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Growing an information infrastructure for healthcare based on the development of large- scale Electronic Patient Records

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Abstract

This thesis aims to provide empirical insights about different socio-technical interdependencies affecting the making and scaling of an Information Infrastructure (II) for healthcare based on the development of large-scale Electronic Patient Records. The Ph.D. study has applied an interpretive research approach, where the empirical data has been collected from 2012 to 2017. The longitudinal data gathering process, made it possible to follow the empirical process across different settings and scales.

In most developed countries, the pressures from politicians and public in general for better IT solutions have grown enormously, not least within Electronic Patient Record (EPR) systems. Considerable attention has been given to the proposition that the exchange of health information is a critical component to reach the triple aim of (1) better patient experiences through quality and satisfaction; (2) better health outcomes of populations; and (3) reduction of per capita cost of health care. EPR systems have the potential to support the triple aim, in which accessibility, efficiency, and effective sharing of clinical information are key concepts. However, there is a gap between the expectations to EPR systems and existing portfolios of EPR's qualities to comply with the expectations. A promising strategy for dealing with the challenges of accessibility, efficiency, and effective sharing of clinical information to support the triple aim is an open health-computing platform approach, exemplified by the openEHR approach in the empirical case.

An open platform approach for computing EPR systems addresses some vital differences from the traditional proprietary systems. The latter one implies user interfaces, application logics and database to be closely integrated and controlled by the vendor, in contrast to an open platform approach where the vendors develop the generic reference model while the clinical communities design the use-independent clinical information models. Accordingly, it was necessary to pay attention to this vital difference, and analyze the technology and open platform approach to understand the challenges and implications faced by the empirical process, starting out as a design collaborating based on local, contextualized user requests and scaling up to a complex infrastructuring process addressing clinical -, technical -, organizational - and politically textured interdependencies. Based on this understanding, the separation of the reference model from the clinical information models influence the design process, gave rise to new collaboration forms between the vendor and users, new roles and new responsibilities in designing and implementing an openEHR based EPR system.

There are two main messages coming out of this Ph.D. study. First, when choosing an open platform approach to establish a regional or national information infrastructure for healthcare, it is important to define it as a process, not a project. Because limiting the realization of a large-scale open platform based infrastructure to the strict timeline of a project may hamper infrastructure growth. Second, realizing an open platform based information infrastructure requires large structural and organizational changes, addressing the need for integrating policy design with infrastructure design.

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List of papers

- Paper 1. Silsand, L. and Ellingsen, G. (2014). Generification by Translation: Designing Generic Systems in Context of the Local. *Journal of Association for Information Systems*, vol. 15, no. 3.
- Paper 2. Christensen, B., Silsand, L., Wynn, R. and Ellingsen, G. (2014). The biography of participation. In *Proceedings of the 13th Participatory Design Conference*, 6-10 Oct. Windhoek, Namibia: pp. 71–74.
- Paper 3. Silsand, L. and Ellingsen, G. (2016). Complex Decision-Making in Clinical Practice. In *Proceedings of the 19th ACM Conference on Computer-Supported Cooperative Work & Social Computing (CSCW '16)*, San Francisco, USA, pp. 993-1004 (Best Paper Award).
- Paper 4. Silsand, L. and Ellingsen, G. (2017). Governance of openEHR-based information Infrastructures. Submitted to ‘Special Issue of the *Journal of Computer Supported Cooperative Work* on Healthcare infrastructures for governance, quality improvement and service efficiency’.
- Paper 5. Silsand, L. (2017). The ‘Holy Grail’ of Interoperability of Health Information Systems: Challenges and Implications. In *Proceedings of the 8th Scandinavian Conference on Information Systems (SCIS 2017)*, 6-9 August, Halden, Norway vol. 294. pp 140-154.

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1 Introduction

1.1 Personal motivation

I had worked as a nurse for 16 years in different departments and organizational levels before I entered the PhD position. When I applied for the PhD position, I was working as a nurse adviser for the Internal Medical Clinical at the University Hospital of Northern Norway. I worked closely with the clinic's departments to increase the quality of treatment and care by updating clinical procedures, and I published the procedures in the hospital's electronic quality and procedure system. I was also in charge of organizing and following up on the nurse students' clinical training at the clinic, which also put a focus on the students' skills of documenting clinical observations in the EPR. Along with this, the clinic was taking part in the hospital's strategy for continual improvement of the organization, in which the basic idea was to identify and eliminate various forms of 'waste' in patient trajectories within the hospitals as well between hospitals. As a nurse adviser working with quality improvements, I was interested in this work and had been an observer in two of the clinic's improvement projects. However, even if the improvement processes often resulted in reorganizing the patient pathway in focus, and subsequently in addressing the need for support by or changes in the Electronic Patient Record (EPR) system, the continual improvements strategy was not connected to an ICT strategy. Moreover, the EPR system in use was, and still is, based on the free-text documentation of clinical information, which makes clinical process and decision support of patient pathways difficult to achieve. With this backdrop, I was happy to be part of a research project targeted to the paradigm shift related to the needs and expectations for health information and communication technology (ICT) systems and particularly to EPR systems as a clinical process-supporting tool. Accordingly, my clinical background, knowledge and interest in contributing to improved clinical work supported by electronic health information systems (ISs) have been my inspiration and guided my research.

1.2 A paradigm shift in health information systems

In most developed countries, the pressures from politicians and the public in general for better IT solutions have grown enormously, not least within eHealth¹ (Ministry of Health and Care Services, 2012) European Commission and Directorate-General for Health and Food Safety, 2015; Bygstad et al., 2015). Considerable attention has been given to the proposition that the exchange of health information

¹ In this thesis, the understanding of the term "eHealth" encompasses all health-related digital information systems used to conduct and administer clinical treatments, monitor public health, conduct research, and inform managers and policy maker (Aanestad et al., 2017). The term "eHealth and "digital health IS" is used in the same meaning.

is a critical component to reach the triple aim of (1) better patient experiences through quality and satisfaction, (2) better health outcomes of populations and (3) the reduction of per capita cost of healthcare (Institute for Healthcare Improvement, 2017). Taking into account the increasing needs for health personnel and the growth in chronic disease and an ageing population, the need for successful utilization of eHealth is considered pivotal for improving the quality and efficiency of healthcare (Aanestad et al., 2017; Hillestad et al., 2005).

EHealth ISs have the potential to support a sustainable and consistent healthcare service within and between organizations, in which accessibility, efficiency and the effective sharing of clinical information are key concepts. In many countries, the trend towards better coordination of care has been the driving force for ICT in healthcare, which implies a change of focus for eHealth from self-contained processes within single healthcare institutions to overall care processes spreading across institutional boundaries (Aanestad et al., 2017). Even though developed countries have reached a level of technological maturity where most healthcare organizations have impressive ICT systems to support their day-to-day operations, advanced process-supporting health ISs are not widely available. The tendency of limited availability of process- and decision-supporting (PDS) systems seems to be representative for healthcare organizations in developed countries in general (Aanestad et al., 2017; Aarts et al., 2007; Berner, 2009; Ministry of Health and Care Services, 2012; Ministry of Health and Care Services, 2014a)

A major concern related to the restricted availability is the extensively use of specialized, non-standard ISs – so-called silo systems – following a best-of-breed approach within every healthcare organization. Another problem with the existing portfolio of digital health systems is that much of the information is free text, which hampers the reuse and processing of clinical information within the same system, as well as sharing information between systems. This makes it hard to use EPRs, for example, for purposes other than registering and looking up patient information (Aanestad et al., 2017; Christensen and Ellingsen, 2014; Ministry of Health and Care Services, 2014b). In line with this, researchers have demonstrated numerous examples of PDS systems that can reduce the incidence of errors in clinical examination and medical treatment and care and ensure that hazardous conditions are captured at an early stage (Duplaga et al., 2004; Franklin et al., 2007; Kawamoto et al., 2005a). In Norway, a ‘state-of-the-art’ review of digital health ISs from 2013 investigated 65,400 cases of in-house patients with adverse events leading to prolonged hospital stay or more serious consequences, in which 60-70% of these happenings could have been avoided by improved ICT systems. A specific challenge related to these happenings was the lack of functionality to support clinical decisions in present ICT systems (Ministry of Health and Care Services, 2014a).

Accordingly, a gap exists between the increased expectations to eHealth systems and the general qualities of the existing portfolio of eHealth systems to comply with these expectations. The latest

national eHealth Action Plan for 2012–2020 states that the promise of eHealth ‘remains largely unfulfilled’ and the vision of a unified, interoperable eHealth Infrastructure in Europe is still not realized (The Norwegian Directorate of eHealth, 2017). This addresses the need for a paradigm shift in terms of phasing out the existing portfolios of eHealth systems, and in particular, EPR systems, and give preference to interoperable process-oriented EPR systems enabling exchanges of clinical information within and between systems in one or several organizations (Ministry of Health and Care Services, 2012; Lenz et al., 2012; Pedersen et al., 2015; Wollersheim et al., 2009).

1.3 Research theme

Following the theme from the brief introduction, the PhD study has followed a large-scale ICT project in the North Norwegian health region, with a specific focus on realizing a new and innovative openEHR-based EPR system enabling clinical process and decision support within and between different organizational units in the region. Accordingly, the new EPR will embrace various healthcare professionals, different work practices and stakeholders and go beyond proprietary or ‘silo’ systems supporting different localities and temporal scales. In this perspective, the scope and the scale of the system has the characteristics of an information infrastructure (II) (Monteiro et al., 2012), which makes it relevant to exploring the empirical process through the lenses from the II research field. The II literature addresses socio-technical challenges of realizing large-scale technological systems, and accordingly, I am particularly interested in how different socio-technical interdependencies affect the development and implementation of large-scale EPR systems.

Based on this, the paramount theme for this PhD study is to investigate the associations between different socio-technical interdependencies affecting the development and implementation of large-scale EPR systems to be an operational tool for clinical process – and decision support.

In accordance with the described need for modernizing eHealth ISs, the North Norwegian Health Authority issued an invitation for tender and asked for functionality that is not yet present in any EPR system in Norway. Even though the same vendor’s company that was given the responsibility to design the new EPR, the future EPR was planned as an openEHR-based system that differs significantly from the existing one. The openEHR approach is an open health-computing platform approach, and the innovative aspect comes from separating the system’s generic reference model from the clinical information layer (Atalag et al., 2016). The separation is a very different approach to system design compared to traditional proprietary EPR systems. In proprietary ERP systems, the clinical information models are hardcoded by the vendor into the system’s software, and each system has its own information and database model. The open-platform approach implies that the system’s developers would not need to know all the organizational or clinical peculiarities in every different context because the clinical information models are developed ‘outside’ the technical system. In the openEHR approach, the clinical

information models are denoted as ‘archetypes’, which is a description of all the information clinicians need to know about a clinical concept (e.g. blood pressure), and the information is thoroughly described to be useful in every imaginable clinical use context.

The development of the clinical information models are given to clinical communities as a bottom-up standardization approach, aimed to empower clinicians to directly produce standardized clinical information models and to enable the control of how the ISs function, in terms of tailoring the use-independent information models to specific clinical contexts. To support clinical communities in this work, the openEHR community provides a web-based tool called the Clinical Knowledge Manager (CKM), whereby healthcare personnel and experienced clinical experts can develop, manage, publish and use the information models. Finally, to ensure the interoperability of use-independent information models that need to be tailored or constrained to different clinical use contexts, the openEHR specification recommends a formalized role in taking responsibility for controlling and governing the clinical information models (Atalag et al., 2016; Garde et al., 2007).

Consequently, it is timely to predict that the innovative platform approach of separating the design of a generic reference model from the clinical information models will bring about new and novel challenges to the design and implementation of an II. These challenges are hard to predict upfront, but addresses my point of departure for the Ph.D. study. The thesis applies a socio-technical perspective on how the innovative platform approach will influence the development and implementation of a new EPR system, and I have operationalized the paramount research theme into two specific issues of interest. First, how will the separation influence the vendor-user collaboration, and second, how will the separation give rise to new roles and responsibilities in designing and implementing an openEHR-based clinical process-supporting EPR system.

1.4 Research questions

The first presented issue of interest evolved into the first research question. A basic principle of an II is that it is never built from scratch; it evolves from the installed base of the existing IS portfolio and work practices in specific contextual practices (Monteiro et al., 2012; Star and Ruhleder, 1996). In line with this, the vendor had used agile development approaches, such as Scrum and Extreme Programming (XP), to design and customize the existing proprietary EPR system, DIPS Classic, over the course of several years. In doing so, the vendor had worked in close collaboration with healthcare personnel, and short, contextualized user stories from clinical personnel have been used as a principal communication tool between developers and healthcare personnel (Johannessen, 2012). Comparing the design and customization of a proprietary EPR system by using agile approaches with an open-platform approach ‘separating’ the reference model from the clinical information model challenges the traditional understanding of vendor-users collaboration. This leads to the first research question:

RQ 1: How does an open-platform design strategy for EPRs influence the traditional vendor-user collaboration informed by agile development approaches?

The trend towards better coordination of care processes within and between organizations addresses the need for accessibility, efficiency, and effective sharing of clinical information across systems and organizational boundaries. IIs are characterized by their supporting or enabling function, which means that an infrastructure is designed to support a wide range of activities (e.g. sharing of clinical information to enable support of healthcare processes). However, sharing and reusing clinical information within and between different organizations presupposes that different components are connected through shared standards (Bowker and Star, 1999; Hanseth and Lundberg, 2001; Hanseth and Lyytinen, 2010; Hanseth and Monteiro, 1998; Star and Ruhleder, 1996). The enabling function of the openEHR platform approach goes through the open clinical information models, in which IIs depend heavily on standards to enable the evolution in scope and functionality. Star and Ruhleder (1996) stated that ‘it is what the users do to the II that makes it grow’, and interpreting this statement with the openEHR platform approach points to the prominent role that clinical communities are given in the evolution of the II. This leads to the second research question:

RQ 2: Which new roles are given to clinical communities in the evolution of an open-platform-based information infrastructure for healthcare?

Following in the wake of RQ 2, the enabling function of II intended to open up new activities for example developing clinical information models argues for new roles within clinical communities. Moreover, an open-platform approach aimed at supporting both local as well as cross-organizational healthcare processes may enable new roles and activities distributed in time and space, in which new roles often affect the distribution of responsibilities and, hierarchies and introduce new tasks, routines or procedures. Accordingly, making and scaling the openEHR II addresses politically textured processes of organizational changes (Aanestad and Jensen, 2011; Berg and Goorman, 1999; Hanseth and Monteiro, 1998). This introduces the third research question:

R.Q. 3: How do the design and implementation of an open-platform-based health information infrastructure play a politically textured role beyond the clinical contexts of use?

In accordance with the described need for modernizing digital health ISs, the new open-platform-based systems are expected to enable clinical process and decision support. However, eHealth ISs supporting sustainable and consistent healthcare services within and between organizations have been difficult to

implement, and adoption has been rather low (Kawamoto et al., 2005a). One important aspect of enabling PDS systems is that it is not only about technical integration and the qualities of the technology. Making medical decisions and conducting treatment and care for complex patient situations are often based on multidisciplinary teamwork, in which decision-making and the execution of treatment and care are intertwined with different technologies and organizational processes (Lenz et al., 2012; Lenz and Reichert, 2007). This calls for research that follows the design and implementation of PDS systems into clinical practice (Bossen, 2006; Bossen and Markussen, 2010) to explore the interdependencies of technology, clinical treatment and organizational processes. This frames the fourth and last research question:

R.Q. 4: How does the interplay between work practices and technology function in the design of process-oriented EPR systems?

Main theme	To investigate the associations between different socio-technical interdependencies affecting the development and implementation of large-scale EPR systems
Research question 1	How does an open-platform design strategy for EPRs influence the traditional vendor-user collaboration informed by agile development approaches?
Research question 2	Which new roles are given to clinical communities in the evolution of an open-platform-based information infrastructure for healthcare?
Research question 3	How do the design and implementation of open-platform-based health information infrastructure play a politically textured role beyond the clinical contexts of use?
Research question 4	How does the interplay between work practices and technology function in the design of process-oriented EPR systems?

Table 1: Main theme and research questions

Paper	RQ 1	RQ 2	RQ 3	RQ 4
Generification by Translation: Designing Generic Systems in Context of the Local.				
The Biography of Participation				
Complex Decision-Making in Clinical Practice				
Governance of openEHR-based information Infrastructures				
The ‘Holy Grail’ of Interoperability of Health Information Systems: Challenges and Implications.				

Table 2: The correspondence between papers and research questions

The colouring of the cells indicates to which degree the different papers answer the research questions of this thesis. Dark grey indicates a full match between the paper and the research, grey indicates a partial match, and white indicates no match between the paper and the research question. As the table shows, the different papers contribute to different aspects of the overall aim of the thesis.

1.5 Research setting

North Norwegian Health Region

The Norwegian specialized healthcare program (hospital care) is divided into four regions. The North Norwegian Health Region is the smallest in population (11% of the Norwegian population), but encompasses approximately half of the Norwegian area. The North Norwegian Health Authority is responsible for the public specialized healthcare service for the inhabitants in the three northernmost provinces, in addition to Spitzbergen, and runs four health trusts:

- The University Hospital in Northern Norway (encompasses three hospitals in different towns and Spitzbergen Hospital)
- Nordlandssykehuset (encompasses three hospitals in different towns)
- Helgelandssykehuset (encompasses three hospitals in different towns)
- Finnmarksykehuset (encompasses two hospitals in different towns)

In addition, the health region has several district psychiatric centres, district medical centres, emergency medical services and air ambulance services.

The empirical project, 'the FIKS² Program'

In 2009, the North Norwegian Health Authority issued a call for tender to replace its portfolio of digital health ISs in all 11 hospitals in the region, also including the district psychiatric and medical centres. The portfolio of clinical ICT systems in the hospitals includes Electronic Patient Records (EPRs), a patient administrative system (PAS), Laboratory Information Systems (LAB), electronic requisition of laboratory services (ERL), pathology, X-ray information (RIS), and a storage and display system for diagnostic images (PACS). Practicing a 'best-of-breed-approach' resulted in choosing four different vendors for the new systems in the portfolio. The EPR constitutes the largest part of this portfolio and has the most users. In addition, in December 2014, the procurement of the Electronic Charting and Medication (ECM) System was published. The new ECM became part of the FIKS program's portfolio, which then embraced five different vendors. The new ECM was intended to be a substitute the existing paper-based charting and medication system in all the hospitals and to be an integrated part of the new EPR.

² A Norwegian abbreviation referring to common ICT system within the Region's hospitals.

The FIKS program was established for a period of five years, spanning from 2012 to 2016. The budget for the FIKS program was estimated at 82 Million EURO, making it an ambitious ICT project for healthcare in Norway.

As the organization responsible for specialized healthcare and 12 500 employees, the North Norwegian Regional Health Authority has outlined some goals for this big investment. The overall goal is to contribute to more standardized patient treatment in the region. In Norway, the National Guidelines outline the standardization of treatment and care for various medical conditions, and the authority sees ICT as a tool for implementing these guidelines in their health trusts. In addition, to overcome the problems of poor information flow between hospitals and to reduce the complexity in maintaining the health ISs, all 11 EPRs (one for each hospital) were to be merged into one installation. Working in a regional EPR would necessitate the following:

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

Furthermore, the described agreements addressed the need for standardization, which evolved into 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 standardization process and implementation of the standards was carried out by a sub-project under the FIKS umbrella.

In accordance with the national strategies for renewing digital health ISs, the invitation to tender asked for PDS functionalities not present in any EPR system in Norway to be developed in close collaboration between the vendor and healthcare personnel. Hence, over 100 clinicians from different health professions and geographical locations within the health region were invited to participate in workshops with the vendor. The development of the new EPR was organized as several sub-projects: surgery planning, process and decision support, structured records, authorization and access control, e-prescriptions, psychiatric documentation and nursing care plans. This thesis has focused on the three first mentioned sub-projects. However, as the development process has proceeded, surgery planning, process and decision support and structured records have been merged into one development track because considerable overlap in the users' needs and dependencies between the different processes was acknowledged.

The time frame for the FIKS program suggested a completion date of 2016. By then, the whole portfolio should have been implemented. However, the development of the new EPR system took much longer

than anticipated. The implementation of the new EPR and ECM systems is going to be accomplished by a new project called 'FRESK'³, set to start at the turn of the year (2017/2018).

The vendor of the new EPR system

DIPS ASA is the leading vendor in the Norwegian healthcare market. During the last 25 years, DIPS ASA has accumulated high-level expertise and a great deal of knowledge about the Norwegian healthcare service and about the complexity of developing and implementing ICT systems that support the heterogeneous healthcare domain. Their product, DIPS Classic, currently has 80 000 healthcare workers as users.

Hospitals and medicine are constantly changing and evolving, and national strategies have pushed the demand for interoperable health ISs. To meet these everlasting changes and national strategies, the vendor started to experiment with a model-driven development approach in 2006. This culminated with the decision in 2011 to use the openEHR specification for their future EPR system, DIPS ARENA. The introduction of DIPS Arena implies moving from a proprietor system to a system based on an open-platform approach. Hence, all the functionality hardcoded in Classic would have to be migrated and recoded according to the open-platform approach. Holding such a large part of the hospital market, DIPS ASA decided to apply a stepwise migration to the new platform. The modularity of DIPS Arena would allow implementing it bit by bit, while still working in DIPS Classic. This approach was taken to reduce customers risk compared to making a 'big bang' shift.

Accordingly, when starting the development in collaboration with the FIKS Program in January 2012, the new EPR system DIPS Arena only existed on the drawing board.

1.6 Data collection and methods for analysis

The PhD study adheres to an interpretive case study approach, aimed to describe, explore and understand the key mechanisms at play during the development and implementation of an openEHR-based EPR (Klein and Myers, 1999; Walsham, 1995). Interpreting the new openEHR platform-based EPR systems as a 'growing' II calls for research approaches that encompass both short-time dynamics and longer-term evolution (Pollock and Williams, 2008). This is because 'growing' an II is a time-consuming process that tends to include many different phases in its evolution. However, the funding for the PhD work was stretched over 5 years⁴ as a part-time position allowing me to collect data from the initial start of the empirical projects in January 2012 to December 2017. Data have been collected through

³ A Norwegian abbreviation referring to the future's clinical ICT systems within the Health Region.

⁴ I have been in maternity leave from June 2014 to August 2015.

different phases of the project by using participant observations at different sites, formal and informal interviews, and document studies.

The chosen research approach calls for detailed case descriptions, which allow the readers to gain insight in the empirical field, followed by an analysis of the data for potential analytical themes. In this thesis, the analysis is based on a hermeneutic approach, whereby the entire data collection is taken into consideration along with the relevant literature (Klein and Myers, 1999; Orlikowski and Baroudi, 1991; Walsham, 1995).

1.7 Structure of the thesis

The rest of the thesis is organized as follows: Section 2 provides an overview of the Norwegian Healthcare policies and visions for the use of digital health ISs. In Section 3, the theoretical framework and perspectives that have informed the research are depicted. Section 4 presents the research approach and methodological approach, as well as the methods applied in the study and reflections about my role as a researcher. Section 5 summarizes the results of the papers included in this thesis. Section 6 provides implications of the research, and Section 7 presents the conclusion and suggestions for further research.

2 The Norwegian healthcare

2.1 The evolution of ICT systems in Norwegian Healthcare

During the eighties, a wide range of digital health ISs were introduced, serving as EPR systems that replaced the paper-based records and systems for specific medical disciplines in hospitals. The digital health ISs were primarily aimed at documenting and storing clinical notes, with limited integration with other inter-organizational systems providing radiology and laboratory results. Compared to many other Western countries, Norway was early in deploying ICT for healthcare, and EPR systems were thoroughly implemented for primary care, general practitioners and specialist care. In recent years, the healthcare services in Norway has lagged behind the leading healthcare service institutions worldwide in the deployment of more advanced ICT solutions because the expectations for digital health ISs have changed dramatically during the last 10 years.

ICT had transformed from being a documentation tool only to becoming a prerequisite to support overall care processes spreading across institutional boundaries, to monitor public health, to conduct research, and to inform managers and policy makers (Aanestad et al., 2017; European Commission and Directorate-General for Health and Food Safety, 2015; Ministry of Health and Care Services, 2014a; WHO | eHealth, 2017). The trend towards better coordination and support of patient pathways crossing organizational borders implies quick and easy access to relevant patient information, addressing the need for clinical information that can be exchanged and still conserving the contextual knowledge of

the clinical information to be reused for various purposes (Ministry of Health and Care Services, 2012). Even though a high degree of digitalization can be seen within the Norwegian healthcare service, integration between systems within and between services is lacking. Specialist ICT systems appear mainly as isolated silos that, at best, can copy selected data between systems and actors, using technical integrations and message-based exchanges (Aanestad et al., 2017). The situation of silos systems makes it challenging for healthcare personnel to gather all the necessary patient information, especially when patient pathways cross organizational borders. As an answer to the addressed limitations of the existing portfolio of digital health ISs, the Norwegian authorities have published a national policy for ICT in healthcare described in White Paper No 9: ‘One Citizen- One Health Record’ from 2012.

In White Paper No. 9, three paramount goals are given:

- 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 addresses the need for digital health ISs that ensure healthcare professionals’ access to updated patient information, such as referrals, discharge summaries, medication lists, test results and x-ray pictures/diagnostics radiographs, including updated knowledge and process and decision support to health professionals. Other requirements relate to the secondary use of data; for example, reporting to national registers should take place automatically, without superfluously double registrations, and be integrated in ordinary clinical workflow processes (Ministry of Health and Care Services, 2012). However, the latest national eHealth Action Plan for 2012–2020 states that the ‘vision of a unified, interoperable eHealth Infrastructure in Europe (including Norway) is still not realized’ (The Norwegian Directorate of eHealth, 2017).

2.2 Status of today’s healthcare systems

In Norway, the healthcare service is organized in many different enterprise units, in which each unit is or might be responsible for different parts of a patient pathway. Legally, every enterprise unit is required to maintain a comprehensive record of each patient in its own health IS and thus to intentionally duplicate the information in accordance with the present regulations. Consequently, a patient’s record is spread in different enterprise units in relation to the medical treatments and care given within different units and stored in several ‘silos’. While smaller enterprises usually use just one EPR system, the situation is completely different in hospitals, where it is common to have a three-digit number of specialized systems from a variety of vendors. Moreover, many enterprises still have recorded medical observations (e.g. body temperature, pulse, blood pressure and body weight) and medication

orders/management on paper. Accordingly, the heterogeneous portfolio of health ISs in Norway make it difficult to fulfil the described expectations and to increase the quality of healthcare service.

In 2013, a ‘state-of-the-art’ review of the health ISs in Norway presented a discouraging result related to the existing portfolio of digital health ISs (Ministry of Health and Care Services, 2014a). The review involved an investigation of 65,400 patient cases in which adverse events prolonged the hospitalization of patients or led to more serious consequences, and roughly 60–70% of these cases could have been avoided by improved digital health ISs. The review summarized the identified challenges with the present portfolio of digital health ISs:

- The information structures and digital health ISs do not support workflow and continuity of patient care, in particularly for patient pathways crossing organizational borders. Data are mainly free text and consequently lacks common terminology and concepts that enable semantic interoperability.
- The digital health ISs lack functionality for clinical decision support and quality improvement, which are necessary to improve patient safety and the quality of healthcare services.
- The electronic patient records are not authoritative when it comes to recording generated patient data because a significant amount of data is generated in medical devices. The data from medical devices are either processed locally in separate specialist systems that are not integrated with the main record, or they are summarized in an unstructured way in text documents in the EPR. In any case, the data are not available for decision support or secondary use such as quality improvement (Ministry of Health and Care Services, 2012).

3 Theory

Research in the IS field examines more than just the computer-based IS or the social system where the technology is to be used. The research aims to investigate emerging phenomena when technology and social systems interact and points to the various ways in which new technology result in intended and unintended socio-technical consequences. This section presents the theoretical perspectives used as a lens to unpack, explain and analyse the socio-technical consequences of the empirical case. The theoretical framework is used to conceptualize how various actors (healthcare professionals, managers and developers/vendors), activities and the technology are interwoven in different contexts and different phases throughout the making and scaling of the new open-platform-based EPR system.

First is a brief summary of the present healthcare situation and the expectations in regard to health ISs supporting healthcare services. Today, people live longer lives, and the consequences of an aging population are complex diseases with potentially coexistent medical, functional, psychological and social care needs. In contrast, healthcare organizations and individual healthcare professionals, typically, are highly specialized nowadays, but for optimal patient care, the various organizations and

healthcare professionals have to cooperate closely during patients' trajectories – the collaboration is often denoted as shared care. In this perspective, digital health ICT systems in general and EPR systems in particular have been associated as means to deal with these complex challenges of collaboration within and between different jurisdictions of healthcare (Aanestad et al., 2017; European Commission and Directorate-General for Health and Food Safety, 2015; Ministry of Health and Care Services, 2012).

Developing, implementing and integrating digital health ICT systems address interrelated factors stemming from diverging needs by healthcare practitioners, heterogeneous groups of patients, diverse procedures and approaches to medical treatment and care, and last but not least, a portfolio of existing heterogeneous digital health ISs. Deploying digital health ISs in such a way that communication and clinical information to support healthcare processes will be improved address various clinical, organizational, technological and political issues, framed as socio-technical interdependencies (Aanestad and Jensen, 2011; Ellingsen et al., 2013; Hanseth and Lyytinen, 2010; Lenz and Reichert, 2007; Monteiro et al., 2012; Star and Ruhleder, 1996). As a point of departure when studying the making and scaling of a new process-supporting EPR system, it is important to have an understanding of what characterizes clinical work and healthcare processes in general.

3.1 Complex healthcare processes and the need for ICT support

Healthcare has always comprised multidisciplinary services, in which the healthcare processes require cooperation and coordination of different organizational units and medical disciplines depending heavily on both information and knowledge management. To understand what clinical work and healthcare processes are about, it is of use to distinguish between organizational and medical treatment processes, even though they are intertwined in practice. Making a distinction between organizational and medical treatment processes contributes to an analytical understanding of clinical healthcare processes when describing and defining support from digital healthcare systems (Lenz and Reichert, 2007).

The organizational processes help to coordinate collaborating clinical personnel, administrative staff and organizational units (e.g. coordinating the patient admission from the emergency department to in-patient clinics or handling a GP's referral), and the medical treatment processes are linked to the patient. In hospitals, organizational processes have a major impact on the medical treatment and care to be given to the patients. For example, surgery planning procedures have to be planned and prepared, such as scheduling appointments with different service providers, transporting in-house patients and arranging visits of physicians from different departments, while reports need to be written, transmitted and evaluated. If information is missing, the surgery planning procedure may become impossible to perform; preparations may be omitted, or a preparatory procedure may have to be postponed or cancelled or may require latency time, which all in all have a negative effect on the patients. Often, these factors cause

hospital stays to be longer than required and increase costs. Clinical personnel are aware of these problems, and due to lack of process-aware ISs coordinating organizational task and providing information at the point of care, the tasks within organizational processes have to be coordinated manually by clinical personnel and administrative staff (Lenz et al., 2012; Lenz and Reichert, 2007).

In addition, medical treatment processes are influenced by medical knowledge and patient-related information. To improve the quality of healthcare processes by the use of health ISs, it is fundamental to understand the nature of medical treatment processes to estimate the potential for the technology. The medical treatment process is often denoted as a diagnostic–therapeutic cycle or clinical process covering observation, reasoning, instruction, action and evaluation. Each pass of this cycle is aimed at increasing the certainty about a patient’s disease or the actual state of the disease process. Accordingly, the observation stage always starts with the patient’s history (if available) and proceeds with observations and diagnostic procedures, which are selected based on available information. It is the job of the EPR to assist healthcare personnel in making informed decisions about the necessary actions or the next step of the clinical process. Consequently, if the EPR system is to assist, it needs to present relevant information at the time of data acquisition and at the time of order entry or instructions. Standardized guidelines provide a source of medical knowledge to guide these decisions. However, the specific patient treatment process depends on case-specific information as well. Medical decisions are made by interpreting patient-specific data according to medical knowledge (ibid.).

The decision process can be very complex, as medical knowledge includes medical guidelines of various kinds and evidence levels, as well as the individual experiences of physicians or other healthcare personnel. Moreover, medical knowledge continuously evolves over time. It is generally agreed that complex cognitive tasks, for example, diagnostic medical decision making, cannot be automated, but the aim of the EPR is to assist the clinician (Berner, 2009; Bonney, 2011; Das and Eichner, 2010; Jaspers et al., 2011; Kawamoto et al., 2005a; Lenz et al., 2007). Therefore, physicians are not supposed to follow a predefined computer-based treatment plan blindly; instead, clinical process and decision support should contribute to providing the best available evidence to the physician in a readily understandable and applicable way. Consequently, explicit medical knowledge and evidence-based guidelines are necessary, but not sufficient for medical decision making because a large part of medical treatment processes is based on social processes between individuals in specific healthcare contexts – coined as tacit knowledge (Bonney, 2011; Kawamoto et al., 2005a; Lenz et al., 2007).

When describing the nature of healthcare processes and medical decision-making, the complexity becomes obvious, and ICT systems are needed to address this complexity (Berner, 2009; Bonney, 2011; Das and Eichner, 2010; Jaspers et al., 2011; Kawamoto et al., 2005).

3.2 Process- and decision-support systems

Well-designed health ISs have the potential to support complex healthcare processes, subsequently improving the quality of treatment and increasing patients' outcomes (Aanestad and Jensen, 2011; Berg and Toussaint, 2003; Ministry of Health and Care Services, 2014a; Star and Ruhleder, 1996). Many different types of clinical tasks can be supported by medical technological devices, for example, patient-monitoring devices such as electrocardiograms or pulse oximeters that warn of changes in a patient's condition (Jaspers et al., 2011). In this thesis, PDS systems are understood as health ISs providing clinicians with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times to enhance patient care. Clinical knowledge can be incorporated in PDS systems based on, for instance, the available evidence-based practices as outlined in standardized guidelines.

One example of PDS integrated in EPRs is computerized physician order entry (CPOE), which is designed to support physicians' medical decision-making. CPOE systems are capable of sending reminders or warnings for deviating laboratory test results and of checking for drug interactions, dosage errors and other prescribing contraindications, such as a patient's allergies (Aarts et al., 2007; Jaspers et al., 2011). Another example of PDS concepts integrated in health ISs are electronic forms or templates used to provide support for decision making in patient care and to generate case-specific advice at various stages in the clinical process. When a patient's medical situation is complex, or when the healthcare practitioner making the diagnosis is inexperienced, a PDS system can help in formulating diagnoses and in devising treatment and care suggestions based on patient data and the system's knowledge base (Berner, 2009; Bonney, 2011; Das and Eichner, 2010; Jaspers et al., 2011; Kawamoto et al., 2005).

Despite widespread agreement on the importance of systems supporting clinical treatment and care processes, these capabilities are not widely available. In the United States, fewer than 10% of the hospitals have implemented decision support, in terms of CPOEs. The tendency of limited availability seems to be representative for healthcare organizations in developed countries in general, as several studies and reports indicate low uptake of PDS systems in hospitals (Aarts et al., 2007; Berner, 2009; European Commission and Directorate-General for Health and Food Safety, 2015; Ministry of Health and Care Services, 2012; Ministry of Health and Care Services, 2014a). It is not easy to suggest a cause-effect explanation of the low uptake of electronic decision support systems in hospitals. However, a major concern is that healthcare organizations tend to use a plethora of specialized, non-standard ISs, often developed to support specialized departments' internal processes, or so-called silo systems. The silo system approach gives access to only a single unified database, which raises problems with integrating different systems installed in different departments and/or in exchanging clinical information between different healthcare organizations (Bygstad et al., 2015; Lenz et al., 2012). In addition, much

of the clinical information is recorded as free text in the existing portfolio of health ICT systems. This hampers reusing and processing clinical information within the same system, as well as sharing information between systems.

Accordingly, shared care (or cross-organizational patient pathways) imposes challenges on the availability and processing of information, including the trust of shared information and the correct and clinically safe interpretation of the clinical information. Consequently, the expected increases in the quality and cost-effectiveness of treatment and care delivery promoted through electronic health ISs are at risk when clinical information during a patient pathway resides in more than one health IS and is not shared effectively between organizations (Christensen and Ellingsen, 2014; Ministry of Health and Care Services, 2014a). Therefore, if not systematically dealt with, health IT can lead to more complex and variable processes imposing additional workload and sources of error on clinicians (Fraccaro et al., 2015).

The increased focus on systems supporting healthcare processes across different healthcare organizations addresses the need for enabling integration between heterogeneous health ISs (IS) across different institutions. Subsequently, governments and healthcare organizations worldwide have coined ‘interoperability of health information systems’ as an overall goal (European Commission and Directorate-General for Health and Food Safety, 2015; Gibbons et al., 2007; Ministry of Health and Care Services, 2012). The different ISs used by the various healthcare providers in and between different organizations must be able to interoperate so that one system can understand the context and meaning of information provided by another system (semantic interoperability) (Garde et al., 2007; Gibbons et al., 2007).

However, the degree of interoperability that is possible to reach depends on the level of agreement of structuring and standardizing the clinical information being communicated. This means that many of today’s health ISs are developed in such a way that every system has its own information and database model, and a large amount of domain-specific knowledge is hard-wired into the software. These systems are only interoperable as long as they subscribe to the same formal model of information or services; otherwise, the information needs to be exchanged through messages. Then, each message has to be implemented in each health IS because each system uses its own proprietary information model in the persistence layer in a database (Freriks et al., 2007). To overcome the complexity of different information models hard-wired into each and every systems’ software, an open-platform approach – exemplified by the openEHR specification – is supposed to offer a high degree of interoperability (Beale and Heard, 2007a; Beale and Heard, 2008; Freriks et al., 2007).

3.3 Interoperability through the openEHR specification

The openEHR approach (What is openEHR?, 2017) is defined as a comprehensive open specifications for electronic health records⁵ and standardized by CEN and ISO in the EN/ISO 13606 standard series (Chen et al., 2009, p. 2).

‘The openEHR technical approach is “multi-level modelling within a service-oriented software architecture”, in which models built by domain experts are in their own layer’ (Atalag et al., 2016, p. 9).

In practice, this means that the openEHR specification is an open health-computing platform (Fig.1), (Atalag et al., 2016), in terms of data, models and APIs are 'open'. It enables its clinical information models to be both accessed directly by users and also published in open formats, it is powered by technology that is freely available through open licenses, and it is a system in which interoperability and integration are the primary design objectives (What is openEHR?, 2017). The openEHR approach is a base to build upon rather than a ‘set of standards’ or monolithic specification or product, which separates the system’s technical design from the clinical information layer. This means that the system’s developers would not need to know all the organizational or clinical peculiarities in every different context because the clinical information models (archetypes) are meant to enable easy reuse of the software across different healthcare organizations.

‘Technical models are developed by software engineers, whilst knowledge concept definitions are developed by the people who know about them – domain experts. 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).

The foundation of the openEHR approach is its reference model, a generic model that defines the logical structures of EPR and demographic data. All EPR data in any openEHR system conform to this reference model. The openEHR Foundation provides the specifications for designing the reference model, which is a formal, logical definition of the information, not a concrete physical data schema (What is openEHR?, 2017). The vendor implements the reference model only once.

The next level consists of a library of clinical information models that are independent of particular use contexts, and these are called archetypes. The creation of a repository of use-independent archetypes removes the need for modelling the same clinical information more than once. The archetypes represent

⁵ In this thesis, the concept ‘EHR’ focused on the total health of the patient—going beyond clinical data collected in one healthcare organization or general practitioner’s office and inclusive of a broader view on a patient’s care (e.g. patient’s own data collection). EHRs are designed to reach out beyond the health organization that originally collects and compiles the information. While EPRs are understood as clinical data collected by healthcare personnel in one healthcare organization.

different kinds of information that is created and needs to be recorded during healthcare processes. The openEHR Foundation provides the archetype model specification and the tools for their authoring and editing, which ‘allows domain experts, clinicians, allied health workers, and other experts, to be directly involved in defining the semantics of clinical information systems’ (Atalag et al., 2016, p. 10). The top level, closest to the end-users, are template-generated artefacts (e.g. application program interfaces, XSDs and UI forms) used by application developers.

Interoperability through the open-platform approach helps to ensure that clinical information can be shared, underpinned by complete and unambiguous information, and subsequently, without re-programming of the receiving open EHR-based health IS, be read, recorded, retrieved, presented and further exchanged (Beale and Heard, 2007, p. 8; Freriks et al., 2007; Garde et al., 2007, p. 333).



Figure 1. Open-platform architecture (DIPS forum 2016, 2016)

3.3.1 Archetypes as ‘meta-data’

An archetype represents a description of all the information a clinician might need about a clinical concept, its sub-elements and a technical well-defined data model. Clinical concepts defined as archetypes include blood pressure, height, weight, fluid balance or a ‘problem/diagnosis’ describing details about a single identified health condition. Archetypes represent ‘metadata used to define patterns for the specific characteristics of the clinical information, for example “problem/diagnosis”, but independent of particular use context’ (Kalra, 2006, p. 138). Therefore, as figure 2 shows, an archetype consists of a large amount of generic information to be able to fit the endless number of use contexts for a medical problem/diagnosis. In the example (Fig. 2), the name of the problem or diagnosis is preferred to be coded with a terminology; if no terminology is chosen, then free text might be used. The name of the problem/diagnosis is accompanied by data describing the context of which symptoms or signs occurred and when and who observed them. However, as figure 2 illustrates, the problem/diagnosis archetype contains several data strings, making it possible to record a thorough description and to conserve the meaning of the clinical concept by explicitly specified and structured clinical information (Garde et al., 2007).

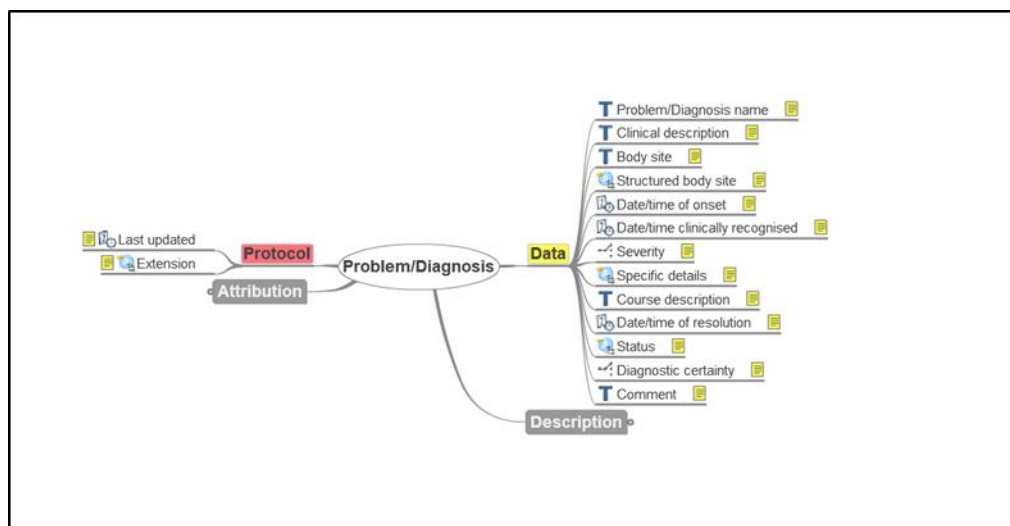


Figure 2. An illustration of an archetype as meta-data (openEHR CKM, 2017)

However, archetypes as ‘meta-data’ that are independent of a particular use context means that it will not be necessary to record all the information represented by every data string in all clinical contexts or situations. Therefore, archetypes can be tailored to different local clinical settings by removing or mandating data strings from the ‘meta-data’ model, which make the standardized clinical concepts highly customizable to various use contexts but still possible to share between different settings and health ISs (Beale, 2002). As part of the customization to local use contexts, it is possible to compose several archetypes into larger structures, denoted as templates, which correspond to screen forms, documents (e.g. an admission report), or eventually, national reports (Beale, 2000; Beale and Heard, 2007a; Duftschmid et al., 2010; Santos et al., 2012).

3.3.2 Empowering the domain experts; new roles and responsibilities

Traditionally, domain-specific knowledge (e.g. a clinical information model) is hard-coded by the vendor into the system’s software, and each system has its own information and database model. To enable sharing of clinical information, data need to be migrated and converted from a vendor-specific format to another. In contrast, archetypes are developed ‘outside’ a vendor-specific system by clinical communities and can be denoted as vendor-neutral clinical information models. Archetypes are, from a technical point of view, formal specifications of the clinical content within a record, and from a clinical perspective, they serve an intuitive means to define and present the clinical information created and recorded during a patient encounter. In this sense, archetypes can be interpreted as the ‘glue’ between clinicians and a healthcare system (Garde et al., 2007).

The key feature of the openEHR approach is that it informs domain experts or experienced clinicians how to model their healthcare practice through archetypes. The approach is supposed to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way

EPRs are built up using designed customizable ‘meta-standards’. This contrasts with the traditional proprietary ‘off-the-shelf’ systems that are ready to use or customized by the vendor. Archetype-based systems are ‘empty’ systems in which the clinicians need to determine and design up front the clinical data that is expected to be created and recorded during a clinical process. Following the openEHR approach, clinical communities are given new tasks and roles in fitting the technology into use by modelling archetypes and customizing them into use contexts by composing templates (Silsand et al., 2012).

The up-front design of clinical ‘meta-standards’ is based on an ontological analysis of the process of care delivery, aimed to produce an understanding of how ISs can support the creation and recording of information during the process. The different steps in a generic clinical process form the basis for which information will be needed to create, record and categorize the information in four different classes corresponding to an ‘archetype-class’ (Fig. 3).



Figure 3. Classes of information during a clinical process (Beale and Heard, 2007b)

As displayed in Figure 3, clinical **observations** together with clinical knowledge and the clinician's experiences form the clinical ‘opinion’, which results in a diagnosis, a plan, a goal and so on. This ‘opinion’ is documented with an archetype from the ‘**evaluation**’ class. The plans or goals are recorded by using ‘**instruction**’ archetypes and inform the clinicians about necessary actions. The performance of an instruction is documented with ‘**action**’ archetypes. To document the results from an ‘action’, ‘observation’ archetypes are used. However, the clinical process (or medical treatment process) is not connected to the organizational process, in which information about admissions, booking, referral and discharge are categorized as ‘administrative events’ ‘outside’ of the clinical processes (Beale and Heard, 2007b).

The increased abstraction level of modelling archetypes as ‘meta-standards’, independent of the use context, mean that the core set of archetypes need to be built by a relatively small group of clinicians (domain experts) given specific training in archetype design. The domain experts need to understand how key clinical concepts relate to one another in accordance to the conceptual clinical process and how to categorize clinical information in accordance to the four classes (Garde et al., 2007). However, ‘end-users’ (fig. 4) contributions of clinical knowledge about their different needs and the use contexts of

clinical concepts are crucial to enabling the design of ‘meta-standards’. Accordingly, archetypes need to be designed in co-construction between domain experts with extended knowledge about archetype design and end-users contributing with their clinical knowledge.

To support the clinical communities in the work with archetype design, the openEHR Foundation provides a web-based tool called the Clinical Knowledge Manager (CKM), whereby domain experts can develop, manage, publish and use archetypes or apply internationally agreed-upon archetypes and translate them to the national language and context. In addition, end-users can participate in the consensus processes when archetypes are in the ‘design loop’ (openEHR CKM, 2017). The web-based CKM enables flexible asynchronous communication between the different contributors in the design process (Atalag et al., 2016; Garde et al., 2007; Kalra, 2006; Silsand and Ellingsen, 2014; Ulriksen et al., 2016).

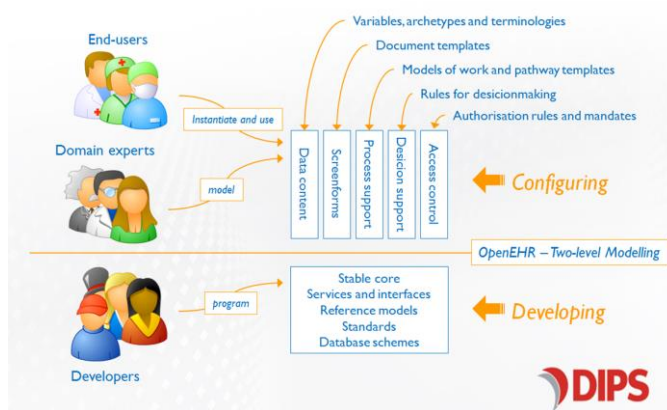


Figure 4. The openEHR platform approach

3.3.3 The need for an evolving repository of archetypes and archetype governance

The openEHR specification does not provide a list of archetypes or a complete CKM repository as part of the standard. Healthcare procedures and health data are not static, but develop with the progress in medicine. Subsequently, the openEHR approach will continually address the need for creating and maintaining archetypes and templates in relation to continual changes in medicine and different needs from medical domains and healthcare contexts. Building an international/national repository of archetypes is a living process whereby initiatives from clinical communities propose standards to be designed and issues them in ongoing programs that include provider organizations, clinicians, vendors and other stakeholders (Atalag et al., 2016; Freriks et al., 2007).

Archetypes designed in accordance to the formalized process and published in the international CKM can be used in any conformant EPR system. This means that the openEHR specification is not only an approach for modelling a specific health IS but also an approach for modelling a vendor-neutral II for

health ISs throughout the healthcare sector (Atalag et al., 2016; Chen and Klein, 2007; Garde et al., 2007; Kalra, 2006). In this sense, the archetype acts as a ‘construction plan’ and is the vehicle in a vendor-neutral health II (Duftschmid et al., 2010). However, if semantic interoperability is to be achieved between different health ISs within and between different organizations, the result depends on every system conforming to archetypes as interoperability standards for exchanging clinical information. In addition, the result of the interoperability depends on archetypes designed in accordance with the formalized process, systematically organized in agreement with the design principles from the openEHR community to ensure interoperability within and between systems (Chen and Klein, 2007; Garde et al., 2007; Freriks et al., 2007). Because clinical concepts overlap between various healthcare domains, such as nursing, an archetype for an oral assessment is applicable to knowledge domains other than nursing, and some archetypes need to be standardized based on a broader understanding of the clinical concepts as they are relevant for various health areas and specialist fields and between several organizations. If archetypes are define for local or for medical sub-fields only, overlapping concepts between healthcare domains may threaten the goal of semantic interoperability.

Even if the clinicians are promised to be in the ‘driver’s seat’ of the archetype development process, someone needs to take a formalized role in controlling and governing the process. Garde et al. (2007) defined the formalized role as ‘domain knowledge governance’, in which all tasks related to establishing or influencing formal and informal organizational mechanisms and structures to systematically influence the building, dissemination and maintenance of knowledge within and between domains (Garde et al., 2007). Domain knowledge governance (which is not depicted in Figure 4) relates to who will take the role of controlling and governing the process and how to organize the governance.

3.4 Connecting technology to clinical practice through the CSCW research field

An important ambition of CSCW research is to understand how healthcare work is collaboratively achieved in everyday practice and to design systems that may support collaborative practices in healthcare (Bardram, 2000; Cardoen et al., 2010; Dourish et al., 1996; Fitzpatrick and Ellingsen, 2012). Research from the CSCW field has contributed extensively in providing an understanding of how ISs or artefacts can support distributed collaborative work among groups of users by mapping out the complexities of coordinating daily activities and documenting practices among healthcare staff (Bossen, 2006; Bossen and Markussen, 2010; Bossen, 2011; Carstensen and Sørensen, 1996; Egger and Wagner, 1993; Fitzpatrick and Ellingsen, 2012). Accordingly, the notion of CSCW is useful in studying the design and implementation of the new innovative EPR system aimed to support complex healthcare processes.

Taking a historical perspective, the definition of the CSCW field has evolved from its first use in the early 1980s as an interdisciplinary workshop on how to support people in their work arrangements with computers to a research field of understanding the nature and characteristics of cooperative work, with the objective of designing adequate computer-based technologies. From this outset, the findings from CSCW research are used in different ways; some reflect on the findings to derive design implications at the same work-practice level, while others take a strategic position and reflect on their findings for more organizational and/or conceptual implications (Fitzpatrick and Ellingsen, 2012). In this thesis, the notion of CSCW has contributed with a set of concepts to unpack the complexities in situated clinical work practices. In this perspective, research within the CSCW field has been of importance throughout the thesis because of its way of exploring, describing and conceptualizing the collaborative nature of healthcare processes in relation to healthcare technologies (Egger and Wagner, 1993; Carstensen and Sørensen, 1996), even though the framework not is explicit in all the papers.

The concept of coordination has been central to the field of CSCW, and it draws attention to how coordination mechanisms structure actors' collaborative activities and support the articulation of those activities. In general, the focus on the use of artefacts that structure coordination tends to emphasize the way people and processes come together around objects, records, reports and information structures for coordination and collaborating purposes in different work domains (Bossen, 2006; Møller and Bjørn, 2011; Holten Møller and Dourish, 2010; Schmidt and Simone, 1996). However, collaborative practices and the coordination of activities have usually been studied in the context of how teams cooperate in small-scale workplace studies. Thus, workplace studies have been a key method to come to understand the collaboration and coordination of healthcare work, giving rich descriptions and understandings of situated practices, usually from clinicians' perspectives, and the ways that ensembles of spaces, artefacts and processes are brought into play.

The collaborative nature of healthcare is in contrast to the more commercial and often glossy pictures whereby individual physicians assess, diagnosis and prescribe treatments of patients (Kawamoto et al., 2005b). Healthcare processes are collaborative work processes built on coordination, awareness and an understanding of other's work tasks, as the actors take past, present and prospective activities into account when planning and conducting their own work (Berg, 1999; Carstensen and Sørensen, 1996; Egger and Wagner, 1993; Schmidt and Simone, 1996; Fitzpatrick and Ellingsen, 2012). Hence, when implementing new artefacts into an existing work practice of collaboration and coordination, the new artefact will affect the way the users that are involved have tacitly monitored each other's performance of activities to get the work done.

The CSCW field has proved to be a strong framework for conducting and analysing single-site workplace studies. While providing tools that focus on the micro-mechanisms of collaboration in a specific context, the CSCW field somehow lacks the ability to present a broader picture of understanding

the collaboration and coordination of many and various professionals, materials and systems across different contexts, during development, implementation and adoption (Fitzpatrick and Ellingsen, 2012, p. 22; Monteiro et al., 2012). Particularly when scaling up to explore and understand the implications for designing and implementing process-supporting systems spanning different work practices in time and space, the focus on mechanisms for collaboration and coordination in local contexts are too limited (Bossen, 2006; Bossen and Markussen, 2010; Fitzpatrick and Ellingsen, 2012). Accordingly, the increased demand for designing and implementing process-supporting health ISs requires an understanding of the collaboration and coordination involved in healthcare processes on a complete different scale than designing tools supporting single-site work practices (Ellingsen and Monteiro, 2003; Møller and Bjørn, 2011; Schmidt and Simone, 1996). In this perspective, the notion of an II is a renowned framework within IS research addressing large-scale, integrated and interconnected workplace information technologies (IIs), but with the same ambition to improve the design of computer-based systems to support the cooperative activities of collaborative practices (Fitzpatrick and Ellingsen, 2012; Monteiro et al., 2012).

3.5 Understanding the new EPR as an Information Infrastructure

To improve the understanding of how different artefacts and technologies are linked together, the collections of artefacts are interpreted as IIs (Hanseth and Monteiro, 1998; Hanseth and Lundberg, 2001; Monteiro et al., 2012; Star and Ruhleder, 1996). In this perspective, infrastructures are not some kind of purified technology; instead, the technology cannot be separated from social and other non-technological elements. II can be defined as a shared, open (and unbounded), heterogeneous and evolving socio-technical system, consisting of a set of IT capabilities and their user, operations and design communities. This definition highlights both the structural characteristics and the emergent properties of IIs that distinguish IIs from an IS (Hanseth and Lyytinen, 2010; Hanseth and Monteiro, 1998; p. 8). This description denotes that IIs are interconnected, distributed collections of systems, going beyond proprietary or ‘silo’ systems, as they span localities and temporal scales. Accordingly, a number of different health ISs are entangled with complex networks of healthcare professionals, activities, stakeholders and socio-technical networks, which comprise a complex II supporting healthcare processes (Berg, 1999; Berg and Goorman, 1999).

The notion of II has been used since the mid 1990s to refer to integrated solutions based on the ongoing fusion of information and communication technologies (e.g. communication networks such as the Internet or specialized solutions for communications within specific business sectors). However, today’s healthcare services have an increased need for easy access to relevant patient information to support cross-organizational patient pathways, which has led to more generic and over-arching IIs serving as common enabling components for a wider eHealth infrastructure, in example e-prescription systems,

message exchange between different healthcare providers, and shared emergency care record systems) (Aanestad et al., 2017). In facilitating eHealth infrastructures that go beyond organizational boundaries, standards are crucial components (Hanseth and Lundberg, 2001). In line with this, the openEHR approach is understood as an II supporting exchange of patient information within a system, as well as between systems within and between organizations, based on the exchange of ‘meta-standards’ (Atalag et al., 2016; Freriks et al., 2007).

The underlying and invisible role of IIs’ healthcare support processes

IIs often have an underlying, supporting and often invisible role involving of a set of technological components and organizational routines. Seen in the context of today’s healthcare services, the coordination of medical treatment and organizational processes is to a large degree conducted manually by clinical and organizational (secretaries and managers) personnel, in which the coordination has co-evolved with organizational structures, personnel skills and work routines over years (European Commission and Directorate-General for Health and Food Safety, 2015; Gibbons et al., 2007; Jaspers et al., 2011; Ministry of Health and Care Services, 2012). Therefore, an II is often deeply embedded into work routines across several departments and often taken for granted; an II’s crucial role is often only realized when instabilities occur, such as when substituting an existing system with a new one (Vikkelsø, 2005). For example, the consequences of implementing a paper form and replacing it with a digital version may not be fully realized if the paper form is interpreted just as an information carrier only and not also as a ‘signalling device’ for the coordination of work (Silsand and Ellingsen, 2016).

Understanding the complexities and mechanisms involved is a core ambition of II studies, and a holistic perspective of the object of study is required. This means that a researcher interpreting the object of study as an II (in this research, the new EPR) acknowledges the importance of focusing on how different users and contexts are related, how micro aspects (e.g. work practices) are related to macro aspects (e.g. large scale technology and/or collaboration over organizational borders), how the present relates to the past (e.g. how design and implementation of new systems have to take into account existing systems and practices), and the integrational aspects of how all components depend on each other and relate to standards (Bowker and Star, 1999; Hanseth and Monteiro, 1998; Hanseth and Lyytinen, 2010; Star and Ruhleder, 1996). Subsequently, research within the II field have taken different approaches in understanding and conceptualizing II, in terms of the convergence of technology and the implications for strategic management, the growth and dynamics of scientific infrastructures, the socio construction of standards, classification systems, management control, technological drift, complexity and risk, and meta-theoretical issues (Ciborra and Hanseth, 1998; Hanseth and Ciborra, 2007; Hanseth and Lyytinen, 2010; Star and Ruhleder, 1996). In this study, the aim has been to investigate the different interdependent factors affecting the development and implementation of the new openEHR-based EPR system, in which

the notion of II is used to frame and unpack the empirical process (Hanseth and Monteiro, 1998; Hanseth and Lyytinen, 2010; Monteiro et al., 2012; Pipek and Wulf, 2009; Star and Ruhleder, 1996).

Subsequently, the new openEHR-based system with its new and innovative technological capabilities has to 'blend in' the already existing II of work routines, existing systems and standards. A challenge is how the new and old can be fitted together, as the complexity and intertwined nature of IIs often make them difficult to change. However, a careful analysis of all its aspects can inform implications for the development and implementation of novel ISs (Aanestad et al., 2017; Hanseth and Lundberg, 2001; Ellingsen and Monteiro, 2003; Silsand and Ellingsen, 2014). By this understanding, two important characteristics of an II are presented below: the installed base and the enabling, shared and open function, both of which have implications for the design and implementation of new novel systems.

The installed base and strategies for II design

A basic principle of an II is that it is never built from scratch; rather, it evolves from the installed base of the existing IS portfolio and work practices in specific contextual practices (Monteiro et al., 2012; Star and Ruhleder, 1996). During the progression of an II in any given context, the installed base may become very large and will shape its environment to an increasing degree. Similarly, the size and complexity of the installed base, in terms of rigid work practices, technical lock-ins and a large number of users, means that it becomes difficult to change or replace. Therefore, newer versions are adjusted or changed carefully to maintain backward compatibility with previous versions (Aanestad et al., 2017; Bowker and Star, 1999; Star and Bowker, 2006).

The II evolution process is best captured by the notion of 'growing' (instead of e.g. 'building' or 'constructing') since it gives a 'sense of an organic unfolding within an existing (and changing) environment'. There is a 'recurring issue of adjustment in which infrastructures adapt to, reshape, or even internalize elements of their environment in the process of growth and entrenchment' (Edwards et al., 2007). These processes of infrastructure evolution happen along different dimensions of multiple contexts (spatial) and over extended periods of time (temporal) to understand the 'growth' of networks (Edwards et al. 2007; Ribes and Finholt, 2009; Karasti et al., 2010). It implies a process-oriented understanding where it becomes crucial to follow and analyse the historical sequence of events and decisions that shape the forming of infrastructures (Aanestad et al., 2017). Nevertheless, it is important to keep in mind that an installed base is not a given 'thing'; it is rather a conceptual tool that can help us to capture the continuities and discontinuities in infrastructure evolution (Aanestad et al., 2017; Fitzpatrick and Ellingsen, 2012; Monteiro et al., 2012).

In line with the evolutionary characteristic of an II, Hanseth and Lyytinen (2010) proposed a design theory with design principles for infrastructure development addressing the dynamic complexity of IIs. The suggested theory discusses the tensions between two design problems related to the II design: (1)

II designers have a *bootstrap problem*, as they have to come up early on with solutions that persuade users to adopt while the user community is non-existent or small – promoted through the slogan ‘users before functionality’. (2) The II has an *adaptability problem*, as it starts to expand by benefitting from the network effects and experiences a period of rapid growth. During this growth, designers need to recognize II’s unbounded scale and functional uncertainty, in terms of unforeseen and diverse demands, and produce designs that cope technically and socially with these increasingly varying needs. Accordingly, these two design-related issues contradict and generate tensions in the II design (Hanset and Lyytinen, 2010).

To some degree, these design principles have dribbled over into modern design methods. Typically, agile methods such as SCRUM, Extreme Programming (XP), and Kanban lean heavily on frequent interaction between users and designers (Kniberg, 2011). The involved vendor DIPS AS had applied an agile development approach related to the present EPR systems and its users. The essence of an agile development methodology is that users’ needs are important for changing the course along the way and for ensuring a robust result. A principal communication tool between users and designers is short narratives, denoted as ‘user stories’ formulated by the users. The stories inform the vendor regarding the users’ needs and enable the developers to design and deliver working software early on in the development process. Another important insight for IS research to succeed with the design and deployment of large-scale systems is the system’s ability to support customization and interoperability (Hanseth et al., 2012; Pollock and Williams, 2008; Rolland and Monteiro, 2002). Normally, a system working in a particular context is fixed in time and space (Berg, 1999), in which ‘transporting’ it to another context requires a complex work of disentanglement (Berg and Goorman, 1999). ‘Transporting’ a system from one context to another implies a tremendous amount of generification work. Pollock and Williams described generification work as ‘the supplier strategy of taking a technology that has worked in one place and attempting to make it work elsewhere, and, in principle, everywhere’ (Pollock and Williams, 2008, p. 129). The vendors have a central role in the generification process because they are responsible for both customizing the system to a particular context and taking it further to multiple other contexts (Wang, 2007).

To summarize this sub-section about the installed base as a conceptual tool to capture the continuities and discontinuities in infrastructure evolution, the design of an II from a technical point of view involves discovery, implementation, integration, control and coordination of increasingly heterogeneous IT capabilities. From the social viewpoint, the design of an II requires organizing and connecting heterogeneous actors with diverging interests in ways that allow for II growth and evolution.

The enabling, shared and open function addresses the need for standardization

An II is characterized by its supporting or enabling function, which means that it is designed to support a wide range of activities, not tailored to one specific activity. The enabling function is intended to open

up a field of new activities, not just to improve something existing, which often affect the distribution of responsibilities and hierarchies and introduce new roles and routines/procedures – and play important roles in policy documents (Hanseth and Monteiro, 1998). An infrastructure is shared by a larger community (or collection of users and user groups), and the need for more generic and over-arching II to support cross-organizational patient pathways expands the communities to share the II even more. IIs are also characterized by openness, in the sense that the number of users, stakeholders, vendors, nodes in the network and other technological components, application areas, network operators and so forth has no limits.

The fact that infrastructures are open and shared, which enables support for a wide range of activities, implies that different components are connected through shared standards. Scaling the development of an II involves stakeholders who may already have invested a great deal of resources in different technologies (Aanestad and Jensen, 2011). To bridge the various infrastructures based on different protocols and standards, standardized gateways are needed for interconnecting the different infrastructures to provide some coherent services. Accordingly, IIs depend heavily on standards to enable the evolution in scope and functionality. Standards are a key means by which an infrastructure is architected, and they establish whom will be inscribed in its development (Hanseth and Lyytinen, 2004, p. 215).

The success with design and deployment of large-scale systems is dependent on the support of local customization on the one hand (bootstrapping mechanisms), and interoperability through standards and continuity (global) on the other hand (theme of adaptability). In much of the existing research, users are viewed as important in the evolution of II. The relational aspect offered by Star and Ruhleder (1996) states that it is what the users do to the II that makes it grow, which matches with the prominent role that healthcare personnel are given in the openEHR approach. The verb ‘to infrastructure’ denotes the activities and processes of integrating materials, tools, methods and practices that make up and change an II, which are activities mainly done by users (Star and Bowker, 2006; Karasti et al., 2010; Pipek and Wulf, 2009). However, the activities done by users will take on new forms in relation to the evolution of an openEHR platform approach where the clinical communities are given a new and prominent role in the standardization and customization processes. Accordingly, the design and implementation strategy of an openEHR platform-based II must deal with multiple new actors and be able to mobilize and coordinate them to succeed with the standardization (Aanestad and Jensen, 2011; Hanseth and Monteiro, 1998).

4 Method

The method chapter includes five sub-sections. The first section is about the interpretive case study approach and its ontological and epistemological foundation. In Section 4.2, follows a description of the

biography of artefacts approach for addressing the need to expand the focus of case studies longitudinally and across different social settings to encompass multiple moments, sites, and the different phases of both short-time dynamics and longer-term evolution. The third section, 4.3, data collection, describes in detail how the empirical data have been collected, and the analyses follow in Section 4.4. The last section, 4.5, reflects the ethical considerations related to my role as a researcher and how this study was conducted.

4.1 Research approach

This PhD study adheres to an interpretive case study approach aimed to provide insights about the key mechanisms at play during the development and implementation of an openEHR-based EPR. Interpretive research has emerged as an important strand in ISs research over the past decades and has led to the adoption of empirical approaches focusing particularly on human interpretations and meanings (Walsham, 1995; Walsham, 2006). Research in the IS field investigates the phenomena that emerge when a computer-based system and a social system interact through social constructions such as language, consciousness/observation, shared meanings and documents. Since the deployment and use of technology is closely intertwined with social aspects, an interpretive research approach is useful at ‘producing an understanding of the context of the IS, and the process whereby the IS influence and is influenced by the context’ (Klein and Myers, 1999, p. 69; Walsham, 1995, p. 4–5).

The ontological underpinning of the interpretive approach is that social reality is produced through the actions of humans. Accordingly, humans produce and reproduce their social world through their subjective meanings, actions and interactions. Meanings are formed, transferred, used and negotiated, and consequently the interpretations of reality may shift over time as circumstances, objectives and constituencies change (Orlikowski and Baroudi, 1991).

Following the ontological belief implies that the empirical field is social constructed, not fixed – but constantly undergoing changes. Thus, understanding empirical processes requires an in-depth examination of the phenomenon of interest. In this thesis, the phenomenon of interest is the socio-technical interdependencies affecting the development and implementation of a new EPR, which seeks an understanding of how the evolving process is spelled out, and how it shapes and is shaped by the people involved (clinicians, stakeholders and developers), the new technology, the existing practices, actions and interactions. The essential objective is not to identify the causes of behaviour, but rather the meanings people assign to actions and events and changes along the process (Walsham, 1995).

Subsequently, the interpretive approach assumes that social realities are not discovered, but interpreted by the people involved (Myers and Avison, 2002). Hence, the starting point in interpretive research is not to write predefined hypothesis or predefined variables. Conducting interpretive research implies studying what is ‘out there’. Interpretivism upholds that the reality and our knowledge thereof are social

products and hence incapable of being understood independent of the social actors – including the researcher(s) that construct and make sense of the reality. Following the epistemological belief of the interpretive approach emphasizes the understanding of social processes by getting involved inside the world of those generating them (ibid.). Accordingly, setting up and carrying out fieldwork is the fundamental basis for any interpretive study (Walsham, 2006).

Interpretive fieldwork is much inspired from ethnography in producing an in-depth understanding of real-world social processes and addresses the need for ‘thick’ descriptions, which are important in trying to understand what is happening in relation to a new and innovative EPR system, involving managers, users and developers. However, the vehicles for an interpretive investigation are in-depth case studies focusing on empirical processes from the view and intentions of the human actors themselves. This requires frequent visits to the field site over an extended time, in contrast to ethnographically fieldwork that calls for a lengthy stay (Walsham, 1995). Case studies can be characterized in several ways. In this thesis, the cases have a descriptive framing that is used to describe the evolving empirical process from different perspectives and contexts. By this understanding, it follows that the empirical field is not fixed to a specific physical context out there waiting to be explored by a researcher. Rather, the empirical field is a multifaceted constellation of people, the evolving technology, activities, and relations – even if some continuities are apparent across the constellations. Accordingly, the ‘field’ site is constructed reflexively by every choice that I, as a researcher, make in selecting, connecting and bounding the site through interaction with the people involved. Making the choice to follow the development track for the PDS system and the structured record in the early phase of the research project had consequence for the overall construction of the research field compared to other choices I could have made (Blomberg and Karasti, 2013).

To conduct interpretive fieldwork to produce in-depth understandings of the socio-technical interdependencies influencing the realization of an open-platform-based EPR, it was necessary to include different perspectives and points of views. Research methods seeking to answer ‘how’ questions (e.g. ‘how did the development process evolve’ and ‘how did the new technology influence the developer-user collaboration’) are required. Consequently, the researchers need different tools, methods and techniques, such as observational participation, semi-structured interviews and document studies (Klein and Myers, 1999; Walsham, 1995) in conducting interpretive fieldwork. The collection of data during this study will be further elaborated on in Section 5.3.

4.2 The Biography of artefacts perspective (BoA)

In the rise of many large-scale ISs, they are expected to encompass entire organizations and include practices that may differ from each other quite considerably, resulting in varying types of user needs and requirements (Mackay et al., 2000). This contrasts earlier decades of IS projects, in which systems

often were developed and implemented locally. Another complicating factor is that the development of these large-scale systems typically extends over considerable time, where policies, budgets, artefacts, suppliers, users, work practices and visions of organizational improvements change. The biography of artefacts (BoA) underscores the importance of moving beyond episodic studies of technology design or organizational implementation settings to the evolution of workplace technologies over multiple cycles of design and implementation. Pollock and Williams (2010) criticized the fact that much of the research into technology and work organization is about single-site implementations of artefacts with limited numbers of users, while we see the emergence of large-scale health ISs intended for long-term use with multiple use contexts and users.

This thesis followed the realization of an open platform-based EPR system to be used in several hospitals in the region. Investigating and understanding the socio-technical interdependencies affecting the evolving EPR system made it necessary to expand the focus of research longitudinally and across different social settings and scales, addressing multiple moments and sites of innovation. I found the BoA perspective interesting in relation to the focus in this thesis and the empirical project's large-scale development and implementation. In addition, as the empirical project evolved, it became evident that the development process and outcomes of the new open platform-based EPR was shaped by a broader context (Johnson et al., 2014).

The BoA approach is not a method; rather, it is a strategic research approach applying different methods and data sources, just like the interpretive field research approach, which presupposes the data to be analysed in a broader perspective. Accordingly, 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 and help to form sufficiently rich observational units to characterize ISs as an extended field of practice (Pollock et al., 2003).

4.3 Data collection

The data have been collected from the initial start of the FIKS program in January 2012 and through different phases of the projects until it was finalized in January 2017. From January 2017 until December 2017, I have observed the establishment of the new program FRESK (an extension of the FIKS program), and I have been participating in the National Editorial Group for Archetypes. In this period (01.01.17 – 01.12.17) there has not been conducted interviews or participating observations for a research purpose, but I have 'kept an eye' on the evolving process. However, the most intensive period for data collection was from 2012 to June 2014. In the paper 'The Biography of Participation', Bente Christensen conducted parts of the data collection by formal and informal interviews, participant observation and document studies.

Interviews:

During the research project, I conducted 31 semi-structured interviews, in which two interviews involved groups of three and two people. The informants, who are only presented as groups to ensure anonymity, are listed in Table 3. Each interview lasted from 45 to 90 minutes.

Informants	Number
Healthcare personnel (physicians, nurses, secretaries)	12
FIKS project members and members of the local/regional governance organization	8
Developers and managers at DIPS ASA	11

Table 3: Semi-structures Interviews

When selecting informants, I tried to get perspectives from the different stakeholders in the project, as well as from different healthcare personnel and developers involved in the process. The interviews were scheduled in advance, and the informants were mainly recruited after I was introduced to them through participant observation in workshops or other project activities. The interviews of the developers at DIPS were agreed upon through email correspondence. In periods of low workshop activities in the empirical project, email was used to recruit healthcare personnel as informants as well. Every informant was given information about the research project in advance of the interview, either by mail or in person, including information about confidentiality and anonymity. The participants were notified that they would not be identified and that their specific positions in written work or in presentations would not be revealed. Every informant gave me permission to use the information for the research purpose and to tape record the interview. The interviews were conducted mainly at the informants' workplaces, except for two interviews conducted at my workplace.

I prepared themes for an interview guide before each interview. The themes were based on observations and reflections related to 'hot topics' at the point of time during the evolving project. However, the interview guide had to be flexible in accordance to the informants' interpretations of the ongoing project, and the interview situations were more like dialogs in which the informants could ask the interviewee(s) questions as well. After each interview, I listened to the recorded material and transcribed it or wrote down themes or issues of impression. This was an approach of great value because if something was unclear, I could follow up the theme in informal talks or ask the next informant for his or her interpretation.

Conducting interviews is not about preparing interview guides and asking questions only. To get access to the informants' opinions and interpretations requires social skills and sensitivity to the specific

situation. The informants should be encouraged to reflect and seek a deeper understanding of their interpretations and meanings. This is a difficult skill to learn for a novice researcher.

Participant observation

The research's purpose and methodological approach addressed the need for attending different venues where the empirical process took place. I started in the PhD position at the same time that the FIKS program set off. The first meetings included participating in workshops with developers from the vendor, clinicians and project members from the FIKS program involved in design activities regarding the new EPR. Because of my background as a nurse, I saw it as important to get 'inside of the developers world' to better understand their perspectives and interpretations of the empirical process. The vendor invited me to spend time with the developers, and I was an observer through their daily work, listening to their discussions and participating in meetings for one week (November 2012). I have participated in an extended number of 'sprint reviews', where the vendor presented the functionalities of the new EPR in progress to the users, both in physical meetings at the University Hospital of Northern Norway and via videoconference meetings. I took part in numbers of project meeting in the FIKS program and in the local governance department responsible for piloting the surgery-planning module. Together with developers and healthcare personnel, I participated in testing and piloting the functionality of surgery planning.

From 2012 to June 2014 and in the spring of 2016, I participated in activities related to the EPR in progress as much as possible. I had a particular focus on activities related to developing a PDS functionality, which merged with developing surgery-planning functionalities by the end of 2012. In the spring 2016, I also took part in workshop activities arranged by the Electronic Charting – and Medication Project. Furthermore, I took part in a meeting initiated by the local governance organization's resource-group for archetypes, focusing on how to organize the work with archetypes on a regional level.

The fieldwork for Paper 3, 'Complex Decision-Making in Clinical Practice', is slightly different from the other papers because it was conducted in a local improvement project at the University Hospital. The aim of the project was to improve the clinical pathway for acute geriatric patients, which started with designing and implementing a decision-supporting tool for triage of elderly patients in the emergency unit. I saw this as an opportunity to get valuable insights about developing and implementing clinical decision support because the improvement project had a much shorter duration time compared to the FIKS program. In addition to the PhD engagement, I was working in a part-time position at the Internal Medical Clinical where the improvement project was initiated. I got the permission to follow the project manager's way of working in the clinical field (e.g. motivating, aligning and engaging clinicians to participate in the project). The project manager was obliging and allowed me to share her office one day a week. Working in physical proximity to the project manager gave me an opportunity for rich discussions about the evolving project and its obstacles and to participate in ad hoc meetings

and formal and informal discussions with other project members and clinicians. Furthermore, being an observer of the evolving project led to acquaintance with the particular medical practice and its organizational challenges. The emergency unit was a central object for doing fieldwork, and for one week, I observed how the clinicians cooperated with each other and with clinicians from other hospital units. The observation also included bedside use of the form when junior physicians assessed acute geriatric patients. In addition, I collected data through interviews with project members and the clinicians involved, participant observation in project meetings, workshops with physicians, informal meetings with project members and project documents throughout the project.

An important tool when doing fieldwork has been my notebook. I have taken extensive field notes during my participation in different field sites (estimated at 10 notebooks of 80 pages of A4 size).

Document studies

I have explored documents, reports and minutes from the FIKS program and reports from the National ICT on ICT architecture and openEHR/standardization strategy, national strategies and visions for eHealth. In accordance with Paper 3 ‘Complex Decision-Making in Clinical Practice’, I have explored the reports and minutes from the improvement projects. All these documents added to my general understanding of the interdependencies influencing the realization of an open platform-based EPR system.

4.4 Data analysis

The objective of analysing the collected data is to organize and structure the gathered material to generate an understanding of how the socio-technical interdependencies influence the evolving open platform-based EPR. As denoted in ‘Research approach’, ‘thick’ detailed case descriptions are needed when trying to understand what is happening in connection with a complex computer-based IS such as the new EPR and the different actors and sites involved (Klein and Myers; 1999 Walsham, 1995). In addition, a thick description of the empirical field provides the readers with a look into the empirical field. This is an important aspect in justifying the research approach, in which ‘authenticity concerns the ability of the text to show that the researchers have ‘been there’ by conveying the vitality of life in the field’ (Walsham, 2006, p. 326).

However, the analysis actually starts during the data collection process because being in an empirical process – through observing participants, talking to them and doing interviews – starts shaping perspectives related to the phenomena of interest (Klein and Myers, 1999; Myers and Avison, 2002; Walsham, 1995). The collecting of field data through participant observations formed the basis for the themes to follow up towards an overall understanding of the evolving empirical process. Accordingly, ‘hot topics’ from the fieldwork shaped the selection of informants and the foci for the interviews. As I described under the section ‘Interviews’, I transcribed the interviews or wrote down themes or issues of

impression when listening to the recorded material, which were taken within the evolving understanding of the empirical process, often addressing new issues to focus on when going back to the field. In addition, to shrink the amount of transcribed material, I used colours to code the interviews in relation to the topics the informant explained. This manual method of colour coding made it easier to put together and compare the different meanings and interpretations from the different informants in relation to the themes or issues in focus.

Accordingly, the order of observing participants and conducting interviews was not lined up as observation first and then interviews. Rather, it was a back-and-forth process of doing fieldwork and making interviews. Hence, the understanding of how the socio-technical interdependencies influence the evolving open platform-based EPR involved an iterative process of ‘understanding a complex whole from preconceptions about the meanings of its parts and their interrelationships’ (Klein and Myers, 1999, p. 71). Subsequently, the themes and case descriptions for each paper included in this thesis represent an evolving understanding because the analysis of the empirical process does not stop when a paper is finished. Hence, the analysis of the empirical data for one paper becomes the preconception for the next case description – in which the understanding can be adjusted as the process proceeds. The interpretive process, informed by the hermeneutic circle, constitutes evolving issues that provide new understandings about the development process (Klein and Myers, 1999; Walsham, 1995). In light of this, interpretive research has been criticized for being heavily dependent on the researcher’s interpretation of the field to be studied and the documents and interview materials, which make it difficult to generalize the findings in the same way as a positivist research approach, for example. However, in accordance with the philosophical framework, theory plays a crucial role in interpretive research, in which the theory is used as a ‘sensitizing device’ to view the world in a certain way (Klein and Myers, 1999). An interpretive approach argues for using theory 1) to inform the initial guide to design and data collection 2) as part of an iterative process of data collection and analysis and 3) as the final product of the research (Walsham, 2006). In this PhD study, theory has been used both to inform the data collection and as part of the iterative data collection and analysis, with the aim of generalizing the findings from this particular empirical process and making the findings interesting for other organizations and contexts.

4.5 Ethical considerations

My role as a researcher

As already described, the interpretive approach assumes that social realities are not discovered, but interpreted by the people involved – including the researcher (Klein and Myers, 1999; Myers and Avison, 2002; Walsham, 1995). This means that it is important to critically reflect on how the research materials or ‘data’ were socially constructed through the interaction between the researchers and

participants (Klein and Myers, 1999, p. 72). Accordingly, interpretive researchers attempt the difficult task of accessing other people's interpretations, filtering them through the researcher's own conceptual apparatus and giving a version of events back to others. Accordingly, the presented case descriptions and analysis of the data are biased by our own background, knowledge and prejudices to see things in certain ways and not others (Walsham, 1995; Walsham, 2006). However, it is important to notice that prejudgment is not considered as a bias in interpretive research, but as the necessary starting point of our understanding of the field (Klein and Myers, 1999).

My background is from the clinical field, as I have worked as a nurse for several years and in different roles as being 'on the floor' to administrative roles. During the PhD study, I continued in a part-time position at the Internal Medical Clinic, which encompassed doing clinical work, organizing the clinical training for nurse students and being part of the clinical nurse advisor team. Since February 2016, I changed my part-time position and started to work at the Governance Department for Clinical ICT systems at the University Hospital and was transferred to the Regional Governance Department for EPR systems when the department opened in January 2017. This background has affected my perception of the ongoing empirical process and informed my choices for the issues to be explored.

Entering the empirical field as a novel researcher made it tempting to take a role as a 'clinician'. I had not reflected thoroughly about my role before entering the field. Subsequently, during the first developer-user workshop, I found myself as a clinical resource during the first workshops – instead of being a participating researcher. Knowing the clinical field and contexts where the EPR system is to be used, it was easy for me to perceive the clinicians' contributions during the workshops. However, the 'insider' role might also bring forward weaknesses to the research process; 'it does not make one an accurate observer as such because the job is not to replicate the insiders' perspective (Forsythe, 1999). Being an 'insider' from the clinical field has presumably made me overlook strands that I should have given more attention to during the data collection process. The researcher's role is to bring about and analyse the informant's perspectives through systematic comparisons between inside and outside views of particular events and processes. However, I found that the best way of solving this problem was taking field notes. Then, I was 'occupied' with listening and writing when being in the field and could not reflect on how the empirical process evolved from a mental distance, in terms of taking the 'bird's view' on the process (ibid.). In addition, to balance my 'insider role', I had to spend time in the 'developers' world'. To have a 'training-post' at the vendor's site was necessary to gain a better understanding of the developers' perceptions and needs in this process, which also made me more prepared for interviewing informants from the vendor's field.

When entering the PhD position, I soon realized that it would be a steep learning process: on the one hand, changing from hospital work to positioning to an academic role, and on the other hand, changing the theoretical framework from nursing science to the IS field. Consequently, I found it difficult to write

case descriptions because I found much of the descriptions to be trivialities of the clinical field. However, the CSCW research gave me theoretical concepts to describe and analyse the everyday practice I used to be a part of and to explain work practices and collaboration in general. This process contributed to my understanding of which kinds of observations and inputs are demanded in developing PDS clinical systems.

Conducting interviews is also an issue of developing skills. Doing my first interviews, I had planned up-front important issues to ask. As a novel researcher, it is of importance to be prepared before doing the interview. It takes training to conduct more open-ended interviews, as you have to address issues to discuss and simultaneously listen to the informant to provide follow-up questions. However, I believe that reflecting on my own role as an interviewer and listening to the interviews to learn the ‘art of doing interviews’ have improved my skills. As Forsyth (1999) observed, interviews conducted as dialogue provide room for mutual learning and knowledge sharing.

Being an ‘insider’ from the clinical field had its positive and negative implications. However, entering a new academic field somehow turned me into an outsider with inside experiences that helped me analyse the empirical process. However, during spring 2016, I started to work at the Governance Department, particularly working with national and regional archetype processes. I changed from being an ‘outsider’ with inside experiences, to be an ‘insider’ having two positions: as a researcher and as a participant in the empirical process. I recognized that I changed focus on the archetype work, in terms of losing critical distance to the work with modelling archetypes and perhaps presenting it from a too-limited view.

Treating the informants

Informed consent is essential in conducting research involving human participation and is incorporated into the legislation in almost every industrialized country (The Norwegian National Research Ethics Committees, 2017a). The informants were given information about the research and its purpose when I contacted them by email. Before the interviews, I gave oral information about the research project, and the informants had to sign the informed consent form before the interview started. The methodological approach requires an open and inquiring attention to the informants’ stories, in which there is an ethical obligation in communicating the informants’ stories and perspectives correctly. This also means that the informants’ perspectives have to be put into context because if not, quotes can be used as ‘evidence’ for wrong conclusions (Klein and Myers, 1999; Myers and Avison, 2002; Walsham, 1995). Nevertheless, when processing and analysing the information, the informant may feel misunderstood or that the information they have given was ‘picked apart’ in such a way that the whole was illuminated differently than the informant initially meant. To respond to this concern, I sent the transcribed interviews back to some of the informants so that they could read through them and give comments. I also sent a part of a case vignette back to an informant for comments. This offered an assurance that the informants found

the communicated material appropriate and not decontextualized because the research approach inhabited an interpretation of the informants' interpretations (Walsham, 1995).

Anonymization of the informants is also part of the informed consent, and it is my responsibility as a researcher to comply with it when writing the case descriptions. This can be challenging, not in terms of making their name and profession anonymous, but because a small number of informants are recruited from the same empirical context. If I describe a role within the vendors, FIKS program or hospital setting, it might be easy for an insider to reasonably determine who this person is.

Even if written individual informed consent is basic in all research involving humans, this claim is difficult to obtain in some situations. To ensure that the ethical principles – such as confidentiality, informed consent and the integrity of the research subjects were complied with, when gathering data through participatory observation in different contexts for example in workshops or in hospital settings, my presence as a researcher and the research's agenda were announced in the beginning. However, I am not absolutely sure that every participant in the different settings understood their roles as 'research objects' when their participation was not primarily related to the research purpose (The Norwegian National Research Ethics Committees, 2017b).

The PhD study collected and processed personal information and interpretations that can be linked to individuals, although all the information was anonymized. Accordingly, the study was reported to the Personvernombudet (Data protection Supervisor) at the University Hospital of Northern Norway. In addition, the study was reported to the Norwegian Social Science Data Service (NSD) because I have a student position at the Arctic University of Norway (UiT), which uses NSD as Personvernombud (Data protection Supervisor) for research. The PhD study was approved in both instances.

5 Results

This thesis includes five papers published or submitted to conference proceedings and peer-reviewed journals. The papers' titles are as follows:

- Paper 1. Silsand, L. and Ellingsen, G. (2014). Generification by Translation: Designing Generic Systems in Context of the Local. *Journal of Association for Information Systems*, vol. 15, no. 3.
- Paper 2. Christensen, B., Silsand, L., Wynn, R. and Ellingsen, G. (2014). The biography of participation. In *Proceedings of the 13th Participatory Design Conference*, 6-10 Oct. Windhoek, Namibia: pp. 71–74.
- Paper 3. Silsand, L. and Ellingsen, G. (2016). Complex Decision-Making in Clinical Practice. In *Proceedings of the 19th ACM Conference on Computer-Supported Cooperative Work*

& Social Computing (CSCW '16), San Francisco, USA, pp. 993-1004 (Best Paper Award).

Paper 4. Silsand, L. and Ellingsen, G. (2017). Governance of openEHR-based information Infrastructures. Submitted to 'Special Issue of the Journal of Computer Supported Cooperative Work on Healthcare infrastructures for governance, quality improvement and service efficiency'.

A former version of the article exists as:

Silsand, L. and Ellingsen, G. (2016). The Implication for Organisation and Governance Through User-Driven Standardisation of Semantic Interoperable Electronic Patient Record Systems. MCIS 2016 Proceedings. 63.

Paper 5. Silsand, L. (2017). The 'Holy Grail' of Interoperability of Health Information Systems: Challenges and Implications. In Proceedings of the 8th Scandinavian Conference on Information Systems (SCIS 2017), 6-9 August, Halden, Norway vol. 294. pp 140-154.

The papers are presented in the order that I wrote them (The new version of Paper 4 included in this thesis has gone through a major review, and was finalized after Paper 5), and they illustrate how the PhD project evolved through different phases and contexts. The papers also illustrate how the development process evolved from designing functionality for specific clinical use to a large-scale II encompassing different clinical contexts: technical, organizational, governance, and politically textured interdependencies.

The rest of the section contains a summary of the papers with a focus on the findings of each paper.

Summary Paper 1: Generification by Translation: Designing Generic Systems in Context of the Local.

In this paper, the FIKS program (referred to as the BigInvestment project herein) is studied, from the initial user-developer workshops to software tests in user groups. The focus is on the vendor-user-developer collaboration and the emerging change of the collaboration is highlighted. The idea of an open-platform approach is that the vendor develops the technical generic reference model, separated from clinical information models defined by clinical communities. In contrast to the idea, the empirical case demonstrated how the design of the generic reference model occurred in co-construction with local practice.

First, the vendor-user collaboration is explored in terms of how it evolved from using an agile development approach asking for short contextualized user stories to the developers' need for narratives

to capture cross-organizational healthcare processes. How and to what extent local practice is embedded in the design of the generic reference model in openEHR-based systems are explored.

Second, the process whereby users' needs are translated into generic functionality is examined, as well as how this functionality is presented to the users in a way that makes sense to them. Due to the generic software's global foundation, it creates a tension with local practice that is often hard to reconcile. Star and Ruhleder (1996, p. 114) argued that 'An infrastructure occurs when the tension between local and global is resolved'. In this paper, we defined the clinicians' work in daily practice as local and the design in accordance with the international openEHR framework as global. We found the notion of translation (Carlile, 2004) helpful as a generification strategy that helps the developers to solve the global/local tension. The designers had to translate the context-bound workplace descriptions into technical or conceptual counterparts that could inform the design of the customizable components in openEHR. Accordingly, the designer developed generic software, in a specific context, to be able to explain to the users how an openEHR approach can possibly support local customization.

Third, the paper discusses how the design strategy gradually changed throughout the project period. From initially being characterized as a lightweight design process, it increasingly turned towards heavy up-front design. However, it would be a mistake to frame the process as a traditionally design strategy by a clear distinction between design and use (Hanseth and Lyytinen, 2010; Karasti et al., 2010; Pipek and Wulf, 2009) because the empirical case illustrates the necessity of a close and transformative design/user interaction. Therefore, in this paper, the change in design strategy is seen as a generification strategy whereby the vendor needs to take a step back and strategically plan how to conceptualize and develop the new open platform-based system (Pollock and Williams, 2008).

Fourth, the findings of the paper have implications for practice. First, we suggest that designing an open platform-based reference model calls for a flexible vendor that is willing to change and adjust its development strategy along with the evolving project. Second, to strengthen the user-developer collaboration, we highly recommend giving the user-participants, at the very early stage of a development project, a basic understanding of the technology and software design related to their role in the development process. Third, even if the paper did not put a particular focus on the project management's role, it is clear that the management's engagement in recruiting clinical personnel and in making it possible for the clinicians to participate in a project is of great importance.

Summary Paper 2: The Biography of Participation

In this paper, the extended vendor-user collaboration related to the development process of the open platform-based EPR system is investigated. The empirical data were gathered from January 2012 to June 2014. The data collection was conducted by the first and second author, which led to rich material spanning over different empirical settings and a comprehensive interview material. The focus of the

paper is how user participation in the design-process changes along the path of the evolving open platform-based EPR system. Following the Scandinavian tradition of user participation in the design of technology for workplaces (Simonsen and Robertson, 2012), an extensive user participation was planned and is emphasized as crucial to the FIKS project.

The paper applies the concept of BOA and practices (Johnson et al., 2013; Pollock and Hyysalo, 2014) in analysing how user participation changes in different phases of large-scale development projects, including when and where to include them along the path of the evolving open platform-based EPR system. The 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 contexts shape innovation processes and outcomes (Johnson et al. 2013). By tracking the movement of entities (artefacts, practices, etc.) across organizational boundaries during the development process, the BoA helped to identify new spaces, sets of relationships and classes of actors that together constitute the knowledge needed to inform the development process software to support cross-organizational healthcare processes.

Accordingly, user participation is not simply a matter of participation, but has to be entangled with the product to be developed (Markus and Mao, 2004). There has been a rise of many large-scale ISs that challenge our understanding of how to integrate users in their development. The systems are expected to encompass entire organizations and include practices that may differ quite considerably from each other, resulting in varying types of user needs and requirements (Mackay et al., 2000). 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, end-users such as secretaries, physicians and nurses from all the 11 hospital within the health region participated in the development project. However, they did not have the overview of clinical pathways that was necessary for defining support for healthcare processes encompassing both medical and organizational processes crossing organizational boundaries. This addressed the need for a new kind of user in the design process: people with considerable organizational competence, such as managers and clinical pathway coordinators.

By using the BOA perspective, the changing strategy of user involvement in longitudinal development processes across various practices is explained. The implication is that the nature of participation is difficult and has to be modified during the development process. The recommendation is that the initial phase of the large-scale IS development process will benefit from users with considerable organizational knowledge (e.g. patient pathways coordinators and managers) before diving into the details of situated practices where clinicians are the expert users.

Summary Paper 3: Complex Decision Making in Clinical Practice

In this paper, the design, implementation and implications of the use of a clinical decision support (CDS) form for the triage of elderly patients in the emergency unit are studied. The form was considered the first step in generating an acute geriatric patient pathway to ensure that these patients are admitted to the in-patient clinic specialized for diagnosing and giving treatment and care to elderly patients suffering of acute confusion or functional deterioration. The data collection for this paper lasted from early 2012 to spring 2015. The focus for this paper is to explore the key challenges of designing and implementing decision-supporting systems in clinical practices.

The paper demonstrates how the empirical project in close collaboration with the clinicians resulted in the design of a paper-based form. The form was tailored to the organizational workflow at the local site of the emergency department and pilot tested in real clinical patient cases over a period of two months. The results of the pilot were promising. The paper form was transformed into the EPR system, in which the feedback from the physicians during pilot testing was implemented in the electronic form. The design of the decision-supporting tool had taken into account the physicians' needs, but implementing an electronic form into ordinary clinical work routines was a much more complex task than presumed and revealed by the pilot test.

By using theoretical perspective from the CSCW field (Berg, 1999; Carstensen and Sørensen, 1996; Egger and Wagner, 1993; Johannessen and Ellingsen, 2009; Kane and Luz, 2006) and the notion of IIs (Monteiro et al., 2012), the paper reveals how the design and implementation of a small locally situated CDS tool scales to infrastructural dimensions related to the existing clinical practices, systems and the hospital's management policy. The perspectives from the CSCW field support the initial strategy of the empirical project by engaging the users and tracing out the local interdependencies as a point of departure. To promote initial use, it is important to design a first version of the new artefact, so it can deliver necessary value to the users and motivate adoption. However, as an electronic form, the local use was disentangled from the organizational processes, in addition to influencing and being influenced by healthcare processes in other departments. The case demonstrates how the use of a paper-based form for decision support in a local context can be scaled to clinical and organizational interdependencies beyond the local context of use. The consequences of implementing a paper form and replacing it with a digital version was not fully predicted. The artefact was interpreted as an information carrier only, not as a 'signalling device' for the overall coordination of work.

By using the notion of II, the evolving complexities were dismantled: organizational, clinical and human/politics/behaviour interdependencies, which are the key challenges for design and implementation in clinical practice.

Putting the empirical case in the wider perspective of improving healthcare through standardized patient pathways, we argue that scaling complexity may appear despite apparently thorough planning, competent project leaders, committed management and involved users. To some degree, this complexity may be inherent in the design and implementation of the decision- support tool itself. An ‘extended design’ perspective is argued for when designing and implementing decision-support systems to capture how workplace technologies and practices are shaped across multiple contexts and over extended periods. Because IIs evolve, they shape and have to be shaped by existing practices and systems (Johnson et al., 2014; Karasti et al., 2010; Møller and Bjørn, 2011). Therefore, studying and evaluating evolving infrastructures in ‘short-term temporal aspects’ will not capture the essential interconnections and interdependencies that occur over time (Ellingsen et al., 2013; Karasti et al., 2010; Monteiro et al., 2012). A practical consequence is that wide-ranging contextual implications are not easy to detect or to solve during a limited project period, but have to be addressed to the management at different departments or to the general management level as well.

Summary Paper 4: Governance of openEHR-based Information Infrastructures

Empirically, this paper is an interpretive case study that draws on the development process of a new openEHR-based electronic patient record (EPR) system in the North Norwegian Health Region over the period January 2012 to December 2017. The first version of the paper was accepted for the Mediterranean Conference on Information Systems 2016. The paper included in this thesis has gone through extensive modifications in both the theory and discussion sections, aimed at improving the account and making the contribution more coherent. The paper looks into the openEHR specification as an approach toward common interoperable standards to ensure that clinical information is understood and interpreted consistently across various contexts (Bowker and Star, 1999; Star and Ruhleder, 1996; Timmermans and Berg, 2003). The openEHR specification seems promising as it offers ‘interoperability standards’ (archetypes) that have the potential to serve different stakeholders’ needs as well as putting users ‘in the driver’s seat’ of the standardization process (Freriks et al., 2007; Garde et al., 2007) . This paper focuses particularly on the underlying process of developing and using a broad range of archetypes, which constitute the backbone of interoperable EPR systems that are based on the openEHR architecture.

Putting users ‘in the driver’s seat’ of the standardisation processes is practically and democratically appealing, but it begs many questions on how this can be accomplished on a large-scale. The openEHR specification has addressed the need to have someone formally responsible for establishing or influencing formal and informal organizational mechanisms and structures in order to systematically influence the building, dissemination, and maintaining of openEHR archetypes within and between domains (Garde et al., 2007). Accordingly, even though the clinicians are in control of developing archetypes, someone needs to have the formalized role of controlling and governing the process. While

such a formalized role of governing domain knowledge is defined conceptually, this paper explores the underlying processes of developing and using archetypes to understand how this can be organized in real life (Hanseth and Lyytinen, 2010; Pipek and Wulf, 2009; Star and Ruhleder, 1996).

Key insights from this study show that user-driven standardization of archetypes, as ‘interoperability standards’, requires smooth-working and partly overlapping governance structures on different organizational levels (Beratarbide and Kelsey, 2009; Constantinides and Barrett, 2014). Firstly, the openEHR framework is notable for its great flexibility, but it is also characterized by a formalized governing bureaucracy. In order to avoid this governance resulting in a static, top-down approach, it is important that its role be supportive and enabling rather than demanding and controlling. This should be carefully monitored. Secondly, the crucial domain expert role calls for the establishment of some form of ‘domain expert education’. Accordingly, the archetypes specify new roles for the clinical communities related to design, deployment, governance and, finally, education as well. In practice, this implies that, to succeed with user-driven standardization within the openEHR approach, it requires support from the management. The management needs to take seriously its responsibility to recruit domain experts and organize the necessary domain expert education, as well as adjusting for the users’ participation in the archetype development processes. Thirdly, the user role is extremely important in information infrastructure studies (Star and Ruhleder, 1996). It is clear from this study, which promised extensive user control, that this is illusory. Future studies on user control would do better to focus on what type of user control can be achieved under the current circumstances and what can be done to improve it.

Summary Paper 5: The ‘Holy Grail’ of Interoperability of Health Information Systems: Challenges and Implications.

This paper reports from the empirical project over an extended period, from January 2012 to January 2017, which encompasses both short-time dynamics and longer-term evolution. The paper focuses on the process of replacing the existing, largely free-text-based EPR with a new semantically interoperable EPR based on the openEHR approach and simultaneously integrating a new electronic charting and medication (ECM) system with the EPR.

First, integrating the new openEHR-based EPR with the existing EPR was technically a success, but it made the clinical work processes more cumbersome because the integration did not rest on common standards allowing seamless integration and interoperability (Monteiro et al., 2012; Star and Ruhleder, 1996).

Second, the integration between the existing and new EPR systems was only an interim solution because the new system was successively replacing the existing one. However, making the new EPR ‘grow’ addressed an organizational interdependency concern: the establishment of a national repository of

archetypes (Gibbons et al., 2007; Hanseth and Lundberg, 2001; Hanseth and Monteiro, 1998; Star and Ruhleder, 1996).

Third, in this empirical case, two best-of-breed systems will support the same healthcare process, in which both systems provide the same or slightly differing functionalities, but using very different standards to support reuse and sharing of information within and between systems. Accordingly, the tension between local customized use and the need for standards and continuity (global) to support the same clinical process within the same context by two heterogeneous systems was not solved (Star and Ruhleder, 1996).

Fourth, the successful integration of health ISs in terms of a transparent II that supports clinicians with contextual clinical information at the point of care requires access to all relevant patient information regardless of where the information originally was created (the EPR or the ECM). A platform of standardized use-independent clinical information models, such as the openEHR archetypes, has the potential to enable sharing and processing of clinical information, despite the situation of heterogeneous health ISs. However, use-independent clinical information models do not solve the goal of semantic interoperability by themselves. An agreement is needed for a change or explicit policy on a regional or national level that determines which clinical information models can act as interoperability standards and serve as a platform between heterogeneous health ISs (Atalag et al., 2016; Bowker and Star, 1999; Gibbons et al., 2007; Hanseth and Lundberg, 2001; Hanseth and Monteiro, 1998).

Finally, the challenges of reaching the goal of interoperability are not only about technical or semantic interoperability or about harmonizing the health ISs to the healthcare processes. The goal of interoperability encompasses a diversity of socio-technical issues, in which political and policy barriers need to be addressed. An open-platform approach offering use-independent clinical information models seems to be promising for reaching the goal of interoperability, but entail large structural changes if 'interoperability standards' are going to form the foundation for integrating heterogeneous health ISs on a regional or national level.

6 Implications

Based on the theoretical framework and the findings from the papers included in the thesis, I will suggest some implications of my research. I have divided the implications into three main categories, and I will first present the practical implications, subsequently the theoretical implications, and finally methodological implications when conducting interpretive case studies.

6.1 Practical implications

In this section, I highlight some practical implications related to developing and adopting an EPR system interpreted as an open platform-based II. The focus throughout the research has been geared towards the

separation of the reference model from clinical information models and how the separation affects the vendor-user collaboration and the clinical community. The practical implications can be understood as ‘lessons learned’, which are valuable in the future for other organizations and contexts, such as the upcoming FRESK program responsible for implementing the new EPR and ECM systems (Walsham, 1995).

The paradox: The need for abstraction and the need for contextualization

A paradox of the open-platform approach is that the design of the reference model calls for abstraction, compared to the traditional design of clear-cut and detailed functional user requirements. However, in practice, the developers need information about clinical scenarios to understand how healthcare work is collaboratively achieved on local sites, as well as scaled up to healthcare processes crossing time and space (Paper 1). An important difference between open platform-based systems and a traditional proprietary system is that the latter implies that user interfaces, application logics and database will be closely integrated and controlled by the vendor. In contrast, an open-platform approach (e.g. the openEHR specification) implies that the vendors develop the generic reference model while the clinical communities design the use-independent clinical information models. The separation as a consequence of open platform-based approaches is often interpreted as two disentangled development processes, while knowledge gained from this study urges the necessity of a close collaboration between the clinical communities and the vendor (Paper 1). However, the collaboration is changed because of the need for altering the design strategy – from traditionally using an agile approach leaning upon short and contextualized user stories, to heavy up-front design based on the abstraction of complex healthcare processes. The changed design strategy addresses the need for users with considerable organizational competence and an overview of clinical pathways (Paper 2).

Paper 1 highlights the emerging change of the vendor-user collaboration. One of the developers framed it as being ‘hit by the archetype lightning’ because in earlier development processes, the developers could ‘zoom’ into ‘bits and pieces’ of the particular functionality to be developed and easily design a screen and add necessary fields. Using an open-platform approach scaled the EPR system to an II supporting healthcare processes within and between different organizations and addressed new complexities. The separation of the technical design from the clinical information models implicated an abstraction of the design process from traditionally designing locally situated software (Hanseth and Lyytinen, 2010). As Star and Ruhleder (1996) metaphorically described the development of a large-scale infrastructure, ‘Developing an large-scale information infrastructure is like building the boat you’re on while designing the navigation system and being in a highly competitive boat race with a constantly shifting finish line’ (Star and Ruhleder, 1996, p. 4). Designing a generic reference model seemed to have similar challenges in terms of being a framework for processing clinical data designed in such a way that it does not need to know a priori which data it will process (Atalag et al., 2016). This

understanding made the vendor change the design strategy during the first year of the empirical project (Paper 1). The paradox of designing an abstract reference model based on clinical scenarios of the collaborative healthcare work, addresses the need for users able to take a ‘birds-eye’ view and abstract their local practices to an overall level of generic healthcare processes (Paper 1 and 2). Accordingly, user participation has to be entangled with the product to be developed (Mackay et al., 2000; Markus and Mao, 2004).

A broadened interdependency between designers and users

As mentioned above, the traditional design process of a proprietary system is controlled by the vendor, in terms of taking the responsibility of delivering working software where the user interfaces, application logics, information models and database are closely integrated. In contrast, when procuring an open platform-based health IS, the approach divides the responsibility that traditionally belonged to the IT supplier’s domain and transfers the responsibility for developing use-independent clinical information models to clinical communities. In such a perspective, the development of an open platform-based system is no longer an activity that is sealed inside a vendor’s company only (Atalag et al., 2016; Freriks et al., 2007). The development can rather be interpreted as a co-construction process, or the ‘hen and egg’ problem, where the system’s suppliers need clinical information models, and clinical practices need system(s) to process these models to enable support of clinical processes, as well as engagement to participate in their design. A lesson learned from the empirical project is that the clinical communities need to take the responsibility of developing clinical information models in parallel with the health IS in progress. A delayed development of clinical information models will hamper the evolving II based on an open-platform approach (Paper 4 and Paper 5). In addition, parallel design processes seem to motivate the clinicians to participate in this kind of ‘distant’ clinical work.

However, how to perform and organize clinical communities to take this responsibility will vary in accordance with the heterogeneous organization of healthcare services worldwide. Nevertheless, the research from this study indicates that on a general level, the new technology and separated responsibility address a hierarchy of new roles, and it is important to organize the responsibility tied up to these different roles (Constantinides and Barrett, 2014; Hanseth and Lyytinen, 2010; Pipek and Wulf, 2009; Star and Ruhleder, 1996).

New end-user role; ‘There is no such thing as a free lunch’

The ‘hen and egg’ problem addresses the need for end-users taking an active role in ‘local’ projects, such as the empirical surgery-planning project, to define which clinical information that needs to be modelled as use-independent clinical information models to enable easy exchange and support of their clinical work processes (e.g. standardized patient pathways) (Paper 4). However, the idea behind the openEHR approach is to ensure universal interoperability among all forms of electronic data by separating the specification of clinical information from the model on which the software operates

(Atalag et al., 2016; Gibbons et al., 2007). Accordingly, the openEHR approach is comparable to other open-source software development approaches, where an innovative system relies on loosely coordinated voluntarily participants who interact to create a product, and anyone can freely join in the fruits of sharing.

This dimension of universal interoperability concerns the need for meta-models to cover the entire healthcare domain, which subsequently requires healthcare professionals to freely participate in design and consensus processes beyond the local context of use to improve the II of healthcare in general. The adage in the heading ‘There is no such thing as a free lunch’ points to the challenges of non-profit collaboration; it is difficult to get something done for nothing. The experiences from the empirical project indicate that clinicians ‘do not easily ‘volunteer’ into design and consensus processes either on the local level or in overall co-construction processes. However, there is no doubt that if an open platform-based health II is to succeed, the healthcare professionals’ contributions in clinical information modelling are crucial (Star and Ruhleder, 1996). Accordingly, the dependency between the technical design on one hand and the contributions from the healthcare professionals on the other indicates a collective contribution from the clinical communities that need to be given particular focus. This understanding gives rise to the practical implications necessary to make the new user-role a success.

First, healthcare personnel need to be guided into their role as designers and ‘co-constructors’. A possible way of arousing healthcare personnel’s interest would be to appeal to their own need for sharing and reusing clinical information in their local clinical work processes. Therefore, in parallel with describing patient pathways and healthcare processes during vendor-user collaboration, the end-users need to be guided into defining which clinical information needs to be standardized in clinical information models aimed to support the described patient pathways and healthcare processes (Paper 1, Paper 4, and Paper 5).

Second, their role as co-constructors will continue along with the evolving II. The co-constructor roles imply an understanding of the II in progress, in terms of the need for continuing the design and consensus processes to support a growing II for the entire healthcare domain. To achieve stability in the end-users’ role as co-constructors, it might be helpful to ask questions about when and how their participation in the infrastructure process becomes significant for healthcare professionals (Aanestad et al., 2017). Based on the knowledge from the empirical project, it is challenging to recruit healthcare personnel to do this kind of ‘distant’ clinical work if they do not perceive any benefit from it in their daily clinical practice. Consequently, this indicates that healthcare personnel, or representatives from different clinical professions and medical specialties, might need to be hired as co-constructors, a new role separate from their clinical work.

Leading healthcare professionals into their new roles requires someone to guide them. The findings from the study suggest giving this role to the domain experts (Fig. 4).

The new expert-user role and the need for specialized education

The new technology built in accordance to on an open-platform approach leaves the responsibility and control over the ‘interoperability standards’ necessary to make the II evolve to clinical communities. As discussed in Paper 4, ‘interoperability standards’ need a ‘catalyser’ to initiate the standardization processes. In the empirical project, the vendor took the role as a ‘catalyser’. However, the responsibility was originally transferred to the clinical communities. Subsequently, the new technology gives rise to yet another new user role that is in between the end-users and the vendor, in addition to being a catalyser of the overall information infrastructure process by guiding end-users into becoming co-constructors. Accordingly, the expert-users need to ‘operate’ at the intersection between local clinical needs and overall healthcare processes to enable meta-standards to evolve. Also, a strategy to build the competence and knowledge to handle and perform the new role as ‘catalysers’ is needed.

When describing and unpacking the different needs and interdependencies through the different phases of the empirical project, the evolving II revealed that a network of actors is necessary to make the II grow (Hanseth and Lyytinen, 2010; Star and Ruhleder, 1996). However, the new role of expert-users need to coordinate their work along different dimensions of time and space, in terms of working in close collaboration with a development project on the ‘local’ level, as well as scaling the collaboration with other actors (expert-users, co-constructors and clinical information designers) to promote growth of the overall II. In this perspective, the expert-user role can be interpreted as a ‘hub’ in the process of modelling use-independent clinical information models, and experiences and knowledge about filling the expert-user role are limited. The implication of the research is the need for establishing an education program for expert-users when initiating an open platform-based II.

Open platform-based information infrastructures require organizational changes

The new EPR system will connect multiple sites, within and beyond organizational borders, to enable support of patient pathways. Subsequently, the use-independent clinical information models will ensure that information is understood and interpreted consistently across various contexts (Bowker and Star, 1999; Bygstad et al., 2015; Star and Ruhleder, 1996). Accordingly, the clinical information models are in a figurative sense the ‘backbone’ of the II and need to be designed in accordance to a formalized process to ensure interoperability between different domains and organizations. This requires establishing mechanisms and structures to systematically influence the building, dissemination and maintenance of the clinical knowledge represented and used in the information models (Garde et al., 2007). Overall, new organizational structures are needed to ensure the governance of an open platform-based II (Paper 4 and 5). Operationalizing the need for governance into the Norwegian Healthcare context has resulted in establishing the Norwegian Repository of Archetypes (NRUA), with

representatives from all the four health regions and three of four health regions having established ‘archetype groups’ as part of their regional governance organizations (NRUA is described in Paper 4 and 5).

Nevertheless, when choosing an open-platform approach to establish a regional or national II to support healthcare, it is important to define it as a process, not a project. This means that limiting the establishment of the infrastructure to the timeline of a development project may hamper the infrastructure’s growth because the development of large-scale systems typically extends over considerable time as policies, budgets, artefacts, suppliers, users, work practices and visions of organizational improvements change (Johnson et al., 2013; Pollock and Hyysalo, 2014). Developing an II is a ‘living’ process that will shape and be shaped by local clinical processes on the one hand and by interoperability through collaboration in design and governance of standards (global) on the other hand (Monteiro et al., 2012; Star and Ruhleder, 1996). Consequently, the redistribution of responsibilities related to the new II in progress inevitably plays a politically textured role related to balancing local and global needs by integrating the responsibilities and new roles in policy documents in different organizations (Aanestad and Jensen, 2011; Hanseth and Monteiro, 1998; Star and Ruhleder, 1996).

Scaling up IIs reveals different interests towards standardization processes

Worldwide, the motivation for ICT in healthcare has been the trend towards better coordination of care, which implies a change of focus from eHealth as self-contained processes within single healthcare organizations to overall cross-organizational care processes (Aanestad et al., 2017). Accordingly, eHealth as cross-organizational processes addresses the need for scaling up the IIs to support these processes. Subsequently, IIs are dependent on standards to grow in scope and functionality (Hanseth and Monteiro, 1998), which involve different interests related to the standardization process. Paper 5 focus on the challenges of developing an II with a clear goal of achieving interoperability among heterogeneous EPR systems. This situation is not unique for the empirical case, but is representative for today’s situation in healthcare, characterized by the use of a plethora of specialized, non-standard ISs – so called silo systems – following a best-of-breed approach. The consequence is that interoperability is not attainable through an open-platform approach only. Scaling the development of an II will involve stakeholders who may have already invested a great deal in different technologies. Semantic interoperable standards are urgently needed to enable advanced PDS systems for individual patients (Bonney, 2011; Lenz and Reichert, 2007), which stresses the importance of a decision for which ‘interoperability standards’ to use (Paper 5). For example, Paper 5 points to a core issue of dealing with larger collectives of actors who are already moving towards the goal of semantic interoperability of large-scale II in healthcare (Aanestad and Jensen, 2011). Accordingly, when scaling up an II, the need for agreements on standards and standardization processes makes politically textured decisions more

important and visible (ibid.). However, the role of the research is to reveal how large-scale infrastructure processes relate to the different interests among stakeholders on local, regional and national levels.

The need for integrating policy design with infrastructure design is still urgent because a general request for common standards or an overall goal of interoperability, addressed by a number of strategies and eHealth visions, is not enough. It is important that the request is connected to and embedded in a broader policy-oriented vision about how to deal with specific challenges (e.g. different interests among stakeholders). In this study, an open-platform approach as a foundation for an II depends on a network of users, developers, vendors, governance and local, regional, national and international standardization initiatives (Aanestad et al., 2017; Atalag et al., 2016). Accordingly, purchasing an open platform-based system brings about responsibilities to the management or governance institutions on local, regional and/or national levels to enable the system to grow (Hanseth and Monteiro, 1998). Star and Ruhleder (1996) stated that it is what the users do to an II that makes it grow, which matches with the significant role given healthcare personnel in designing openEHR clinical information models. Policies are needed at each of the management or governance levels to organize the participation of healthcare personnel in the development and maintenance of use-independent clinical information models.

Finally, political decisions will also have impacts on new health IS purchases, in terms of requiring new vendors to use use-independent clinical information models for sharing clinical information across different systems. Then, healthcare organizations will be removed from the delicate situation described in Paper 5, where two (probably more) different systems are supposed to support the same clinical processes through different information models.

6.2 Theoretical implications

The theoretical implications should be viewed as extensions of the existing research, based on the contributions from the papers and the practical implications. In that sense, the practical and theoretical implications complement each other in terms of gaining a better understanding of the shift towards open platform-based health ISs.

From traditional design to complex coordination

The empirical project has offered unique access to study a complex infrastructure process from several angles and how the different aspects emerged and were addressed. A key aim of the FIKS program was to replace an existing, largely free-text-based EPR with a semantically interoperable EPR that enables advanced process and decision support within and between the hospitals in the region. What is special with this case, is that it is not a digitalization process as such (e.g. the transition from paper to electronic system only), but a process in which one collaborative infrastructure (the existing EPR, other ISs and human actors) has to be aligned, replaced and reorganized with a new, open platform-based EPR system. In addition, the open-platform approach requires a parallel dimension of establishing

organizational and governance mechanisms and structures to systematically influence the building, dissemination and maintenance of clinical information models, which are the ‘backbone’ of the new EPR system (Paper 4 and 5) (Garde et al., 2007). Accordingly, the empirical process scales up the complexity of the interdependencies along different dimension of time and space and addresses the need for coordination of the large-scale infrastructure process itself.

The concept of coordination has traditionally been used within CSCW research and drawn attention to how coordination mechanisms and the use of artefacts structure actors’ collaborative activities and support the articulation of the activities in small-scale workplace studies (Fitzpatrick and Ellingsen, 2012; Møller and Bjørn, 2011; Holten Møller and Dourish, 2010; Schmidt and Simone, 1996). The findings from this study suggest that local contexts are not just local. As described in Paper 3, the use of a paper-based form for decision support in a local context scaled to clinical and organizational interdependencies beyond the local context of use. The consequences of implementing a paper form and replacing it with a digital version was not fully predicted. The artefact was interpreted as an information carrier only, not as a ‘signalling device’ for the overall coordination of work (Aanestad et al., 2017; Silsand and Ellingsen, 2014).

Taking a broader perspective, this study describes and unpack how the design of the new open platform-based system within a health region evolved and addressed organizational, governance, and politically textures interdependencies on local, regional and national levels. Accordingly, collaborative technologies are increasingly taking on II qualities, in which the notion of II precisely addresses the large-scale, integrated and interconnected workplace technologies. The II perspective supplements a local view and short time frames with an ‘extended design’ perspective to capture how workplace technologies can be shaped across different dimensions of multiple contexts (spatial) and over extended periods of time (temporal) to understand the ‘growth’ of networks (Aanestad et al., 2017; Karasti et al., 2010; Monteiro et al., 2012,).

Traditionally, healthcare services and organizations have been organized in different jurisdictions as vertical ‘silos’ with their own ISs and infrastructures. In this perspective, the notion of II has been useful to describe and unpack different interdependencies affecting a vertical II. However, the trend towards better eHealth infrastructures supporting the coordination and collaboration of cross-organizational care processes has resulted in several studies that focus on more generic, over-arching II (e.g. e-prescription systems, message exchanges between different healthcare providers and shared emergency care record systems) (Aanestad et al., 2017). An open platform-based II has the same enabling functions as the wider eHealth infrastructures when it comes to supporting the collaboration and coordination of healthcare processes through sharing and reusing clinical information within a single EPR system and between ‘vertical’ silos of different jurisdictions (Atalag et al., 2016; Freriks et al., 2007). In addition, the open-platform approach addresses a horizontal dimension beyond exchanging clinical information within and

between different organizations, seeking to enable the collaboration and coordination between the distributed healthcare personnel and associated actors in designing use-independent clinical information models (Freriks et al., 2007). The horizontal dimension consists of the collaborating activities conducted by healthcare personnel, healthcare providers, different vendors and governance organizations in different jurisdictions (Aanestad et al., 2017; Freriks et al., 2007). Accordingly, the horizontal dimension of the open-platform approach scales the complexities of a generic, over-arching II, which has not been given a particularly strong focus in previous research of healthcare IIs.

The findings from this study indicate that the expanded complexities of the horizontal dimension might benefit from being coordinated to support an evolving II. I suggest that the traditionally CSCW concept of coordination needs to draw attention towards coordinating mechanisms and artefacts supporting the horizontal dimension of open platform-based health information infrastructure processes (Fitzpatrick and Ellingsen, 2012; Møller and Bjørn, 2011; Holten Møller and Dourish, 2010; Schmidt and Simone, 1996).

The openEHR approach affects the design theory of II

A basic principle of an II is that it is never built from scratch, but evolves from an installed base, in which the infrastructure shapes and is shaped by the work practice in an ongoing co-construction process between technical and social elements (Monteiro et al., 2012; Star and Ruhleder, 1996). From the evolutionary characteristic of an II, Hanseth and Lyytinen (2010) proposed a design theory with design principles for II development that precisely addressed the dynamic complexity of IIs. They discussed the tensions between two design problems of II design and evolution: the bootstrap problem and the adaptability problem. However, the understanding from this study implies an alteration of the dynamic complexity of IIs addressed in the design theory.

The design process started out as a lightweight process of initially designing useful locally situated software, in cooperation with a large group of heterogeneous users. In practice, the separation of the technical design from the clinical information models implied an abstraction of the design process, which did not persuade users to adopt to the new EPR system. Subsequently, the bootstrapping problem – requiring the early delivery of software solutions from the developers to motivate the users to adopt to the new EPR system – was not possible for the developers to overcome because of the need for heavy up-front design. However, when designing the reference model, the developers solved the adaptability problem by developing a generic reference model that took into account the unbounded scale and functional uncertainty and technically enabled support for varying needs (Hanseth and Lyytinen, 2010). Accordingly, the openEHR-platform approach brings a novelty to the existing research on II development processes through altering the dynamic complexities of II design. This understanding prompts me to carefully suggest the need to revisit the preconceptions of the existing design theory (ibid.) and to revise the dynamic complexities to the advancing open-platform approach.

The openEHR approach affects the traditional customization of information systems

Taking an infrastructural perspective not only places focus towards interconnections and relationships but also to issues of durability, permanence and strategies for effectively managing the future evolution of the II (Karasti et al., 2010; Ribes and Finholt, 2009). To succeed with the evolution of large-scale systems, such as open platform-based systems, an important insight from IS research positions the attention to the system's ability to support customization and interoperability (Hanseth et al., 2012; Pollock and Williams, 2008; Rolland and Monteiro, 2002). Pollock and Williams termed the ability to support customization and interoperability as *generification work*, which is 'the supplier strategy of taking a technology that has worked in one place and attempting to make it work elsewhere, and, in principle, everywhere' (Pollock and Williams, 2008, p. 129). In accordance with the openEHR approach, the traditional understanding of generification work is now changing because the responsibility for modelling the interoperability standards and customizing them into use contexts has been handed over to clinical communities (Silsand and Christensen, 2017). Accordingly, the openEHR approach implies extending the generification process beyond the vendors' domain, and the extension of the concept needs to be further explored by following the deployment of open platform-based systems.

6.3 Methodological implications

Empirical participation: From data collection to scientifically based engagement

As previously described, the PhD study adheres to an interpretive approach, in which I have participated extensively in project activities throughout the empirical project's duration time. It is actually the close connection to the empirical field that needs to be given attention when suggesting the methodological implications for further research projects. Frequent calls have been made for making IS research more relevant for practice, in terms of not only studying the socio-technical complexity of IS phenomena but also simultaneously studying the process and creating changes (Baskerville and Myers, 2004). When large-scale empirical projects grow into complex IIs, they shape and have to be shaped by existing practices and systems. Subsequently, during empirical complex information infrastructure processes, different interests and diverging expectations will arise from the actors involved. In this perspective, scaling the role of the researcher to be a moderator of the empirical process by highlighting different perspectives from the actors may have a positive effect on large-scale processes. The researcher brings in scientifically based knowledge and theories about the empirical process, while stakeholders and participants in the project bring situated, practical knowledge (Baskerville and Myers, 2004). Taking a scientifically based engagement in the empirical field (Van de Ven, 2007) implies that the researcher is not collecting data for research purpose only, but just as much for discussing scientifically based findings and preliminary process analysis.

Even though the interpretive approach implies interaction with the actors in the empirical field, going back and forth between collecting data and analysing, the results and contributions of the research are mainly presented in scientifically based papers and conference proceedings after the process. My role in the empirical project was defined by being a PhD student collecting research data. A slight change in the role through increased participation based on a scientifically based engagement in the empirical field could have contributed to a co-constructive learning process for both parties. On one hand, a step-wise evaluation of the empirical project may promote a necessary change of course and adjustment of the original goals in relation to what is possible to reach during a project period. On the other hand, the collaboration could have improved the quality of the data collection and the analyses and influenced the research's contributions.

Scientifically based engagement requires ethical considerations

In February 2016, I was offered a part-time position as an EPR advisor within the Governance Department for Clinical ICT systems at the University Hospital, and I was transferred to the Regional Governance Department in January 2017. Because of my acquaintance with the new openEHR-based system through the PhD study, my position was targeted to work with openEHR archetypes in the health region. Possessing an insider role has implications both for my role as a PhD student and for my EPR advisor role.

First, the knowledge I have gained through the PhD study influences my work and forms my role as an EPR Advisor (e.g. insights from the research have influenced the establishment of the new 'archetype' team). Moreover, the practical implications addressed in this thesis are discussed with stakeholders in the new regional implementation program 'FRESK' and with stakeholders in the governance organization.

Second, being employed in a field in which research data evolves has implications for the described scientifically based engagement in the empirical field. As already described in Section 4.5 (Ethical considerations), I changed from being an 'outsider' with inside experiences to being an 'insider' having two positions, as a researcher and as a participant in the empirical process. As a PhD student only, it was easier to keep a distance to the empirical field, in terms of noticing the different 'voices' of the participants representing similar or different perspectives. Being engaged in the work with archetypes me 'socialized' into the 'archetype community', which resulted in a more thorough understanding for the modelling work itself and the 'philosophy' behind the user-driven standardization of clinical information model. However, being 'socialized' also means a risk of losing the necessary critical distance, in terms of not being able to have an eye for other perspectives towards the goal of interoperability. To solve this situation, other 'unbiased' researchers (e.g. my supervisor) have been of great value in discussing data and their presentation to balance my insider perspective.

From my point of view, an important implication of being an ‘insider’ in a two-fold position is connected to the ontological underpinning of the interpretive case study approach, in which the social reality is produced through the actions of humans. Accordingly, being an employee in the empirical field of study affects the objectiveness or analytical position of the researcher’s role as well. It is difficult to take the necessary bird’s-eye view of the process one is involved in personally. This means that researchers have to analyse their own participation and contribution as an employee in the process from a scientifically point of view. Thus, understanding social processes in the empirical field required an understanding of how the evolving process actually emerged, how it was formed and informed by the people involved (clinicians, stakeholders, developers), as well as an understanding of the new technology, the existing practices and its socio-political and symbolic actions (Walsham, 1995). It is obvious that the knowledge and experiences one obtains through being an employee will influence the analytical understanding of the process. Consequently, holding a double position within the same empirical field might challenge the researcher’s role of being a scientifically informed moderator to the empirical process, in terms of highlighting different perspectives and diverging expectations from the actors involved.

Finally, the double role might blur the relationships with an individual’s colleagues. Traditionally, people in the field do not perceive researchers as being aligned with a particular individual or group within an empirical project or as having strong prior views of specific agencies. However, the double role might blur the ‘neutral’ researcher position expected by the people in the field, which emphasizes the importance of researchers clearly stating the ‘mission’ with others involved.

7 Conclusion

In this thesis, I have discussed how different socio-technical interdependencies affect the making and scaling of an II for healthcare based on the openEHR-platform approach. I have paid particularly attention to how the separation of the reference model and the clinical information models influenced the design process and how it gave rise to new collaborative forms between vendor and users and resulted in new roles and new responsibilities in designing and implementing an openEHR-based EPR system. To unpack and understand which socio-technical challenges and interdependencies are in play and how they relate to the evolving II process, research from the II field was mainly applied as a theoretical basis throughout the thesis. In addition, as described in Section 4.5, the CSCW research provided theoretical concepts to observe and analyse clinical practices and work practices in general, which assisted in understanding the complexity of local and global interdependencies in the empirical project from an analytical point of view.

As described in Section 1.1, my clinical background made me interested in how digital health ISs could improve healthcare processes. To understand the phenomena in an environment in which technology is supposed to support healthcare processes, I had to understand the technology. In this case, an openEHR

platform-based EPR system was established to assist healthcare personnel in making informed decisions about the necessary actions or the next steps in the clinical process. However, it became clear early in the empirical process that an openEHR platform-based EPR had some vital differences with the existing EPR system and with the previous development collaborations with the vendor. These differences were due to the separation of the reference model from the clinical information models, which came to guide the focus of my research. It was necessary to analyse the technology and the open-platform approach to understand the challenges and implications in the development and implementation process, which started out as a design collaboration based on locally contextualized user requests that scaled up to a complex infrastructure process addressing clinically, technically, organizationally and politically textured interdependencies.

Two main messages are clear from this PhD study. First, when choosing an open-platform approach to establish a regional or national II for healthcare, it is important to define it as a process, not a project. Limiting the realization of a large-scale open platform-based infrastructure to the strict timeline of a project may hamper the infrastructure's growth. The study has highlighted different interdependencies affecting the making and scaling of large-scale open platform-based II, which typically extends over considerable time in consideration of policies, budgets, artefacts, suppliers, users, work practices and visions of organizational improvements change (Johnson et al., 2013; Pollock and Hyysalo, 2014).

Second, the study argues that making and scaling an open platform-based II for healthcare have the potential to comply with the goal of enabling interoperable infrastructures, but they require much more than creating a goal and having the necessary technological capabilities in place. Realizing an open platform-based II through use-independent clinical information models requires large structural and organizational changes to integrate policy design with infrastructure design (Aanestad and Jensen, 2011; Hanseth and Monteiro, 1998). Moreover, the open-platform approach in the empirical case reveals a horizontal dimension related to the collaboration in building use-independent clinical information models, which scales the complexities compared to IIs within and between 'vertical' silos of different organizational jurisdictions (Aanestad et al., 2017; Atalag et al., 2016; Freriks et al., 2007).

7.1 Limitations

Although the PhD study has followed the empirical project from start to finish, the implementation of the openEHR-based EPR system into clinical use has not been attained. Accordingly, we do not know how the II will evolve in use.

From the methodological point of view, the ontologically underpinning of the interpretive research approach implies that the social reality is produced through the actions of humans involved in the empirical process, including the researcher(s) that construct and make sense of the reality. In addition, the 'field' site was constructed reflexively by every choice that I have made, as described in the Section

5.1 (Method). Accordingly, the construction of which ‘site’ influences which data can be established. Even though the methods used in this thesis included detailed case descriptions, it also involved decisions to exclude details or to not follow up on threads that could have affected my overall understanding of the evolving process.

Being an ‘insider’ from the clinical field had both positive and negative implications for the study. However, it was troublesome to be an ‘insider’ having two positions: as a researcher and as an employee in an adjoining and supporting organization of the empirical project. Being engaged in the work with use-independent clinical information models as an employee in the Governance Organization made me ‘socialized’ to the work of modelling clinical information models with the risk of losing the necessary critical distance to the empirical process, in terms of not being able to have an eye for other perspectives towards the goal of interoperability.

7.2 Further research

As mentioned, the empirical process of realizing the openEHR-based EPR system is just about entering a new phase, in which the implementation and integration with the Electronic Charting and Medication systems is going to be accomplished by a new project called ‘FRESK’. The new project is an extension of the FIKS program, and is set to start at the turn of the year (2017/2018). The new project will form the empirical basis for further research, making it possible to follow the ‘loose threads’ that develop under practical implications.

First, it will be interesting to follow how the clinical communities will organize and educate the healthcare professionals who are given new roles, on local, regional and national scales.

Second, it will be interesting to explore how the need for integrating policy design with infrastructure design will spell out. A policy will be needed in each of the management or governance levels to organize the participation of healthcare personnel for the development and maintenance of the use-independent clinical information models.

I have also addressed the theoretical implication that the concepts and theories can be extended by further research after the deployment of the open platform-based II for healthcare. Finally, if my methodological implications are considered in further research projects, they will bring about interesting contributions to the methodological field and contribute to the learning process for future researchers.

References

- Aanestad, M., Grisot, M., Hanseth, O., Vassilakopoulou, P. (Eds.), 2017. Information Infrastructures within European Health Care. Springer International Publishing, Cham.
https://doi.org/10.1007/978-3-319-51020-0_1
- Aanestad, M., Jensen, T.B., 2011. Building nation-wide information infrastructures in healthcare through modular implementation strategies. *J. Strateg. Inf. Syst.* 20, 161–176.
<https://doi.org/10.1016/j.jsis.2011.03.006>
- Aarts, J., Ash, J., Berg, M., 2007. Extending the understanding of computerized physician order entry: Implications for professional collaboration, workflow and quality of care. *Int. J. Med. Inf.* 76, Supplement 1, S4–S13.doi.org/10.1016/j.ijmedinf.2006.05.009
- Atalag, K., Beale, T., Chen, R., Gornik, T., Heard, S., McNicoll, I., 2016. openEHR - A SEMANTICALLY ENABLED, VENDOR-INDEPENDENT HEALTH COMPUTING PLATFORM [WWW Document]. URL
http://www.openehr.org/resources/white_paper_docs/openEHR_vendor_independent_platform.pdf (accessed 6.1.16).
- Bardram, J.E., 2000. Temporal Coordination –On Time and Coordination of CollaborativeActivities at a Surgical Department. *Comput. Support. Coop. Work CSCW* 9, 157–187.
<https://doi.org/10.1023/A:1008748724225>
- Baskerville, R., Myers, M., 2004. Special Issue on Action Research In Informaton Systems: Making IS Research relevant to practice foreword. *Manag. Inf. Syst. Q.* 28.
- Beale, T., 2002. Archetypes: Constraint-based domain models for future-proof information systems, in: OOPSLA 2002 Workshop on Behavioural Semantics.
- Beale, T., Heard, S., 2007a. Archetype Definitions and Principles [WWW Document]. URL
http://www.openehr.org/releases/1.0.2/architecture/am/archetype_principles.pdf (accessed 7.14.16).
- Beale, T., Heard, S., 2007b. An ontology-based model of clinical information, in: *Medinfo 2007: Proceedings of the 12th World Congress on Health (Medical) Informatics; Building Sustainable Health Systems*. IOS Press, p. 760.
- Beale, T., Heard, S., 2008. OpenEHR Architecture. Architecture Overview. [WWW Document]. URL
<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.204.1693&rep=rep1&type=pdf> (accessed 7.14.16).
- Beratarbide, E., Kelsey, T., 2009. eHealth governance, a key factor for better health care: Implementation of IT Governance to ensure better care through better eHealth, in: *Ethical Issues and Security Monitoring Trends in Global Healthcare: Technological Advancements*. IGI Global, pp. 72–92.

- Berg, M., 1999. Accumulating and Coordinating: Occasions for Information Technologies in Medical Work. *Comput. Support. Coop. Work CSCW* 8, 373–401.
<https://doi.org/10.1023/A:1008757115404>
- Berg, M., Goorman, E., 1999. The contextual nature of medical information. *Int. J. Med. Inf.* 56, 51–60.
- Berg, M., Toussaint, P., 2003. The mantra of modeling and the forgotten powers of paper: a sociotechnical view on the development of process-oriented ICT in health care. *Int. J. Med. Inf., Working Conference on Health Information Systems* 69, 223–234.
[https://doi.org/10.1016/S1386-5056\(02\)00178-8](https://doi.org/10.1016/S1386-5056(02)00178-8)
- Berner E. S., 2009. Clinical decision support systems: State of the Art. AHRQ Publication No. 09-0069-EF. Rockville, Maryland: Agency for Healthcare Research and Quality.
https://healthit.ahrq.gov/sites/default/files/docs/page/09-0069-EF_1.pdf (accessed 19.07.15)
- Blomberg, J., Karasti, H., 2013. Reflections on 25 Years of Ethnography in CSCW. *Comput. Support. Coop. Work CSCW* 22, 373–423. doi.org/10.1007/s10606-012-9183-1
- Bonney, W., 2011. Impacts and Risks of Adopting Clinical Decision Support Systems, in: Jao, C. (Ed.), *Efficient Decision Support Systems - Practice and Challenges in Biomedical Related Domain*. InTeh, p. 328.
- Bossen, C., 2011. Accounting and Co-Constructing: The Development of a Standard for Electronic Health Records. *Comput. Support. Coop. Work CSCW* 20, 473–495.
<https://doi.org/10.1007/s10606-011-9141-3>
- Bossen, C., 2006. Representations at work: a national standard for electronic health records, in: *Proceedings of the 2006 20th Anniversary Conference on Computer Supported Cooperative Work*. ACM, pp. 69–78.
<https://doi.org/10.1145/1180875.1180887>
- Bossen, C., Markussen, R., 2010. Infrastructuring and Ordering Devices in Health Care: Medication Plans and Practices on a Hospital Ward. *Comput. Support. Coop. Work CSCW* 19, 615–637.
<https://doi.org/10.1007/s10606-010-9131-x>
- Bowker, G.C., Star, S.L., 1999. *Sorting Things Out: classification and Its Consequences*. MIT Press, Cambridge, Mass.
- Bygstad, B., Hanseth, O., Truong, D., 2015. From IT Silos to Integrated Solutions. A Study in E-Health Complexity. *ECIS 2015 Completed Research Papers*. Paper 23. ISBN 978-3-00-050284-2. http://aisel.aisnet.org/ecis2015_cr/23
- Cardoen, B., Demeulemeester, E., Beliën, J., 2010. Operating room planning and scheduling: A literature review. *Eur. J. Oper. Res.* 201, 921–932.
<https://doi.org/10.1016/j.ejor.2009.04.011>

- Carlile, P.R., 2004. Transferring, Translating, and Transforming: An Integrative Framework for Managing Knowledge Across Boundaries. *Organ. Sci.* 15, 555–568.
<https://doi.org/10.1287/orsc.1040.0094>
- Carstensen, P.H., Sørensen, C., 1996. From the social to the systematic. *Comput. Support. Coop. Work CSCW* 5, 387–413. <https://doi.org/10.1007/BF00136712>
- Chen, R., Klein, G., 2007. The openEHR Java reference implementation project. *Stud. Health Technol. Inform.* 129, 58-62.
- Christensen, B., Ellingsen, G., 2014. Towards a Structured Electronic Patient Record for Supporting Clinical Decision-Making, in: Rocha, Á., Correia, A.M., Tan, F. B., Stroetmann, K. A. (Eds.), *New Perspectives in Information Systems and Technologies, Volume 2*. Springer International Publishing, Cham, pp. 297–306.
- Ciborra, C.U., Hanseth, O., 1998. From tool to *Gestell*: Agendas for managing the information infrastructure. *Inf. Technol. People* 11, 305–327. <https://doi.org/10.1108/09593849810246129>
- Constantinides, P., Barrett, M., 2014. Information Infrastructure Development and Governance as Collective Action. *Inf. Syst. Res.* 26, 40–56. <https://doi.org/10.1287/isre.2014.0542>
- Das, M., Eichner, J., 2010. Challenges and Barriers to Clinical Decision Support (CDS) Design and Implementation Experienced in the Agency for Healthcare Research and Quality CDS Demonstrations (AHRQ Publication No. 10–00 64–EF). Agency for Healthcare Research and Quality, Rockville, MD.
https://healthit.ahrq.gov/sites/default/files/docs/page/CDS_challenges_and_barriers.pdf
 (accessed 02.09.15).
- Dourish, P., Holmes, J., MacLean, A., Marqvardsen, P., Zbyslaw, A., 1996. Freeflow: Mediating Between Representation and Action in Workflow Systems, in: *Proceedings of the 1996 ACM Conference on Computer Supported Cooperative Work, CSCW '96*. ACM, New York, NY, USA, pp. 190–198. <https://doi.org/10.1145/240080.240252>
- Dufts Schmid, G., Wrba, T., Rinner, C., 2010. Extraction of standardized archetyped data from Electronic Health Record systems based on the Entity-Attribute-Value Model. *Int. J. Med. Inf.* 79, 585–597. <https://doi.org/10.1016/j.ijmedinf.2010.04.007>
- Duplaga, M., Zielinski, K., Ingram, D. (Eds), 2004. *Transformation of Healthcare with Information Technologies, Studies in Health Technology and Informatics*. IOS Press, Amsterdam; Washington, DC.
- Edwards, P.N., Jackson, S.J., Bowker, G.C., Knobel, C.P., 2007. Report of a Workshop on “History & Theory of Infrastructure: Lessons for New Scientific Cyberinfrastructures.”
- Egger, E., Wagner, I., 1993. Negotiating temporal orders. The Case of Collaborative Time Management in a Surgery Clinic. *Comput. Support. Coop. Work CSCW* 1, 255–275.
<https://doi.org/10.1007/BF00754330>

- Ellingsen, G., Monteiro, E., 2003. Mechanisms for producing a working knowledge: Enacting, orchestrating and organizing. *Inf. Organ.* 13, 203–229. [https://doi.org/10.1016/S1471-7727\(03\)00011-3](https://doi.org/10.1016/S1471-7727(03)00011-3)
- Ellingsen, G., Monteiro, E., Røed, K., 2013. Integration as interdependent workaround. *Int. J. Med. Inf.* 82, e161–e169. <https://doi.org/10.1016/j.ijmedinf.2012.09.004>
- European Commission, Directorate-General for Health and Food Safety, 2015. Disruptive innovation: considerations for health and health care in Europe. Publications Office, Luxembourg. ISBN: 978-92-79-48151-2
<http://bookshop.europa.eu/uri?target=EUB:NOTICE:EWBA15004:EN:HTML> (accessed 15.12.17)
- Fitzpatrick, G., Ellingsen, G., 2012. A Review of 25 Years of CSCW Research in Healthcare: Contributions, Challenges and Future Agendas. *Comput. Support. Coop. Work CSCW* 22, 609–665. <https://doi.org/10.1007/s10606-012-9168-0>
- Forsythe, D.E., 1999. “It’s Just a Matter of Common Sense”: Ethnography as Invisible Work. *Comput. Support. Coop. Work CSCW* 8, 127–145. <https://doi.org/10.1023/A:1008692231284>
- Fraccaro, P., Arguello Casteleiro, M., Ainsworth, J., Buchan, I., 2015. Adoption of Clinical Decision Support in Multimorbidity: A Systematic Review. *JMIR Med. Inform.* 3. <https://doi.org/10.2196/medinform.3503>
- Franklin, B.D., O’Grady, K., Donyai, P., Jacklin, A., Barber, N., 2007. The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study. *Qual. Saf. Health Care* 16, 279–284. <https://doi.org/10.1136/qshc.2006.019497>
- Freriks, G., De Moor, G., Kalra, D., 2007. White paper: archetype paradigm: an ICT revolution is needed. *EPR Future Demands Flex. Plug--Play Exch. ICT Syst.* Version 1. http://members.quicknet.nl/hpfrer/conexis/News/4664385A-1ADC-44CE-AFF8-D0D0BF8C9950_files/GF%20Archetype%20Paradigm%20February%202007-1.pdf (accessed 25.11.17).
- Garde, S., Knaup, P., Hovenga, E., Heard, S., 2007. Towards semantic interoperability for electronic health records. *Methods Inf. Med.* 46, 332–343. <https://doi.org/10.1160/ME5001>
- Gibbons, P., Arzt, N., Burke-Beebe, S., Chute, C., Dickinson, G., Flewelling, T., Jepsen, T., Kamens, D., Larson, J., Ritter, J., others, 2007. Coming to Terms. <https://hln.com/assets/pdf/Coming-to-Terms-February-2007.pdf> (accessed 02.12.16).
- Hanseth, O., Bygstad, B., Ellingsen, G., Johannessen, L.K., Larsen, E., 2012. ICT standardization strategies and service innovation in health care. *Proceedings of The Thirty Third International Conference on Information Systems (ICIS)*, Orlando, Association for Information Systems 2012 ISBN 978-0-615-71843-9.
- Hanseth, O., Ciborra, C. (Eds.), 2007. *Risk, Complexity and ICT*. Edward Elgar Publishing Ltd.

- Hanseth, O., Lundberg, N., 2001. Designing work oriented infrastructures. *Comput. Support. Coop. Work CSCW* 10, 347–372.
- Hanseth, O., Lyytinen, K., 2010. Design theory for dynamic complexity in information infrastructures: the case of building internet. *J. Inf. Technol.* 25, 1–19. <https://doi.org/10.1057/jit.2009.19>
- Hanseth, O., Lyytinen, K., 2004. Theorizing about the design of Information Infrastructures: design kernel theories and principles, in: *Sprouts: Working Papers on Information Environments, Systems and Organizations* 4(Fall 2004): Article 1. W, pp. 1-35.
- Hanseth, O., Monteiro, E., 1998. Understanding Information Infrastructure. <http://heim.ifi.uio.no/~oleha/Publications/bok.pdf>.
- Hillestad, R., Bigelow, J., Bower, A., Girosi, F., Meili, R., Scoville, R., Taylor, R., 2005. Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. *Health Aff. Proj. Hope* 24, 1103–1117. <https://doi.org/10.1377/hlthaff.24.5.1103>
- Holten Møller, N., Dourish, P., 2010. Coordination by avoidance: bringing things together and keeping them apart across hospital departments, in: *Proceedings of the 16th ACM International Conference on Supporting Group Work*. ACM, pp. 65–74.
- Institute for Healthcare Improvement: The IHI Triple Aim [WWW Document]. URL <http://www.ihl.org:80/Engage/Initiatives/TripleAim/Pages/default.aspx> (accessed 11.27.17).
- Jaspers, M.W.M., Smeulers, M., Vermeulen, H., Peute, L.W., 2011. Effects of clinical decision-support systems on practitioner performance and patient outcomes: a synthesis of high-quality systematic review findings. *J. Am. Med. Inform. Assoc.* 18, 327–334. <https://doi.org/10.1136/amiajnl-2011-000094>
- Johannessen, L.K., 2012. Lightweight methods, heavyweight organisations. Transforming a small tailored product to a large integrated health information system. Doctoral thesis submitted at University of Tromsø.
- Johannessen, L.K., Ellingsen, G., 2009. Integration and Generification—Agile Software Development in the Healthcare Market. *Comput. Support. Coop. Work CSCW* 18, 607–634. <https://doi.org/10.1007/s10606-009-9097-8>
- Johnson, M., Mozaffar, H., Campagnolo, G.M., Hyysalo, S., Pollock, N., Williams, R., 2014. The managed prosumer: evolving knowledge strategies in the design of information infrastructures. *Inf. Commun. Soc.* 17, 795–813. <https://doi.org/10.1080/1369118X.2013.830635>
- Kalra, D., 2006. Electronic health record standards. *IMIA Yearb. Med. Inform.* 136-144.
- Kane, B., Luz, S., 2006. Multidisciplinary Medical Team Meetings: An Analysis of Collaborative Working with Special Attention to Timing and Teleconferencing. *Comput. Support. Coop. Work CSCW* 15, 501–535. <https://doi.org/10.1007/s10606-006-9035-y>

- Karasti, H., Baker, K.S., Millerand, F., 2010. Infrastructure Time: Long-term Matters in Collaborative Development. *Comput. Support. Coop. Work CSCW* 19, 377–415.
<https://doi.org/10.1007/s10606-010-9113-z>
- Kawamoto, K., Houlihan, C.A., Balas, E.A., Lobach, D.F., 2005a. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ* 330, 765. <https://doi.org/10.1136/bmj.38398.500764.8F>
- Kawamoto, K., Houlihan, C.A., Balas, E.A., Lobach, D.F., 2005b. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ* 330, 765. <https://doi.org/10.1136/bmj.38398.500764.8F>
- Klein, H.K., Myers, M.D., 1999. A Set of Principles for Conducting and Evaluating Interpretive Field Studies in Information Systems. *MIS Q* 23, 67–93. <https://doi.org/10.2307/249410>
- Kniberg, H., 2011. *Lean from the trenches: Managing large-scale projects with Kanban*. The Pragmatic Bookshelf, Dallas, Texas Raleigh, Raleigh North Carolina.
- Lenz, R., Peleg, M., Reichert, M., 2012. Healthcare process support: achievements, challenges, current research. *Healthcare Process Support: Achievements, Challenges, Current Research*. *International Journal of Knowledge-Based Organizations (IJKBO)*, 2 (4).
- Lenz, R., Reichert, M., 2007. IT support for healthcare processes – premises, challenges, perspectives. *Data Knowl. Eng., Business Process Management Where business processes and web services meet* 61, 39–58. <https://doi.org/10.1016/j.datak.2006.04.007>
- Mackay, H., Carne, C., Beynon-Davies, P., Tudhope, D., 2000. Reconfiguring the User: Using Rapid Application Development. *Soc. Stud. Sci.* 30, 737-757. Doi: 10.1177/030631200030005004
- Markus, M.L., Mao, J.-Y., 2004. Participation in development and implementation-updating an old, tired concept for today's IS contexts. *J. Assoc. Inf. Syst Ems* 5, 514–544.
- Ministry of Health and Care Services, 2014a. Overall summary of ICT in Norwegian Healthcare. Utredningen av “en innbygger - èn journal”: IKT utfordringsbilde i helse-og omsorgssektoren. https://www.regjeringen.no/contentassets/355890dd2872413b838066702dcdad88/ikt_utfordringsbilde_helse_omsorgssektoren.pdf?id=2293241 (accessed 17.12.17).
- Ministry of Health and Care Services, 2014b. Comparative analysis of the regional health authorities in the ICT field. Utredning av “en innbygger - en journal”. Komparativ analyse av de regionale helseforetak på IKT-området. Helsedirektoratet. https://www.regjeringen.no/contentassets/355890dd2872413b838066702dcdad88/komparativ_analyse_rhf_ikt.pdf (accessed 11.12.17).
- Ministry of Health and Care Services, 2012. Whitepaper. no. 9 (2012 - 2013): "One citizen – one Health Record". St.Meld. nr. 9 (2012–2013) Én innbygger - én journal (Whitepaper (Stortingsmelding)).

- <https://www.regjeringen.no/no/dokumenter/meld-st-9-20122013/id708609/> (accessed 10.12.17).
- Møller, N.H., Bjørn, P., 2011. Layers in Sorting Practices: Sorting out Patients with Potential Cancer. *Comput. Support. Coop. Work CSCW* 20, 123–153. <https://doi.org/10.1007/s10606-011-9133-3>
- Monteiro, E., Pollock, N., Hanseth, O., Williams, R., 2012. From Artefacts to Infrastructures. *Comput. Support. Coop. Work CSCW* 22, 575–607. <https://doi.org/10.1007/s10606-012-9167-1>
- Myers, M.D., Avison, D., 2002. *Qualitative Research in Information Systems: A Reader*. SAGE.
- openEHR CKM, Clinical Knowledge Manager [WWW Document]. URL <http://openehr.org/ckm/> (accessed 12.18.17).
- Orlikowski, W.J., Baroudi, J.J., 1991. Studying information technology in organizations: Research approaches and assumptions. *Inf. Syst. Res.* 2, 1–28.
- Pedersen, R., Wynn, R., Ellingsen, G., 2015. Semantic Interoperable Electronic Patient Records: The Unfolding of Consensus based Archetypes. *Studies in Health Technology and Informatics* 2015; Volum 210. ISSN 0926-9630.s 170 - 174. <https://doi.org/10.3233/978-1-61499-512-8-170>.
- Pipek, V., Wulf, V., 2009. Infrastructuring: Toward an Integrated Perspective on the Design and Use of Information Technology. *J. Assoc. Inf. Syst.* 10, 447–473.
- Pollock, N., Hyysalo, S., 2014. The Business of Being a User: The Role of the Reference Actor in Shaping Packaged Enterprise System Acquisition and Development. *MIS Q* 38, 473–496. <https://doi.org/10.25300/MISQ/2014/38.2.07>
- Pollock, N., Williams, R., 2010. e-Infrastructures: How Do We Know and Understand Them? Strategic Ethnography and the Biography of Artefacts. *Comput. Support. Coop. Work CSCW* 19, 521–556. doi:10.1007/s10606-010-9129-4
- Pollock, N., Williams, R., 2008. *Software and Organisations: The Biography of the Enterprise-Wide System Or how SAP conquered the world*. Routledge.
- Pollock, N., Williams, R., Procter, R., 2003. Fitting Standard Software Packages to Non-standard Organizations: The ‘Biography’ of an Enterprise-wide System. *Technol. Anal. Strateg. Manag.* 15, 317–332. <https://doi.org/10.1080/09537320310001601504>
- Ribes, D., Finholt, T.A., 2009. The Long Now of Technology Infrastructure: Articulating Tensions in Development*. *J. Assoc. Inf. Syst. Atlanta* 10, 375–398.
- Rolland, K.H., Monteiro, E., 2002. Balancing the local and the global in infrastructural information systems. *Inf. Soc.* 18, 87–100.
- Santos, M.R., Bax, M.P., Kalra, D., 2012. Dealing with the Archetypes Development Process for a Regional EHR System. *Appl. Clin. Inform.* 3, 258–275. <https://doi.org/10.4338/ACI-2011-12-RA-0074>

- Schmidt, K., Simone, C., 1996. Coordination mechanisms: Towards a conceptual foundation of CSCW systems design. *Comput. Support. Coop. Work CSCW* 5, 155–200.
<https://doi.org/10.1007/BF00133655>
- Silsand, L., Christensen, B., 2017. Generification in change: the complexity of modelling the healthcare domain. Presented at the InfraHealth, Aarhus, Denmark.
https://doi.org/10.18420/ihc2017_020
- Silsand, L., Christensen, B., Ellingsen, G., 2012. Towards an “empowered” user role in the design of large-scale electronic patient records, in: *Proceedings of the 12th Participatory Design Conference: Exploratory Papers, Workshop Descriptions, Industry Cases - Volume 2*, PDC ’12. ACM, New York, NY, USA, pp. 65–68. <https://doi.org/10.1145/2348144.2348165>
- Silsand, L., Ellingsen, G., 2014. Generification by Translation: Designing Generic Systems in Context of the Local. *Journal of the AIS 2014; Volum 15 (4)*. ISSN 1536-9323.s 177 - 196.
- Simonsen, J., Robertson, T., 2012. *Routledge International Handbook of Participatory Design*. Routledge.
- Star, S., Bowker, G., 2006. How to Infrastructure, in: *Handbook of New Media LA*. Updated Student Edition. Lievrouw and SL Livingstone (Ed.). SAGE, pp. 230–246.
- Star, S.L., Ruhleder, K., 1996. Steps Toward an Ecology of Infrastructure: Design and Access for Large Information Spaces. *Inf. Syst. Res.* 7, 111–134. <https://doi.org/10.1287/isre.7.1.111>
- The Norwegian Directorate of eHealth, 2017. Nasjonal handlingsplan for e-helse 2017-2022 (PDF) [WWW Document]. URL [https://ehelse.no/Documents/Nasjonal%20e-helsestrategi%20og%20handlingsplan/Nasjonal%20handlingsplan%20for%20e-helse%202017-2022%20\(PDF\).pdf](https://ehelse.no/Documents/Nasjonal%20e-helsestrategi%20og%20handlingsplan/Nasjonal%20handlingsplan%20for%20e-helse%202017-2022%20(PDF).pdf) (accessed 06.11.17).
- The Norwegian National Research Ethics Committees. Declaration of Helsinki [WWW Document]. Etikkom. URL <http://www.etikkom.no/en/library/practical-information/legal-statutes-and-guidelines/declaration-of-helsinki---ethical-principles-for-medical-research-involving-human-subjects/> (accessed 12.19.17a).
- The Norwegian National Research Ethics Committees. General guidelines for research ethics [WWW Document]. Gen. Guidel. Res. Ethics. URL <http://www.etikkom.no/en/ethical-guidelines-for-research/general-guidelines-for-research-ethics/> (accessed 12.19.17b).
- Timmermans, S., Berg, M., 2003. *The Gold Standard: The Challenge of Evidence-Based Medicine: The Challenge of Evidence-based Medicine and Standardization in Health Care*. Temple University Press, Philadelphia, Pa.
- Ulriksen, G.-H., Pedersen, R., Ellingsen, G., 2016. Establishing ICT Governance for Regional Information Infrastructures in Healthcare. *Proceedings of the Annual Hawaii International Conference on System Sciences 2016; Volum 2016-March*. ISSN 1530-1605.s 5137 - 5146.s
<https://doi.org/10.1109/HICSS.2016.636>

- Van de Ven, A.H., 2007. Engaged Scholarship: A Guide for Organizational and Social Research. OUP Oxford, Oxford, UNITED KINGDOM.
- Vikkelsø, S., 2005. Subtle Redistribution of Work, Attention and Risks: Electronic Patient Records and Organisational Consequences. *Scandinavian Journal of Information Systems*: Vol. 17 : Iss. 1 , Article 10. Available at: <http://aisel.aisnet.org/sjis/vol17/iss1/10>
- Walsham, G., 2006. Doing interpretive research. *Eur. J. Inf. Syst.* 15, 320–330. <https://doi.org/10.1057/palgrave.ejis.3000589>
- Walsham, G., 1995. Interpretive case studies in IS research: nature and method. *Eur. J. Inf. Syst.* 4, 74–81. <https://doi.org/10.1057/ejis.1995.9>
- Wang, M., 2007. Cultivating the 'Generic Solution'—The Emergence of A Chinese Product Data Management (PDM) Software Package (PhD thesis). The University of Edinburgh.
- What is openEHR? [WWW Document]. URL http://www.openehr.org/what_is_openehr# (accessed 11.20.17).
- WHO | eHealth [WWW Document]. URL <http://www.who.int/ehealth/en/> (accessed 12.15.17).
- Wollersheim, D., Sari, A., Rahayu, W., 2009. Archetype-based electronic health records: a literature review and evaluation of their applicability to health data interoperability and access. *HIM J.* 38, 7–17.

Paper 1

Paper 2

Paper 3

Paper 4

Paper 5