.76) Through interaction with the participants in the field, continuously learning and discussing, and through literature that provided a theoretical lens, my understanding of the object of study has been formed along the way. Hence, data analysis is a continuous process and difficult to separate as a distinct activity. Klein and Myers (1999, p.71) describe this as an "iterative process, moving from a precursory understanding of the parts to the whole and from the global understanding of the whole process back to an improved understanding of each part". Accordingly, the informal talks that I had with people in the field for clarification of my perception worked not only as information gathering, simultaneously they were an important part of the data analysis, because they brought new perspectives to the data.

Because I extensively participated in activities on a range of activities, writing field notes was very important. I always carried my notebook and made notes continuously, but also took the time to write down reflections and summaries afterwards activities, or whenever an interpretation turned up in my mind. When working with the papers, I read the notes repeatedly and grouped themes that emerged. This process also gave me new ideas for aspects to look for, and for questions to be posed in interviews.

Interviews were transcribed immediately after the recording, and meanings were identified by colour-coding the emerging themes. Then the transcripts were read and discussed in my research group, clarifying the scope for further data collection. The field notes were also

discussed in these meetings. Some of the meetings were dedicated to discussing the data related to the literature we had reviewed.

The role of theory in interpretive research is a sensitizing device that makes it possible to view the world in particular ways (Klein and Myers, 1999). According to Walsham (1995), there is three different ways to see the use of theory in IS research: As initial guide to design and data collection, as part of an iterative process of data collection and analysis, and as the final outcome of research. In this work, theory has been part of an iterative process of data collection and analysis, as it has opened new ways to understand and interpret the data along the way.

Ethical considerations

My role as a researcher

In qualitative research, the researcher herself is an instrument, and my previous experiences influence how I meet the research field. My background is as a nurse, coordinating nurse and head of department within the hospital that now is my empiric field. All of these different roles have given me a picture of how the hospital as an organization works. This background surely affects my perception of what are the interesting issues to be explored and thus what data I look for and how I interpret them. Even if prejudgment is not considered a source of bias in interpretive research, but recognized as the necessary staring point of our understanding (Klein and Myers, 1999, 76), I think it is important to be aware of this. Also, many of my informants are former colleagues. Knowing the background and the context of the informants affects how I perceive what they say. In doing fieldwork in this project, I come in very close relation to the field that I am researching. The close relationship to the field is both strength and a weakness. Positively, I do not need to spend time wondering what the participants in the project are talking about. I can easily comprehend details about the job performance, their experiences with EPR systems and their anticipations for a new ICT system. At the same time, this familiarity may make me overlook strands that should have been pursued in the data gathering process. I might be blinded for new perspectives.

Conclusively, my background as a researcher effects my focus and interpretation of the data, just like theories can inform and influence the perspective of the research (Walsham, 1995). It is hence important to be aware of this, to keep the mind open for what the data show me. A systematic, thoroughly analyzing process is important to ensure the quality of the research.

According to Walsham (1995), whatever role of an outside observer or a participatory observer (insider or outsider) one take must be stated, considered and reported on its consequences for the results.

How I treat the informants

In interpretive research, it is an ethical consideration how the informants are treated, as the researcher reports his interpretation of the informants' interpretations (Walsham, 1995). The informant may want to keep distance to the researcher, depending on the theme for the interview, and to be aware of this and behave accordingly is important. What the informants tell must be treated with respect. Even if the iterated analyze twist the data to bring out a certain concept, the respect for the informant must be kept in mind. To me as an insider in the organization, I needed to be aware that my acquaintance with the informants as former colleagues, might make them say things or use an informal language that they would not have used taking to an outsider and keep this in mind if I make quotes in the data presentation.

Anonymizing the informants is another issue that is complicated by two aspects: Firstly, in qualitative research, there is a small number of informants[7]. Secondly, the value of case studies in interpretive research is to describe the sites in rich details. Hence, if I describe a role within the hospital setting, insiders may be able to reason whom this person is. Even if the interviews do not go into personal issues, we are talking about themes related to use of the EPR system, the informants should be kept anonymous.

Leaning on ethnographic methods in interpretive research, it is common to use different data sources in the collection process. In addition to semi-structured interviews, my fieldwork is conducted in large meetings, in some instances even with some of the participants in videoconference. Although Informed consent is basic in all research (Fossheim, 2009), it is not possible to have this in written from all the informants in a field work setting. The way to go about this is to announce my presence and agenda in the beginning of the sessions of this character. Still, I am not quite comfortable if there might be someone present that does not wish to be regarded as informant, but find it difficult to declare in the setting.

In making the descriptions of work practices to inform design, it is a principle not to tell (users) informants what their work is or what it means to them (Robertson and Wagner, 2013). This means aiming at taking on the informants perspective, in what Walsham (1995) says is the "interpretation the informants` interpretations".

[7] http://www.etikkom.no/Forskningsetikk/God-forskningspraksis/Publisering/

In the magazine Forskningsetikk nr 1/08, Kirsti Malterud names the most important ethical considerations in qualitative research to be the aspects of the interrelation between the researcher and the informants, the aspects of consent, and protection of privacy. She says that the interrelation may give the researcher information that one might not be prepared for, and that it is important to handle this with care. That is both in how the informants are ensured in the situation (and maybe reactions afterwards) and how data is published ensuring privacy. Interesting data that could underpin a theory or a concept might have to be left out of publication if privacy is threatened. The open-ended character of qualitative research has consequences for the principle of informed consent as it presupposes knowing to what you give your consent. These dilemmas make it important that researchers adhering to qualitative methods reflect on their role, how they treat their informants and the material they gain.

Even if my research is not about such sensitive material as health science brings about, I think that the same principles for qualitative research and my role as a researcher must be considered.

Picking the informants

In the production of work place descriptions, we are only partly telling the truth, told from specific perspectives (Robertson and Wagner, 2013). This is grounded in our choice of informants, thus picking the informants is another ethical issue. Like Wagner(1993) points to, in the hierarchical structure in the hospital the different occupational groups involved are not equally valued. This is in fact noticeable in my project, in what professionals that has been picked to join the vendor of the EPS system in development workshops. Still, all groups will use the new ICT tool, from different perspectives and with different roles. A better tool for all the users is an explicit goal for the project, hence ensuring that "all the voices are heard" is an issue. Silencing or missing one group of users who will be affected by a new system will be a weakness in the study, both in ethical understanding and in the result as well. Taking the different professional roles into consideration in the design process might give totally different functionalities in the system (Roberson and Wagner, 2013).

5. Results

Four of the papers in the thesis are published in Conference proceedings and one is published in a peer-reviewed journal.

1. Christensen, B., Ellingsen, G.: Standardizing Clinical Pathways for Surgery Patients through ICT. Presented at the Practical Aspects on Health Informatics , Edinburgh, Scotland. CEUR Workshop Proceedings http://ceur-ws.org/Vol-984/paper2.pdf (2013).

2. Christensen, B., Silsand, L., Wynn, R., Ellingsen, G.: The Biography of Participation. In: Proceedings of the 13th Participatory Design Conference: Short Papers, Industry Cases, Workshop Descriptions, Doctoral Consortium Papers, and Keynote Abstracts - Volume 2. pp. 71–74. ACM, New York, NY, USA (2014). Presented in Windhoek, Namibia.

3. Christensen, B., Ellingsen, G.: USER-CONTROLLED STANDARDISATION OF HEALTH CARE PRACTICES. ECIS 2014 Proc. (2014). Presented in Tel Aviv.

4. Christensen, B., Ellingsen, G.: Evaluating Model-Driven Development for large-scale EHRs through the openEHR approach. Int. J. Med. Inf. 89, 43–54 (2016).

5. Christensen, B.: Formalization and Accountability in Surgery Planning. In: Proceedings of the 19th International Conference on Supporting Group Work. pp. 293–302. ACM, New York, NY, USA (2016). Presented in Sanibel Island, Florida.

Before giving a short summary of the papers I would like to point to that they reflect my journey to become a researcher. From a paper mainly describing work practice (no 1) with only little theory, moving towards more use of theory as the analytical lens for the cases in each paper. Accordingly, paper 4 and 5 evolved over time, including several rounds of review. The papers are theoretically interconnected, as my departing point is the understanding of the project of study being the growth of an Information Infrastructure. Although II as theoretical frame is not explicit in the papers, it is the lens through which the

data has been interpreted. Hence, the papers look into different aspects of growing IIs: Papers 1 and 5 are about the work practice that is a part of the Installed base, and hence wields a strong influence on what the II may become in the future. I have applied the CSCW perspective on work practice to analyze how the installed base and the new technology that is introduced mutually affects and shape each other. Paper 2 deals with user participation in design of the new EPR. Because the EPR will provide process support for business-processes in the hospital in addition to the workflow support, it becomes an issue what kind of competence the users participating in the design of the system need to have. This represents another aspect of fitting the new tool to the already existing work, simultaneously allowing for future needs. Paper 3 focuses the standardization aspect of IIs. The heterogeneity of II standards, the fact that one standard includes, encompasses, or is intertwined with a number of others, is an important aspect of II. This paper looks into how standards work as boundary object between different users of data. Paper four focuses the vendor and the technology for the new EPR, particularly the vendors' effort to establish a new standard necessary for their system to grow into an II. In a socio-technical perspective, work practice, use of IT and the technology itself are mutually dependent and affected. Hence, taking a closer look at the technology in play was something that "forced" itself to bring understanding on what was happening in the FIKS project. On this backbone, it was possible to write paper five, which deals with the new technology put into work practice, and analyzes how inter-disciplinary work is affected by the process supportive abilities that are introduced.

Summary paper 1: Standardizing clinical pathways for surgery patients through ICT.

As I started to follow the design process of a surgery planning tool, I had a hunch that the planning process was pictured to be much simpler than my experience as a managing nurse implied. Hence, I wanted to do a fieldwork looking into the planning process in order to bring in-depth understanding of the process that the surgery- planning tool should support. I conducted initial fieldwork in the Department of Gastroenterological Surgery at the University Hospital of North Norway, but I also interviewed health care personnel from other medical disciplines to extend the perspective. This paper is an ethnographic-inspired detailed case write-up on surgery planning for patients with ventricular cancer.

Modern Electronic Patient Record systems (EPRs) are expected to standardize the surgery planning process in order to improve utilization of the hospitals' resources. However, the paper argues that empirical insight into the practical planning process is crucial for both

standardization and the design of EPRs. I argue that the work related to planning for surgeries is not sufficiently understood, particularly the way it is distributed, negotiated and proceeding. Accordingly, I describe and analyze how surgery planning is actually conducted in practice. Based on participatory observation and interviews, I pinpoint the stakeholders involved, state what they do, and identify critical issues for ensuring successful streamlined surgery planning within the EPR. What comes to the fore in this detailed description of the work practice, is that surgery planning work is highly uncertain and heterogeneous. The paper shows that the practice of planning does not take place through the filling out and subsequent 'use' of one artefact – the electronic surgery plan. Rather, planning unfolds (i) distributed across a network of material/technological and human resources and (ii) continuously through ongoing and negotiated additions, deletions and changes. The official plan is in this sense merely a node in a network of interconnected, mutually dependent nodes of material arrangements, practices and different professionals (Ellingsen et al., 2007). The resources to be planned are part of different units and are planned for more or less independently. At some point the plans on resources converge into a schedule for surgery. Clinical information as well as resources is gathered along the planning process, deciding the actions of the next step. The process of planning itself in a way generates the information that is needed for surgery. It is not just booking fixed resources. Hence, managing clinical pathways takes a lot of articulation work (Møller and Bjørn, 2011), and lot of considerations for every step. The paper also point out the multidisciplinary cooperation that goes into surgery planning. Task are initiated by the surgeon and carried out by nurses and secretaries. Nurses and secretaries are the ones monitoring the process, ensuring there is progress for the patient in the pathway. Knowing how the work is distributed is important to inform the design process of the new planning tool, as became evident in paper 5, where the consequences of introducing workflow support for this work is discussed.

Summary Paper 2: The Biography of Participation

This paper looks into how user participation in the design process changed along the path. Following the Scandinavian tradition of user participation in design of technology for workplaces (Simonsen and Robertson, 2012), extensive user participation was planned in the FIKS project. However, designing large-scale systems is different from designing single-sited artefacts. Because the introduction of workflow supportive EPR presupposed mapping of the ongoing work processes, the FIKs project acknowledged that business processes, like clinical pathways, are not equal to work processes. A business process entails many work processes,

and typically encompasses entire organizations that include practices that may differ from each other quite considerably, resulting in varying type of user needs and requirements (Mackay et al., 2000). Hence, work flow and business processes call for different functionality to be supported. This recognition led to the question of how to organize user participation in such a large-scale project, and what competence users participating in the design process ought to have. Initially, it was end-users like secretaries, physicians and nurses from all the 11 hospital within the health region that participated. However, it became evident that they did not have the overview of clinical pathways that was necessary to define support for such processes, particularly when it came to pathways that crossed medical disciplines and organizational boundaries. This called for an additional kind of users in the design process; people with considerable organizational competence like managers and clinical pathway coordinators.

Additionally, the development of such large-scale systems typically extends over considerable time where policies, budgets, artefacts, suppliers, users, work practices and visions of organizational improvements change. This implies that user participation in different phases of a project may spell out very differently.

In order to respond to these questions, the paper applies the concept of Biography of Artefacts and Practices (BoA) (Johnson et al., 2013; Pollock and Hyysalo, 2014). BoA underscores the importance of moving beyond episodic studies of settings of technology design or organizational implementation to the evolution of workplace technologies over multiple cycles of design and implementation. It also reflects the necessity to engage more coherently with the ways in which broader context shape innovation processes and outcomes (Johnson et al. 2013). The biographic perspective offers a way to clarify the connections between the individual and the socio-historical. By tracking the movement of entities (artefacts, practices, etc.) across organizational boundaries, rather than limiting enquiry to particular moments and sites, BoA helps identify new spaces, sets of relationships and classes of actors that together constitute particular technological fields. As systems encompass entire organizations and involve numerous practices, the nature of participation is difficult and has to be modified during the development process. The BOA perspective is applied to explain the changing strategy of user involvement in longitudinal development processes across various practices that, at the time they happened, seemed incomprehensible.

Summary Paper 3: User-controlled standardisation of health care practices.

While the previous paper dealt with user participation in the design process of a novel EPR system, this paper deals with how users relate to and apply standards in their work. The need to access information across different levels of the health care system has prompted attention to standardizing electronic patient record (EPR) systems. This paper look into when users were asked to standardize the use of, and entry of data in the EPR when 9 installations were merged into 1, which was one of the tracks of the FIKS project. The example in this case is how the Norwegian national performance standard "cancellations of surgery" is adapted locally in ways that promote many different understandings and thus applications of the standard. Leaning on Timmermans and Berg (1997) and Timmermans and Epstein (2010), we demonstrate how performance standards and procedural standards are intertwined in how the standardization of EPR content relates to standardization of working routines and practices. At one point, performance standards call for some kind of "best practice" (in form of procedural standards), particularly when the comparing power of standards is the premise. Pursuing the power to compare aspect of standards, we have identified differing interests in the performance standards relating to the various organisational levels of users, spanning form the national level to managers within the hospitals' departments. To analyze how information can be "translated" between different levels, we lean upon Bjørn et al. (2009) and conceptualize standards as boundary objects. Boundary objects are plastic enough to be adapted to local needs and thus are meaningful across borders and contexts. Even though they inhabit different meanings, the structure is stable and in this way comprises a mean for translations. Contextual contingencies describe the parts of work that clash with the standardized structure of the boundary object and that are closely related to the particular context. Thus, the more contextual the standard becomes, the more aspects must be defined in order for it to be useful, while still building on the definitions of the level above (Braa and Hedberg, 2002). This may have implications for how archetypes should be modelled as part of openEHR standard in the emerging EPR; given the divergent interests in standards for users at different levels of an organization, the flexibility of the openEHR standard must carefully balance the need for interoperability against local usefulness. While the flexibility of openEHR technology may be evident, the organisational processes implicated in standardisation processes are still painfully complex. The way the technology subject in this study poses and affect standardization of work is looked into more deeply in the following paper.

Summary paper 4: Evaluating Model-Driven Development for large-scale EHRs through the openEHR approach.

Socio-technical issues must be dealt with carefully in the implementation of new ICT systems (Aarts, 2012; Aarts et al., 2007; Berg, 1999). Moreover, this is particularly valid when the scope and size of an ICT system increase and where organizational politics more readily come into play (Ellingsen et al., 2013; Silsand and Ellingsen, 2014). This paper aims to identify key socio-technical challenges when the openEHR approach is put to use in Norwegian hospitals. Fundamental assumptions of the approach like a clear separation of technical and domain concerns, users being in control of the modelling process, widespread user commitment and an easy way to model and map complex organizations are investigated empirically through the research question: What are the major socio-technical challenges of the openEHR approach for large-scale systems?

Theoretically, we picture the openEHR as a standard fundamental to an information infrastructure (Hanseth et al, 1996). Archetypes make the backbone of this infrastructure, and it is to the making and construction of it that we pay socio-technical attention. Even if openEHR puts the clinicians in lead of the modelling of the domain and hence the standardization process, this paper focuses the vendors' perspective: without the standards, they cannot demonstrate their technical system. Hence, we follow their strategy in bootstrapping the modelling of archetypes. Given our departing point that the new EPR is an evolving II, it confronts an installed base. To change an II will always be to further develop something that already exists. Integrating new components or changing parts of the II might be difficult due to rigid work practice, technological lock-ins and large number of users which makes the installed base conservative and carries huge inertia. The new EPR has a considerable challenge in this matter, as it rests upon a new standard, and implies both new tasks and is changing existing work. Through four phases, we describe the efforts of the vendor from introducing the archetypes as local standards, giving the clinicians the possibility to define "on the fly" while documenting, to asking the international openEHR society to contribute to the modelling of archetypes to speed the process of defining. Through questioning the assumption of separation of domain specific and technical concerns, we show that in fact, the emerging EPR system, as an infrastructure resting on standards like archetypes, involves many stakeholders working together (Edwards et al. 2007). A broad assemblage of contributors seems to be needed for developing an archetype-based system, in which roles, responsibilities and contributions cannot be clearly defined and delimited. The

separation of clinical and technical concerns seems rather illusory and echoes a technology-deterministic idea where technical change is in some sense autonomous outside the organization it is supposed to change. The questioning of the assumptions of users being in control of the modelling process, widespread user commitment and an easy way to model and map complex organizations all illustrate how the user-led standardization turns out to be a cumbersome process, not exempted from the negotiations and compromises that any standardization process comprises. Like the previous paper touched upon, this case also shows how standardizing of EPR content (the archetypes) inevitably standardizes work practice. The scaling from local users to especially interested clinicians worldwide in the modelling of archetypes means that local users influence is lost. Hence, to them, there is little difference whether the standardization is posed by a formal standardization body, or come from other clinicians. The way MDD occurs has implications for medical practice per se in the form of the need to standardize practices to ensure that medical concepts are uniform across practices. Because archetype modelling is a task that comes as a consequence of the technology chosen for the new EPR, it is fair to say that it is the technology that poses this standardization to work practice.

Summary of paper 5: Formalization and Accountability in Surgery Planning

This paper build on the insight I gained from working with the previous papers. The understanding of the work practice in surgery planning and the understanding of the technology as work and process supportive tool prepared me for applying a CSCW theoretical lens to what happened to the work practice when the technology was introduced.

By conceptualizing workflow systems as ordering systems (Bossen and Markussen, 2010), I analyze how the ordering of tasks and roles may affect the work in surgery planning. Typically, ordering systems concatenate and configure items in certain spatial-graphical ways. The inscribed models in workflow systems characterize cooperative work in terms of a "processable" flow of resources, information and responsibility handovers that occur between well-circumscribed units of work, tasks or activities (Ko et al., 1995). The actor who is supposed to interpret, react and produce this information flow is characterized in terms of roles that define the capabilities and constraints of classes of actors who are supposed to operate within an activity (Cabitza and Simone, 2013). Hence, the concept of role is inextricably connected to task ownership, task responsibility and to the concept of accountability regarding the actions performed. Ordering systems thus inherently have dual

roles as coordination devices and accountability systems (Bossen, 2006a; Bossen, 2006). According to Dourish (2001), it is accountability that makes workflow systems successful, despite critiques of how the embedded models of work may constrain work practice.

This theoretical frame is applied to a longitudinal case study of the development process, and the testing and piloting of a surgery planning module within the EPR. This paper contributes by exploring empirically how the emergence of a surgery planning tool, with its linear logic and formalization of work, affected the informal coordination and communication in the interlinked multi-professional activities that went into the surgery planning. The case shows that the way workflow systems work through process models - that control the order in which a sequence of tasks should be performed, and by whom - affects the interdisciplinary cooperative work in surgery planning. The formalization of roles and responsibility led to a redistribution of tasks, and the surgeons were the ones who had to take on more work. Also, the collective responsibility for work changed due to the assignment of tasks and responsibility assigned to the surgeon. The surgeon's role became the "owner" of the work process, as opposed to the informal sharing of responsibility and task hand-overs that are the main characteristics of the existing way of planning for surgery. However, the formalization of responsibility due to the definition of roles in the work flow system in fact made the planning process more transparent and accountable for the actors involved. The contribution is thus to show that accountability comes from the formalization of responsibility, which workflow systems force by assigning tasks to user roles.

6. Implications

Interpreting the object of study as a making and scaling of an II has allowed me to focus how different users and contexts are related, how micro aspects like work practices are related to macro aspects like large-scale (potentially global) technology, how the present are related to the past (i.e. how development must take existing systems and practices into account) and the integrational aspects in how every component depend on each other, and relate by standards. This perspective has some implications that I will outline in the following. The implications of this work are mainly geared towards the practical for implementation and adoption of the EPR in this study, in order for it to grow into an Information Infrastructure based on the openEHR architecture. Nevertheless, there are also some political, theoretical and methodological implications that I would like to point at initially.

Political Implications for decision makers:

So far, the acquisition processes for information systems in Norwegian Health Care has followed a best-of-breed strategy, resulting in many different suppliers. The EPR DIPS Arena is not the only artefact in health infrastructures. In fact, in Norwegian context, the EPR itself comprise many systems, as defined by the Government in regulations on patient records : "*An electronic collection or compilation of recorded / registered information about a patient in connection with health care*"[8] . Typically, this encompass notes, evaluations and summary in what is commonly is referred to as the EPR, but there are also radiology picturing and storing systems, lab requiring and analysis storing systems, medical chart and medication systems. In addition, there are numerous of specific applications for the different medical disciplines like ophthalmology, obstetrics, diabetes and so on. Also, medical devices for i.e. Electro Cardio Gram and Ultrasound record and store data from the patient, and bedside devices continuously store and feed clinical data (like blood pressure, SO2, respiratory frequency) into the EPR, all in order for clinicians to make and document their evaluation of the patient and to decide proper care. Thus, the EPR may consist of more than one system, and this is why it makes sense of talking about an EPR as an Information Infrastructure. Structurally an II is recursively composed of other infrastructures, platforms, application and IT capabilities (Hanseth and Lyytinen, 2010). This underscores the need for standards. The aspired functionality of decision support illustrates the necessity of semantic interoperable standards: CDS depends on good quality clinical data repository and thus reinforces the need for standardized data representation and storage. Data mining algorithms require good quality clinical data repositories to be able to extract knowledge to support clinical decision-making (Bonney, 2011). Thus, CDS systems depend profoundly on large volumes of readily accessible, existing clinical datasets usually extracted from the repository content of EPRs. Lack of standardized data in the repository may lead to datasets not representative of the patient population (ibid). It is therefore essential that standardized data representation is used for leveraging the knowledge base repositories to facilitate the generation of patient-specific care recommendations for physicians. Such advanced decision support put heavily demands on application logic and semantic interoperability if the guidance should be provided in an automatic way then computerized (Lenz and Reichert, 2007; Lyng, 2013).

[8] Regulations relating to the Documentation of Patient data in Patient records. Lovdata https://lovdata.no/dokument/SF/forskrift/2000-12-21-1385.

Applying the understanding of the ongoing effort as a making and scaling of an information Infrastructure implies that there is a need for a political decision to use the openEHR standard for information sharing in order to achieve an information infrastructure for health care in Norway. An Information Infrastructure is never complete, always extending and connecting to other infrastructures. Undisputable, the condition for this is standards: "Standards enable the evolution in scope and functionality, and they are a key means by which the infrastructure is architected and who is inscribed in its development" (Hanseth and Lyytinen, 2004, p. 215). Even if the National ICT Health Trust has recommended and initiated use of the openEHR standard, their jurisdiction comprises only hospital-, or specialized health care. Consequently, there are no such initiative for primary health care and the system vendors in this market, and no activities to achieve semantic interoperability with other care providers systems are ongoing.

Theoretical implications

Traditionally, CSCW have been focused on workplace studies and smaller scale interactions, though most studies do offer implications for design. While this emphasizes a sound commitment to understanding the users' perspectives, this also shows a lesser engagement in larger-scale projects. This is unfortunate as currently Western healthcare is moving towards large-scale integrated systems and new ways for delivery of healthcare services (Fitzpatrick and Ellingsen, 2012). Generally, CSCW has strongly focused on the intertwined agendas of understanding cooperative work and designing tools to support that work. In their seminal paper, Schmidt and Bannon (1992, p. 12) argued that "*CSCW should be conceived as an endeavour to understand the nature and requirements of cooperative work with the objective of designing computer based technologies for cooperative work arrangements*." They also presents various possible interpretations of the term cooperative work (ibid, p.15): *"...should be taken as the general and neutral designation of multiple persons working together to produce a product or service.*" Further, they go on to caution that this should not imply that the relations among those working together be amicable or that the boundaries of the "group" be clearly specified.

Even so, workplace studies typically focus single settings (Grudin and Poltrock, 1995; Randell et al., 2011). No doubt this is a valuable contribution to design of ICT for health care, but as Fitzpatric and Ellingsen (2012) timely points to, Western healthcare is moving towards large-scale integrated systems and new ways for delivery of healthcare services. The fact that

I in my initial literature studies used the search term “process support” and found no matches, whereas workflow support came up with lots of hits supports this perception. This calls for a broader perspective, and this is where this thesis contributes theoretically. Health care is not only about doing clinical work, it is about providing a service as well. Cooperation in a line of service takes another support than task-oriented cooperative work because it is distributed in time, many tasks, locations and providers. In management literature, this is termed business processes (defined by Wikipedia as :” A business process is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal) for a particular customer or customers”). Based on my work on this thesis, I suggest that CSCW should adopt this as a research theme and apply its unique perspectives to it.

The insight into work practice and particularly the surgery planning process has raised the consciousness that work processes are not equal to business processes, and the two calls for different support from a process-supportive EPR. This is something that should have implications for the further design of the system. Visualization and overview of the clinical pathway and the patient trajectory, the possibility of assembling resources and make a plan for treatment, subsequently monitoring status for the actual patient in his pathway are important functionality to support business processes. So is the possibility to reuse data entered in one step in another step, depending on structured data. However, when it comes to work process support, one must bear in mind that the way work is carried out, each user does not move that much between tasks, but do the same task repetitively. To exemplify; when the secretary puts patients on the waiting list, they do so with 20 patients. Then there is perhaps another secretary that gives the patients an appointment for surgery, and they do so for 10 patients at a time. So for the secretaries that do the work, it is just as important that every step has a good flow as is good flow between tasks. These are issues that typically come to the fore when the system is put in use, and that extend the design phase in use (Simonsen and Hertzum, 2008).

Liv Karen Johannessens’ work (2012a) contributes with a wider understanding of Infrastructuring than applied in the II literature (Karasti and Syrjänen, 2004; Pipek and Wulf, 2009). She argues that the contribution of ICT personnel, vendors and public authorities should be included in this concept. Further, she argues that designers and end-users are co-designers, and that the main contribution from the users was not to give feed-back on tested functionality, but to design work practices that accompany the technology. This thesis support the view that infrastructuring takes a web of different stakeholders and contributors. Additionally, a new user group is identified as an important actor. The dual level modelling

approach has redistributed configuration of the systems functionality from a developer's to a user's task, hence the domain experts are emerging as a user group that contributes to the infrastructring. Markus and Mao (2004) argue that user participation in development projects today can easily extend into business process redesign and IT infrastructure development. Hence, there is a need to describe participation in different phases of a systems development lifecycle. Karasti (2014) also calls for studies on infrastructuring that contribute to a broader understanding of information infrastructure and infrastructuring issues involved. This thesis contributes by describing user roles and users contribution in the making and scaling of and infrastructure for health care based on the openEHR specification.

Practical implications

The findings in this work as well as the theoretical lens I have provided in my interpretations ought to have some practical implications for the upcoming project for implementing DIPS Arena. As I have particularly focused the roles and contributions of the users in my work, I will highlight some of these implications.

The different user roles in infrastructuring.

Traditional IS participation theory and research understand participants in terms of the monolithic concept of users. Users as participants are typically assumed to be employees of the organization engaged in solution development. Furthermore, they are generally viewed as hands-on users or operational personnel.

This work has identified user-roles way beyond what traditionally is understood by users participating in design of information systems, quite in accordance with Marcus and Maos' (2004) statement " *user participation in development projects today can easily extend into business process redesign and IT infrastructure development*". In paper 3 we look into just what the different roles are, and how participation could be organized in a large-scale project. The paper reports only from the development of a smaller module of DIPS Arena, but the lessons learned have value for how the large implementation project should pick and organize user participation. In paper 4, the concept of user roles is additionally expanded, by the way modelling of archetypes brings in new user tasks as well as assign work to global users.

According to Markus and Mao (2004) and Mackay et al. (2000) it is important to pick the right users to participate in development projects. As paper 3 discusses, whom to include in development of large-scale ICT projects may vary during project time. Because process and decision supportive systems presupposes templates of clinical pathways to be embedded,

users with considerable knowledge of the organization and business processes should be brought in early in the implementation preparations, whereas end-users familiar with the actual work practices need to inform the domain experts on how to design the workflow.

The new user role

The next practical implication I would like to point at is the fact that the new technology built on a dual level architecture, leave the user domain facing new tasks and responsibilities. Accordingly, there is a need to build the competence required to handle and perform these tasks. As discussed in paper 4, making models of a clinical concepts calls for actors with new competencies – domain experts – who besides being familiar to the unique characteristics of the domain also need to understand data modelling. This "cross-competence" must be achieved in a multidisciplinary collegium, in which it is difficult to differentiate roles and responsibilities. This contrasts with the assumption embedded in dual level modelling that separating the technical concerns and the domain allows developers to concentrate only on the technical aspect while the users themselves model the domain. The implication therefrom for the upcoming implementation project would be to establish an education program for domain experts.

Standardization as infrastructuring

Electronic Patient Records (EPRs) are moving towards Information Infrastructures – that is they are connected and merged with more systems to provide Health Care professionals with proper tools to support their work, and hence they are also merged with the work. The aspired decision and process supportive abilities put even more emphasis on merging technology and work. Literature have identified success factors for developing CDSS to be (a)providing decision support automatically as part of clinician workflow, (b) deliver decision support at the time and location of decision making, (c) provide actionable recommendations (Bennett and Glasziou, 2003; Greenes, 2007b; Kawamoto et al., 2005b; Osheroff et al., 2007). Automatic provision of decision support as part of workflow and support at the time and location of decision making both presupposes the system to also behave process oriented. That is, it must have some models of work incorporated to recognize these points of care where support should be provided. Templates of clinical pathways would typically be such models of work. Hence, clinical pathways bring the standardization that information technology requires.

In socio-technical understanding, standards are socially constructed, achieved as results of negotiation processes. (Bowker and Star, 2000; Hanseth and Monteiro, 1997). Standardization

efforts are, however, often promoted in a top-down and uniform manner (Ellingsen, 2004). The openEHR approach is interesting in this regard, because it promises a high degree of local customisation for users (Garde et al., 2007b) and ensures that clinical users can take the helm of standardization and structuration processes. Global clinicians and local clinicians can actually work on standardization from both perspectives, in the way global users contribute in defining archetypes, and local users put these models into use: " *As a standard is intertwined with local practice, it both shapes local practice and is being shaped by it. Consequently work is required to reach agreement about a standard and, subsequently, maintenance-work is required to keep it 'alive"*(Karasti, 2014).

Templates of clinical pathways represent what Timmermans and Berg (2003) denotes as procedural standards. Preparing templates of clinical pathways would hence imply to standardize work practice, which is known to be extremely difficult (Berg, 2005; Ellingsen et al., 2007). Procedural standards specify processes by delineating a number of steps to be taken when specified conditions are met. These standards may be more or less detailed and more or less wide in scope. They may be restricted to indicate what should be done or describe in detail how each step should be performed. Procedural standards are the most difficult to achieve and the most contested as they bring people together from a variety of professional background: "*Such standards attempt to achieve the seemingly impossible: prescribe the behavior of professionals….. practice standards raise issues about human autonomy, flexibility, creativity, collaboration, rationality and objectivity*." (Timmermans and Berg 2003, p.26). According to Timmermans and Berg (1997), the universal character of medical protocols depends on previously established networks, how universality is contingent and collectively produced, and how localization and universality are inevitably intertwined.

The practical implication of this is to recognize the complexity in preparing templates of clinical pathways to implement in the EPR as models of work. The work should be organized with heavy representation of clinicians that implement such treatment protocols in their everyday work, even if they are today merely in paper form, or learnt as part of membership. Taking a co-constructive perspective to standardization (Ellingsen et al., 2007; Hanseth and Monteiro, 1997; Meum and Ellingsen, 2011), would imply to allow local clinicians affected by the changes to take part in the design of workflow templates. A co-construction approach would also narrow the gap between world-wide users and local users in defining the standards, that we have described in paper 4.

By also applying a business process perspective in the modelling, an important feature of process support would be reuse of data from prior actions in the clinical pathway. This is where workflow and business processes meet: Reuse of data could automate or facilitate many steps in subsequent workflows.

To implement protocols and guidelines as process and decision support in EPRs inevitably imply to change work. In paper 5 I describe how the interdisciplinary work in surgery planning is affected by the embedded models of work, particularly how it redistributes tasks and responsibility. This knowledge should be communicated in the implementation phase, to the clinicians that will be affected by such changes. Being aware of such effects of the systems process supportive features may enhance the likeliness of implementation success and adoption.

Methodological implications

The methodological implications of this PhD thesis relates to my close connection to the field of study. The fact that I know Health Care services and processes from working within the system in different positions for more 20 years meant that my presence in the field had value for the field itself. At a point, I was offered a position in the FIKS project and continued my research in a part time position. This allowed me to extend the data collection period and get an even closer connection to the field of study. My active participation in the field of study allowed me to bring in knowledge from the theoretical work on the thesis into the decisions made along the project, hence applying science to the field of study. This may have changed the direction of the project, but in accordance with the constructive paradigm, which interpretive research adhere to, the inquirer and the inquired are mutual influenced, and the findings are constructed in this interaction (Guba et al., 1994). Thus, the findings of an inquiry is not a report of what is out there, it is more of a residue of a process that creates it. It describes knowledge as a consequence of human activity, a human construction never certifiable (Guba, 1990). However, this necessitated methodological and ethical considerations on my role as a researcher, which are outlined in the methodology chapter of this thesis. The work on this thesis was financed by Tromsø Telemedicine Laboratory, which had the aim of integrating research and industry. I experienced that my perspectives based both on the knowledge of health care work, the experience with DIPS Classic as the present EPR system, and the research had much interest for DIPS ASA as they designed their novel EPR system, particularly the surgery planning module.

7. Conclusion

In this thesis, I have discussed socio-technical challenges in growing and information infrastructure for Health Care based on the openEHR specification, particularly focusing users' role and contribution. Conceptualizing the emerging EPR system as the growing of an Information Infrastructure, the different happenings and activities in the development project have been interpreted as infrastructuring work on the different aspects of an emerging infrastructure.

This research has been going on for 5 years which has allowed us to expand the focus of research longitudinally and across different social settings and scales, addressing multiple moments and sites of innovation. This apply to Pollock and Williams'(2010) Biography of Artefacts perspective, particularly suited to study the emergence of large-scale information systems intended for long-term use. Methodologically, the study adheres to interpretive research and makes use of semi-structured interviews, participatory observation and document studies as methods.

Given my background as a nurse, I was especially interested in how the new technology could fit work practice, understood as how it could reach into and extend the installed base. To understand the inertia of the installed base, work practice has been given much attention. Subsequently, the peculiarities of the given technology had to be analyzed, to understand the challenges that were faced in the development project, and in order to understand how the socio-technical interplay mutually shaped work and technology. Given that decision and process support are governments' most prominent ambitions for the next generation EPR system, I have focused on how these features will affect work, as literature describe the effect on work as a potential challenge for adoption and use of such systems. I find that because process and decision support features presupposes models of work embedded in the system, they will affect work (Bossen, 2006b). In this case models of work are grounded in clinical guidelines and clinical pathway templates that are procedural standards, known to be very hard to implement (Timmermans and Berg, 2003).

By analyzing the new technology, I have identified new tasks and roles for the users in the infrastructuring work. The dual level approach promises to "*empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way EHRs are built up*" (Garde et al., 2007). This, however, takes a new user role (domain-experts) to do the configuration of the system to fit into organizations and work in organizations.

Limitations

This study is based on an in-depth study of an ongoing large-scale openEHR project (2012-2016). Although we have studied this project over the whole period, we do not know the final outcome of the project, which I believe would have enriched the conclusions. In addition, there are some limitations following the method applied: Although the researcher's involvement in the generation of data is recognized and accepted in qualitative research, it is nevertheless important to point out that the researcher's point of view, including experiences, values, norms, perceptions and feelings, also called pre-understanding, are important elements for which data are generated and how they are interpreted and presented. The findings thus constitute a construct of the understanding and interpretation of the researcher and the informants. It cannot be said to be the truth, but rather a possible truth. While I have strived to give the different stakeholders a voice, it has not been possible to include each and every stakeholder's perspective on a detailed level. The choices of what to include and what to exclude have been motivated by the focus on ursers' infrastructuring work to realize a new EPR.

Further research

The work on this thesis has raised many question and interesting topics that could not be pursued as part of this project, but should be looked into in future research.

Firstly, a more systematized and thorough analysis of the new user role and contribution in infrastructuring for health care based on openEHR should be performed. This work has identified that there is much more to user participation than giving feedback to designers in the development of IT-functionality. The roles, tasks and responsibilities should be elaborated, subsequently how this should be organized and governed as sustainable infrastructuring efforts.

Second, the dual level modelling approach gives a network of voluntary clinical users and domain experts a prominent role in the configuring of the system. Hence, the customization is no longer "in the hands" of the vendor and the generification (Pollock et al., 2007, 2003) concept could be said to be in change. How this folds out is a topic that that can be explored both form vendors and users perspective.

Last, because development of the novel technology has taken much longer than anticipated, implementation as described in the research protocol for this project could not be studied. Even if testing and piloting has been part of the work with this thesis, research on the implementation of this technology into the "real world" should be a work of its own.

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