

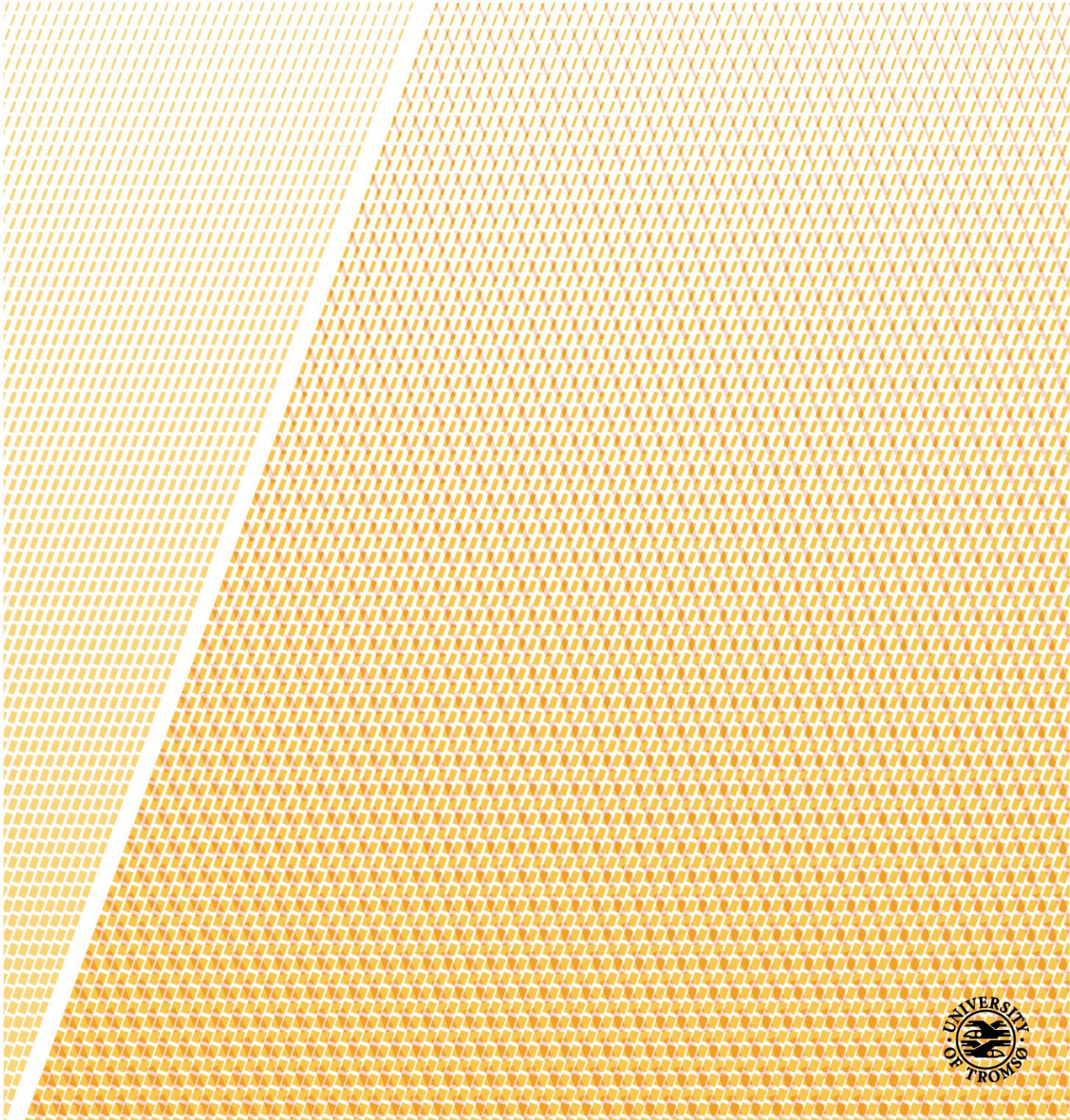


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Growing an information infrastructure for healthcare based on the development of large- scale Electronic Patient Records

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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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My six-year PhD-journey is ending, and it has taken me through an enormous transition from the collegium of healthcare practice to a research position. However, I am happy that I took the chance and went aboard the ‘research ship’, which took me into unknown waters. Sailing away from familiar work in clinical practice challenged my comfort zone in several ways, but most of all it extended my professional knowledge and brought me new professional relationships. Firstly, I want to thank my supervisor, Gunnar Ellingsen, for keeping the ‘ship’ on a steady course, for always being encouraging, and willing to listen to, and discuss, my ideas. I also want to thank my informants for sharing their time with me, especially Anne Pauline Anderssen for several formal and informal talks during these years. The journey brought me to several conferences, workshops and ‘PhD days’ at the University of Oslo. Those meetings were great experiences characterized by a wonderful atmosphere and delightful people.

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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).

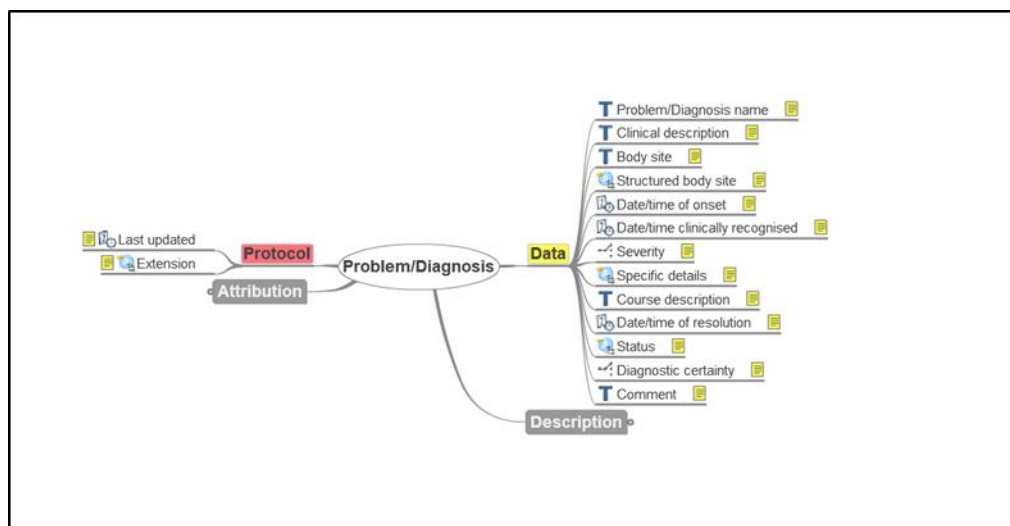


Figure 2. An illustration of an archetype as meta-data (openEHR CKM, 2017)

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).

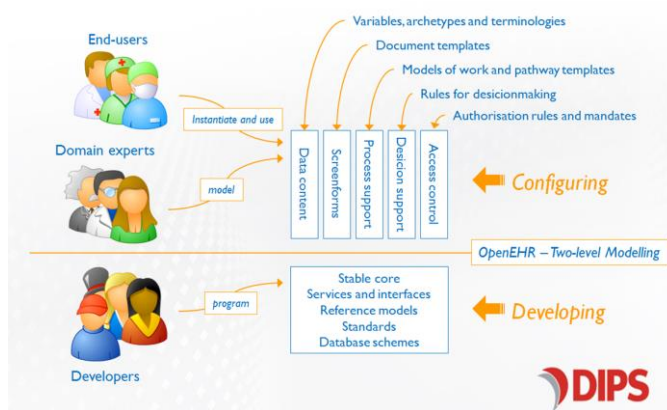


Figure 4. The openEHR platform approach

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 (Hanseth 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.

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Paper 1

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Generification by Translation: Designing Generic Systems in Context of the Local

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Abstract

While the mechanisms of generification during implementation and use of large-scale systems are well known, this paper extends and analyzes the notion into the design phase of generic systems and provides insight into the associated socio-technical key mechanisms at play. The paper draws on the information infrastructure literature, and emphasizes how generic systems' designs always face infrastructural challenges and opportunities in the development process. The paper illustrates how a vendor solved the infrastructural challenges by (to a large degree) lending on local practice, translating perspectives, and carefully adjusting their design strategy over time. We argue that our findings have implications for practice because they underscore the malleability of the collaboration process between vendor and users. First, we suggest that designing a generic system calls for a flexible vendor willing to change and adjust the 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 software design, and raising their skills in making precise contextual narratives. Third, we emphasize the importance of the project management's engagement in recruiting clinical personnel and in making it possible for the clinicians to participate in the project. Empirically, the paper presents the initial stages of a large electronic patient record (EPR) development project that has been running from 2012 in the North Norwegian health region and is due to finish in 2016.

Keywords: Design, Information Infrastructure, Generification, Local Practice, Translation.

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1. Introduction

The implementation of large generic systems in organizations is associated with many benefits. Some of these are institutional-wide coverage, streamlining of work practices, and the possibility to reuse systems across many institutional settings. However, many studies have noted how organizations are different and therefore may have diverging needs (e.g., Berg, 1999; Berg & Goorman, 1999; Star & Ruhleder, 1996). Accordingly, it is crucial for an organization's vendors and project managers to align local needs with technical opportunities in order to establish a well-working system. Pollock and Williams (2008) have coined this process "generification", and describe it as the vendors' strategy of making a generic system work in several settings. Together with customization capabilities of the software, generification involves social processes of ordering, prioritizing, and persuading users in order to motivate them to use similar versions of the same system that is installed in different organizations (Pollock & Williams, 2008). Currently, the mechanisms of generification during implementation and use are well known (see, e.g., Pollock & Williams, 2008), but we have less insight about the generification processes in the design phase and to what extent local knowledge is exploited in the process. Therefore, this paper extends the notion of generification to the formative stages of generic systems and provides insight about the key mechanisms at play in this crucial phase.

A key characteristic of generic systems is that they contain a standardized core supplemented with a customizable part that is a range of clearly defined building blocks (Baldwin & Woodard, 2008; Beale & Heard, 2007, 2008). The idea is that designers can take a step back from the users' context and leave the tailoring of the building blocks to skilled users and domain experts. This sustains a more or less distinct boundary between the designers' technical domain and the users' work domain. An interesting example from healthcare is the emerging openEHR architecture (Beale & Heard, 2007, 2008) developed by the openEHR foundation and standardized by CEN and ISO in the EN/ISO 13606 standard series (Chen, Klein, Sundvall, Karlsson, & Ahlfeldt, 2009, p. 2). Electronic patient records developed in accordance with this architecture are supposed to offer both a high degree of interoperability of data (through so-called archetypes) between different healthcare domains, and a high degree of customization in various use contexts. The openEHR architecture consists of a two-level modeling approach for electronic patient records (EPRs) (Chen et al., 2009, p. 2; Garde, Knaup, Hovenga, & Heard, 2007, p. 333) that separates a system's technical design from clinical concerns. Many pilot projects have so far reported on openEHR pilot projects (Bernstein, Tvede, Petersen, & Bredgaard, 2009; Chen et al., 2009), but very few (if any at all) have studied large-scale implementations (Wollersheim, Sari, & Rahayu, 2009).

We pose the following research question: what characterizes the socio-technical process of designing generic software? We organize our discussion along the following three dimensions: First, we analyze how and to what extent local practice is embedded in the design of generic systems. By this, we explore what domain knowledge the designers need and how they use it for generification purposes. Second, we examine the process whereby users' needs are translated into generic functionality, and, in turn, how this functionality is presented to the users in a way that makes sense to them. Third, we look into how the design of generic software tends to widen the gap between users and designers by requiring considerable planning and up-front design.

Theoretically, our paper draws on the information infrastructure literature (Aanestad & Jensen, 2011; Hanseth & Lyytinen, 2010; Star & Ruhleder, 1996). We emphasize how design of generic systems always faces infrastructural challenges and opportunities in their formative stages. Empirically, we draw on the initial stages of a large EPR project, run by the Northern Norway Regional Health Authority and referred to as BigInvestment, that began in 2012 in the North Norwegian health region and is scheduled to run to 2016. The involved software house, BigVendor, is the largest EPR vendor in the Norwegian healthcare market. BigVendor has started to develop a new EPR infrastructure that will allow skilled users to define and tailor standardized user interfaces and screen workflows (in accordance with clinical workflows) based on an openEHR/archetype methodology (Kalra, 2006).

This paper is organized as follows: in Section 2, we outline our theoretical perspective on generic systems and information infrastructures. In Section 3, we present the Northern Norway Regional Health Authority and the BigInvestment project, and reflect on methodological issues. In Section 4, we present the involved vendor's design strategy. In Section 5, we present the case and elaborate on several steps of the project's history. In Section 6, we discuss the case, and, in Section 6, we conclude the paper.

2. Theory

2.1. Generic Systems

Large-scale generic systems typically encompass extensive parts of the organizations they operate in, and employees use the systems in various ways. Moreover, large-scale generic systems have an "ability to transcend their place of production" (Pollock, Williams, & D'Adderio, 2007, p. 255). One fundamental idea inherent in large-scale generic systems is that their generic capabilities means that organizations need less resources to implement a system used by other organizations. Some examples of such systems are enterprise resource planning (ERP) systems and, in healthcare, electronic patient record systems (EPRs).

Two concerns have emerged as particularly important when designing generic systems; namely, their ability to support customization and their ability to support interoperability. The degree of interoperability with other systems has so far proved to be limited (Wang, 2007, p. 108), and, if supported, the integration is typically asymmetric (i.e., the integration mechanisms are outlined solely by those who control the generic system) (Sahay, Aanestad, & Monteiro, 2009), which potentially leads to less-robust integrations. A system's customization capability is a fundamental issue when implementing new practices because it deals with some of the rigidity associated with generic systems (Hanseth, Bygstad, Ellingsen, & Johannessen, 2012; Pollock et al., 2007). The ability to customize a system enables domain experts in user organizations to tailor it to local use. Examples of customization capability might be locally generated variables, templates, and definitions of rule-based workflow support. Then, a generic system can be defined as consisting of **the standardized core** in which certain components remain stable and **the complements** that are encouraged to vary across practices or over time (Baldwin & Woodard, 2008, p. 2).

For users, this might be seen as a big leap forward because extensive parts of generic systems can be tailored to their practice. For designers, this also might be beneficial because they would not need to know all the peculiarities and nuances of each specific healthcare practice because tailoring a generic system to an organization would be handed over to domain experts (Chen & Klein, 2007). Thus, an essential issue is to exercise control of the generic software's core. Here, the vendors need to establish some principles of what should remain the standardized core and what should be offered as customizable components to the users (Baldwin & Woodard, 2008).

Still, normally these systems exercise an inevitable impact on routines, practices, and collaboration in organizations. This implies a tremendous amount of generification work, described by Pollock and Williams (2008, p. 129) 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". Central in a generification process is the trade-off between particularization and generification. For the developers, typical questions include: what are particular/specific system requirements for a few customers compared to the general system requirements for a larger customer group; how particular are those requirements for the few customers; should diversity be built into the system or should functions meeting these particular needs be customized at each site?

While we appreciate Pollock and Williams' (2008) perspective, our study differs in two principal ways. Firstly, their account of generification focuses primarily on the implementation and adaptation of generic systems in organizations. In comparison, our study deals with generification in the design phase of these systems. Second, in their analysis, Pollock and Williams conceptualize the generic system as "the standard" in the form of a standardized package. In our study, we focus on how the

new generic system is expected to adhere to an international standardized framework (i.e., openEHR) in order to ensure interoperability between systems built in accordance with this framework. Accordingly, this scales the complexity.

2.2. The OpenEHR Architecture—A Global Standardized Framework

The openEHR architecture was developed by the openEHR foundations and standardized by CEN and ISO in the EN/ISO 13606 standard series (Chen et al., 2009, p. 2). It was created to support a high degree of interoperability of data between different healthcare domains and a high degree of customization in various use contexts (Beale & Heard, 2007, 2008). It includes a two-level modeling approach for EPRs (Garde et al., 2007, p. 333; Chen et al., 2009, p. 2) that separates the system's technical design from clinical concerns. A standardized reference information model represents the first level, while the openEHR archetypes based on the reference model represent the second level (Garde et al., 2007, p. 333; Beale & Heard, 2007, p. 8). A "blood pressure (BP) archetype, for example, represents a description of all the information a clinician might need or has to report about a blood pressure measurement" in a patient's record (Garde et al., 2007, p. 333). The actual blood pressure value is accompanied by additional data on whom (who measured the BP), how (which type of equipment was used, if the patients was sitting/bed resting), when (related to datum and time of day), and where (refers to "where" on the patients body; for example, intra-arteria BP, right/left arm or leg, and so on) as a way of describing the context around the blood pressure measurement. Archetypes are therefore "metadata used to define patterns for the specific characteristics of the clinical data, for example the blood pressure, in this case" (Kalra, 2006, p. 138).

Skilled users are encouraged to embed internationally agreed-on archetypes in systems based on the openEHR architecture to ensure interoperability, but are also free to define their own local archetypes. Archetypes can be seen as generic building blocks (i.e., customizable components) in the hands of clinical personnel or domain experts. In turn, these building blocks can be used to construct templates and compose archetypes into larger structures that often correspond to screen forms, documents, or reports (Beale & Heard, 2007, p. 8). In this way, archetypes are supposed to support a high degree of local customization for users and domain experts:

A fundamental aim of the archetype approach ... is to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way EHRs are built up using designed structures to express the required clinical data and assuring that all necessary constraints on the values of record components are observed. (Garde et al., 2007, p. 336)

Beale & Heard (2007) also point to that an archetype approach will ensure an easier development process for developers because it separates the technical design and clinical concerns. Hence, a system's developers would not need to know all the organizational peculiarities in every different context because the use of archetypes enables easy reuse of the software across different healthcare organizations. Moreover, the separation of concerns enable system's developers to build stable EHR systems without knowledge about specific clinical content necessary in different fields. The specification of clinical content can be authored and amended later (Chen & Klein, 2007).

The literature has so far reported many successful pilots on the openEHR approach, but very few (if any at all) have applied it on a large scale (Wollersheim et al., 2009). This makes large-scale projects in this domain extremely interesting because there is no definite solution on how these systems should be designed. As such, the information infrastructure concept is a way of gaining more understanding about this process.

2.3. Information Infrastructures

The theoretical framework of information infrastructure has been used to study the design, implementation, and use of large-scale information systems (Aanestad & Jensen, 2011; Hanseth & Lyytinen, 2010; Star & Ruhleder, 1996). These systems are never seen as standalone entities, but are integrated with other information systems and communication technologies, and with non-technical

elements (Aanestad & Jensen, 2011, p. 162). Therefore, analyses of information infrastructures need to consider a broad range of socio-technical issues shaping the implementation process.

A basic principle of an information infrastructure is that it is never built from scratch; rather, it evolves from the installed base, the existing information system (IS) portfolio in specific contextual practices. As a part of this, the infrastructure shapes and is shaped by the work practice in an on-going co-construction process between technical and social elements (Monteiro, Pollock, Hanseth, & Williams, 2012; Star & Ruhleder, 1996). During the progression of an information infrastructure 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 means that it becomes difficult to replace or change. Therefore, newer versions are adjusted or changed carefully in order to maintain backward compatibility with previous versions (Bowker & Star, 1999). This is a process of on-going negotiation and compromises for achieving stability or alignment (Latour, 1987).

In this regard, many studies do not refer to infrastructural design as construction, but rather conceptualize it as an “evolving socio-technical system” (Hanseth & Lyytinen, 2010, p. 4) or infrastructuring (Karasti, Baker, & Millerand, 2010; Pipek & Wulf, 2009) that needs to be carefully cultivated (Aanestad & Jensen, 2011). Hence, it is crucial to seriously engage with local contexts when designing information systems (Fitzpatrick & Ellingsen, 2012).

However, few researchers have explicitly addressed design strategies for infrastructure development, but Hanseth and Lyytinen (2010) specifically suggest:

- Designing simple IT capabilities that are initially useful
- Mobilizing many users, which frequently is promoted through the slogan “users before functionality”
- Drawing on the existing installed base, and
- Modularizing the II by building separately its principal functions and sub-infrastructures.

To some degree, this insight has spilled 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 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 in these methods is “user stories”, which are short narratives 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.

However, the design of generic systems adds a new dimension to the above-mentioned insights. While local practice is important for design, so also is the need to carve out generic elements and to adhere to global principles such as the openEHR framework. This inevitably creates a local/global tension that needs to be resolved (Star & Ruhleder, 1996). The move from local insights to developed generic concepts appears to be a crucial generification process that needs to be considered.

3. Method

Empirically, this paper presents the initial stages of a large electronic patient record (EPR) project, referred to as BigInvestment. After a prolonged bid for tendering process, the North Norwegian health region decided in 2011 to invest in new clinical ICT systems from BigVendor for all 11 hospitals in North Norway. The BigInvestment project was established for the 2012-2016 period. Moreover, it is estimated to cost 82 million EURO, which currently makes BigInvestment one of the most ambitious healthcare-related ICT projects in Norway. The Northern Norway Regional Health Authority employs about 12,500 person-years, which means there are many users that will make use of the new clinical systems and

have to be heard in the development process. The University Hospital of Northern Norway (UNN) is by far the largest of the 11 hospitals and has around 5,900 employees and 600 beds.

A key goal in the BigInvestment project was to make the new EPR more generic to allow users to tailor the EPR software to their specific needs, such as the possibility to define more structured content of the EPR, in line with an openEHR approach (Beale & Heard, 2007, 2008). The new EPR would also allow users to define templates for the support of specific user needs, such as standardized patient pathways for specific diagnoses. Accordingly, a core element outlined in the BigInvestment project was the involvement of end users, the healthcare practitioners who hold clinical expertise, in the development process. Therefore, over 100 clinicians from different healthcare professions and geographical locations were recruited to participate with BigVendor in six different EPR development tracks: decision module for psychiatry; surgery planning; process support, decision support, and structured record¹ (hereafter named PDS); authorization and access control; e-prescription; and nursing care plans. The first five first tracks started in February 2012 and were expected to end in the beginning of 2014. The latter track, nursing care plans, started in spring 2013.

This study applies the interpretive approach to case study research to provide insight about the key mechanisms at play in the formative stages of generic systems (Klein & Myers, 1999; Walsham, 1995), and narrowed to the PDS development track. The epistemological belief in interpretive research emphasizes the understanding of social processes by getting involved inside the world of those generating them, and not by hypothetical deductions or predefined variables. The approach also assumes that social realities are not discovered, but interpreted (Orlikowski & Baroudi, 2002).

In line with the interpretive approach, the first author primarily collected the empirical data by becoming involved in the development process through different settings such as user-designer workshops, video conference meetings, participant observation at the vendor's site, formal and informal discussions with project members, document studies, and formal semi-structured interviews. The second author contributed in some of the semi-structured interviews. The data collection lasted from January 2012 to January 2013. In addition, the first author has worked as a nurse in different fields of the Norwegian healthcare service over the last 15 years. The second author has a long history of studying the implementation and use of ICT in healthcare, particularly about EPRs in hospitals.

Furthermore, the interpretive approach calls for detailed case descriptions covering the different sites involved (see Table 1), followed by an analysis of the data for potential analytical themes guided by the philosophical perspective of hermeneutics and the information infrastructure framework. The chosen philosophical perspective implies considering the entire data collection in an iterative and interpretive process. Therefore, our examination has been a back-and-forth process between fieldwork, case descriptions, and the use of relevant literature emphasizing the concepts of information infrastructure, generic systems, archetypes, agile development methodology, and the notion of translation. In addition, we discussed the data and case description with other members of the IS community in healthcare. The interpretive process, or the hermeneutic circle, constituted evolving issues that provided a new understanding about the development process. Accordingly, we need to understand the presented case as a complex whole "from preconceptions about the meanings of its parts and their interrelationships" (Klein & Myers, 1999; Walsham, 1995).

¹ Structured record points to the clinical use of pre-defined clinical contents items from a library of such definitions, in this case "archetypes". Then all recorded data will ultimately just be instances of the standard content definitions, which affords a basis for standardized querying to work (www.openehr.org).

Table 1. Timeline of Data Collection

Period	Formal meetings, workshops, video conference meetings	Informal meetings, interviews, participant observation
February-June 2012	<ul style="list-style-type: none"> • One formal meeting with key members of the BigInvestment project and employees in the trust (3 hours) • Eight days of workshops • Three video conferences: BigVendor, BigInvestment project, and users (approx. 6 hours) 	<ul style="list-style-type: none"> • Three informal meetings with key members of the BigInvestment project (approx. 8 hours) • One interview with the hospital Department Manager
August-December 2012	<ul style="list-style-type: none"> • Four days of workshops • Three video conferences: BigVendor, BigInvestment project, and users (approx. six hours) 	<ul style="list-style-type: none"> • One informal meeting with key members of the BigInvestment project (approx. 2 hours) • Three interviews with developers • Three occurrences of participant observation at BigVendor (approx. 9 hours)
January 2013		<ul style="list-style-type: none"> • Two interviews with managers at BigVendor

4. BigVendor's Design Strategy

During the last 25 years, BigVendor has accumulated high-level expertise and a great deal of knowledge about the Norwegian healthcare service and the complexity of developing and implementing ICT systems that support the heterogeneous healthcare domain. The vendor currently enjoys approximately 73 percent of the hospital-based EPR market in Norway relative to the number of institutions that run the BigVendor portfolio (Ellingsen & Monteiro, 2012).

Over several years, BigVendor has applied an agile development approach such as Scrum and Extreme Programming (XP). Short development cycles lasting two to four weeks and continuous release of working software characterize the agile approach. The approach implied working in close collaboration with customers (users) in earlier development projects. A principal communication tool between the users and developers was user stories informing the vendor about the users' needs. User stories are short (2-3 lines) but sufficiently detailed stories, based on requests from the users, and formulated in non-technical language. Both users and developers could formulate these stories, although they were created in order to add value for the user. A developer at BigVendor described it by saying: "Every time we make software based on a user-story, somehow we make the users satisfied, because the users will gain a value of the delivered software".

Relying on an agile development methodology, Big Vendor found it appropriate to organize the developers into several teams mainly supporting specific software development. Each team included six to eight people who had daily meetings and worked in close collaboration with each other. Each team used its own backlog, which was a collection of user stories in prioritized order, to guide the development process. While discussing software in progress, the developers frequently turned to the specific user story as a guideline for ensuring that the software produced or modified was valuable to the users.

Approximately five or six years ago, BigVendor started to use a model-driven architecture, which culminated in 2011 by its decision to use the openEHR architecture. The vendor's decision also conformed to the National Norwegian strategy on archetypes. By committing to the openEHR architecture and the notion of archetypes, BigVendor started to use the the open source library from

Ocean Informatics². According to BigVendor, openEHR provides an excellent model (see Figure 1) of the generic core of the intertwined and heterogeneous healthcare domain, and the model serves as a fundament for model-driven design.

OpenEHR's model illustrates how the overall clinical workflow proceeds, independent of the healthcare domain or specific clinical professions. However, it is easy to target the model to a specific clinical context (e.g., when a physician (investigator) prescribes a new medication, a nurse (investigator agents) receives this message, and forwards "the baton" to the next person in line—another nurse, who gives the medication to the patient). The patient, nurses, and physician observe the effect of the new medication (observations) and inform the physician (investigator) if other "instructions" have to be made. The whole process demands coordination and communication by and between clinicians and administrative personnel directly and indirectly involved with the actual patient. Moreover, how the workflow in particular proceeds will differ depending on the department. Another argument for using the openEHR architecture was the separation of technical and clinical concerns. According to the BigVendor's strategy, this would make it less resource demanding to maintain the system after it was developed. Consider the following statement:

The profit by using the "archetype approach" is that it allows us (the developers) to live in "our own little developers' world"—though, not the developers who implement the system. (...) the designers don't need so much clinical contextual knowledge, and the domain experts don't need extended technical skills—but we have to know a little bit of each other's domains. (Manager, BigVendor)

The openEHR architecture implies that the vendor offers a generic platform, also promoted as an important benefit for the clinical community as the separation enables the users to source and build archetypes (standardized clinical information), and recommend screens that is workflow description tailored to different local needs.

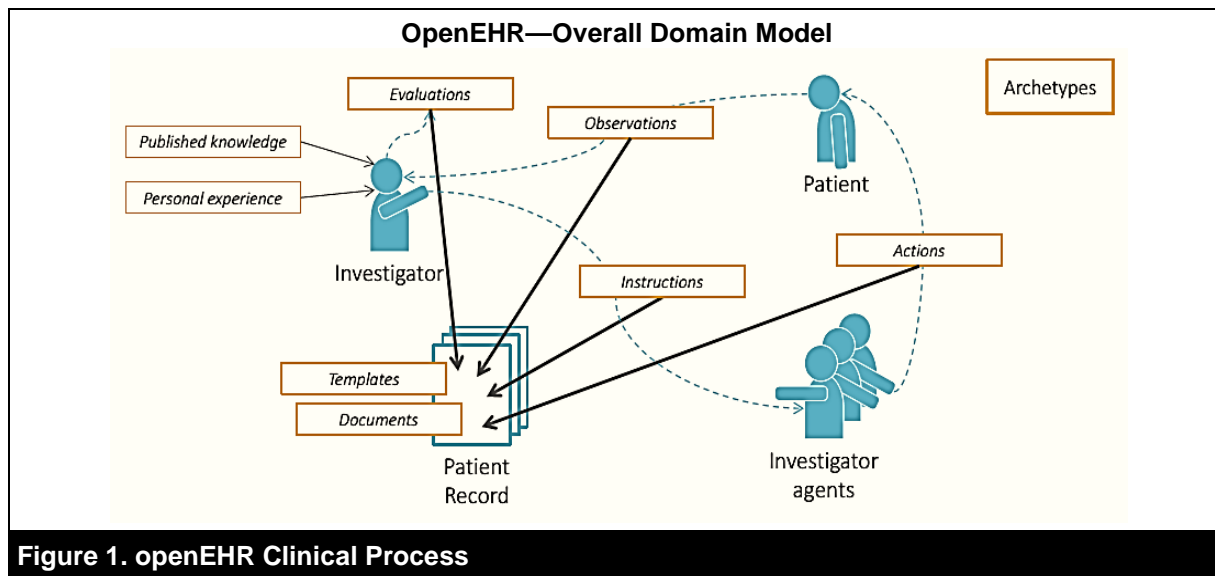


Figure 1. openEHR Clinical Process

² www.oceaninformatics.com

5. Case

5.1. Phase 1: Invitation to Write User Stories for Generic Functionality

The PDS development track started out ambitiously: its overall goal was to carve out the system's generic platform, which is fundamental for enabling flexible process- and decision support. As a point of departure for the collaboration, BigVendor invited the users to make user stories addressing needs for generic functionalities by linking the invitation to openEHR's clinical process (see Figure 1). To emphasize the innovation potential of the new technology, BigVendor encouraged the users to think about their future needs. One developer said: "You should forget about your current EPR and make wishes for what you really need".

The aim of separating the users' from their present EPR system was to make them more emancipated when communicating their needs. Yet, the strategy of making requests as generic as possible turned to be rather difficult, as exemplified in the following user story: "As a healthcare practitioner, I want the system to make it possible to easily display all compulsory treatment given" (Therapist, Hospital).

This particular user story started with the line "As a healthcare practitioner..." that address a general healthcare role. Nevertheless, the required need of "an easily display of all *compulsory treatment given*" strongly reflected a need for healthcare practitioners working in specialist psychiatric care because Norwegian legislation only permits the use of compulsory treatment for patients in jurisdictions of compulsory psychiatric care. However, this user story was just randomly chosen to exemplify the difficulties of making generic requests separated from their professional occupation and clinical work. Other user stories were incompatible with each other. For example, in a department for rehabilitation, the clinicians typically approached a patient's problems in interdisciplinary manners, as indicated by the following quote:

As users of the system, we like to write and approve parts of a shared document and at the same time have the opportunity to see what other healthcare practitioners have written to ensure the quality of the document and make a comprehensive presentation.
(Occupational therapist, Hospital)

In comparison, several of the participating physicians from different specialities expressed that, from their point of view, they were overwhelmed by too much information. One physician proposed another user story that was clearly incompatible with the occupational therapist's user story: "As a physician, I like to have the opportunity to avoid seeing letters, therapist notes, etc., but must have access if I like to see them."

In addition, there were user stories pointing to general issues of different clinical roles as illustrated by the following examples:

As a secretary, I want a warning on the display if different kind of patient information has to be verified or/and an update is necessary.

As a nurse, I want to get an overview of the examinations, lab tests, etc ordered by the physician in one screen shot on the computer's display.

These user stories addressed definite needs in a more general manner, but, unfortunately, along with several other user stories, they were too fragmented in that they were not connected to a specific moment in the clinical process (see Figure 1) **when** the clinicians needed EPR support to perform a particular task.

The users contributed with about 100 user stories during the first collaborative phase, but the developers thought that they lacked coherence. The fragmented, context-bound user stories were not a convenient communication tool anymore because the user stories did not give the developers the

information necessary to build the generic platform. BigVendor realized that approaching the user-developer collaboration with traditional short and to-the-point user stories did not facilitate the two-level modelling approach. A developer from BigVendor stated: “We are not going to develop specific functionality for surgery planning, but rather generic functionality that makes surgery planning possible”.

To develop a generic EPR platform enabling local tailoring, the developers needed a new way of approaching the development process.

5.2. Phase 2: Longer User Descriptions—A Foundation for Shared Concepts

Turning toward a two-level modeling approach meant shifting from developing specific software based on specific user needs to developing generic software enabling local user needs. Still, the developers called for insight into the “reality” in which the generic software intended to provide support. Instead of asking for more user stories, the vendor changed strategy and asked the users to make descriptions of clinical processes and activities surrounding the processes. At the vendor’s request, a participating specialist physician (SP) made a comprehensive description, referred to as a clinical narrative, related to a specific clinical symptom. It proved to be successful and the user-developer collaboration proceeded along similar tracks. The selected clinical symptom, well known from the specialist physician’s practice, was urination disorders among elderly men. The clinical narrative started with the specialist physician receiving an elective referral from the general practitioner (GP):

*NN is a 73-year-old man. Previous diseases: hypertension, cardiac arrhythmias, diabetes—insulin dependent. Medication: Metoprolol 100mg*1, Warfarin dosage by list, Insulin dosage by list. Current medical problem: Increased urination affiliations latest years. Increased need to urinate, 3-4-time every night and at daytime every second hour. Small micturition volumes. Weak urine flow. The patient express a lasting need urinate, even when urination is done. No urine leakage, but sometimes “urgent incontinence”. On two occasions, the patient has observed blood in the urine. PSA slightly increased to 6.9, controlled by two measurements. Refer the patient for further examinations. Best regards, GP BB.*

Based on the GP’s referral, the specialist physician (SP) addresses three problems: urination disorder, haematuria and elevated PSA—all together making the SP to suspect prostate cancer. The SP refers the patient to the outpatient clinic for an extended examination. As a part of the process, the patient has to go through several examinations, for example, different blood tests, x-rays, cystoscopy and biopsy. The result of these examinations give way for how to proceed with the patient’s problems. According to the GP’s information about the patient’s medication, the patient has to cease Warfarin three days in advance of the appointment at the outpatient clinic. Warfarin exposes the patient to severe bleeding during surgical intervention, like the planned cystoscopy and biopsy. In addition, when making the referral to the outpatient clinic, the SP has to ensure the urgent matter of the patient’s problem in accordance with the national guidelines of prioritized treatment.

Although the patient pathway description was very thorough, the SP emphasized that the story reflected her point of view and not the intertwined story of the healthcare practitioners involved. However, the presentation initiated a rich discussion where healthcare practitioners added their perspective and concerns to the clinical description:

The patient uses anticoagulation and this medication has to be ceased before the intervention. In practice, the physician gives the instruction to “cease medication”, and the nurses put the instruction into action. So who is going to give the patient this message? (Nurse, workshop)

When the patient arrives the hospital for surgery, who has the role of ensuring that the patient actually has ceased the medication? (Nurse, workshop)

Maybe we could have some pop-up alarms for patients using medication that have to be ceased as well as pop-ups for patients approaching deadline of the waiting-lists?
(Secretary, workshop)

By discussing the clinical narrative, the users contributed with information about the collaborative work necessary to bring a patient through the clinical process. For instance, while the physicians performed interventions and determined the next step, nurses and secretaries had important roles in coordinating different examinations, in preparing the patients for different procedures, and in ensuring that the necessary equipment was available (cf. Figure 1). From the developers' point of view, the context-bound information gave them important insights into the intertwined clinical collaboration and contextualized tacit knowledge necessary to take the patient through the clinical process. One BigVendor developer said

We [the designers] have to open the “magic black box” of what actually happens from the time the patient get his notice of admission till he shows up, and the way through his pathway of treatment and care. We ought to know who ensures and enables that the clinical process comes through.

The discussions “opened” the “magic black boxes”, which revealed a very complex network of people and tasks—much more complex than the OpenEHR clinical process model managed to picture. A BigVendor developer underscored the complexity by stating that “One by one the steps in a clinical process are quite simple, but putting the steps together makes the process very complex”.

By taking the complexity of clinical processes into the developers' context, the narratives served as a map to develop the generic platform. In addition, the shift from single-user stories to narratives forced the vendor to evaluate the internal team's organization. In earlier development projects, the developers had “zoomed” into “bits and pieces” of the particular functionality to be developed. The two-level model approach addressed a higher degree of complexity for every single developer because developing the generic software called for an overall understanding of **what** a clinical process actually was and accordingly an overall understanding of the concept “generic platform”.

5.3. Phase 3: Engaging with the openEHR Framework in Design

Looking into the user-developer collaboration, the discussions about the context-bound narrative materialized a variety of needs from the different healthcare professions. However, even if the healthcare practitioners discussed software support from different clinical experiences, the steps in the process were recognizable for every clinician involved. In that way, the discussions about software supporting specific clinical processes generated desired software support on a more general level. In other words, the different health personnel could agree on relevant software independent of a specific clinical context. Moreover, the involved healthcare practitioners and developers had come to a common understanding of what a process- and decision system actually is, and the potential of such a system. In this sense, the user-developer collaboration was “on-track” and benefitted the development process.

Still, the adherence to the two-level modelling approach escalated the challenges for BigVendor's internal development process. Generally, a key innovation of the openEHR framework is the possibility of reuse of clinical information in numerous contexts. The reuse is related to the concept of a two-layered model that separates the clinical content from the reference model (information model), in which the clinical content strictly must be based on the pre-defined archetype “library”.

Though, in the initial development process, the developers had not taken into account the “concept of reuse”, and the consequences this concept claimed for developing the generic platform. For example, initially in the development process, a measurement registration (e.g., blood pressure) in the patient's medical curve would appear as a stand-alone registration not connected to a document in the patient's EPR. Moreover, the new system did not provide access control for stand-alone

registrations of clinical information, and consequently these registrations did not fulfill the national legislation's claim of reuse of sensitive personal information.

To comply with this claim, the developers had to use the openEHR's notion "composition" as a overall, collective term for different documents (e.g., discharge summaries, antenatal visits or operative notes). Then, connecting every single registration to a composition made it possible to manage access control for all clinical information about a patient, and consequently to reuse information in other documents. This example highlights the complexity the developers had to face: the openEHR framework, the clinical workflow, and how the clinical information had to relate to the national legal framework. Another technical implication in the initial stage was the interaction between the vendor's software and the open source library from Ocean Informatics. The clinicians addressed the need to register several procedures connected to, for example, a surgical intervention or clinical information (height, weight, allergy, etc) connected to an examination in one document, but initially the integration between the open source software and the vendor's software could not support multi-registrations of clinical information by archetypes in one document.

Nevertheless, the developers characterized the initial work with a two-level system as an enormous conception to perceive:

If you make software for surgery planning only, you can (easily) design a screen and add necessary fields... [However] if you are going to make something generic, you don't know the all pieces inside because what you make should not only work for surgery planning, but also for the laboratories and so on ... and the concerns and complexities becomes much bigger. (Developer, BigVendor)

To overcome the challenges of carving out the generic process-supporting elements of a clinical process in general, the two-level modeling approach called for a lot of work in-house and a massive upfront design in contrast to earlier development projects characterized by short development cycles and early delivery of working software.

5.4. Phase 4: Changing Communication Patterns with the Users

The necessary up-front design resulted in less regular feedback and user-developer interaction; consequently, the developers raised another concern. One said: "There are lots of small user stories that are impossible to implement, because the basic framework is not ready yet—and maybe the users feel that they haven't gotten any feedback on their requests".

This made it even harder for the developers to maintain an overview of how the generic elements matched the users' practices, and increased concern about whether the generic elements inherit the qualities of making local tailoring possible later on in the development process. When discussing one of the generic software modules, a developer complained:

We don't know the context where this will be used... We need feedback from the users to guide us... What is the use case and what do the clinicians require? Do we make a functionality that nobody needs?

Accordingly, the vendor had to find a way to present generic software-in-progress to the clinicians, and a way to facilitate dialogue between clinicians and developers during the presentations. To face the concern of an extended development process with no working software to present, the vendor saw it as important to increase the users' understanding of the two-level model approach and its inherit qualities of local tailoring, and the vendor aimed to trigger the users' ability to give feedback on software "in-progress". Moreover, BigVendor made a presentation of the two-level model concept by using the LEGO® analogy (see Figure 2), and broadcasted the presentation to users at all the hospitals. As one developer said: "We are going to build a LEGO® city, but at this stage we are making the description of how to put the single bricks together".

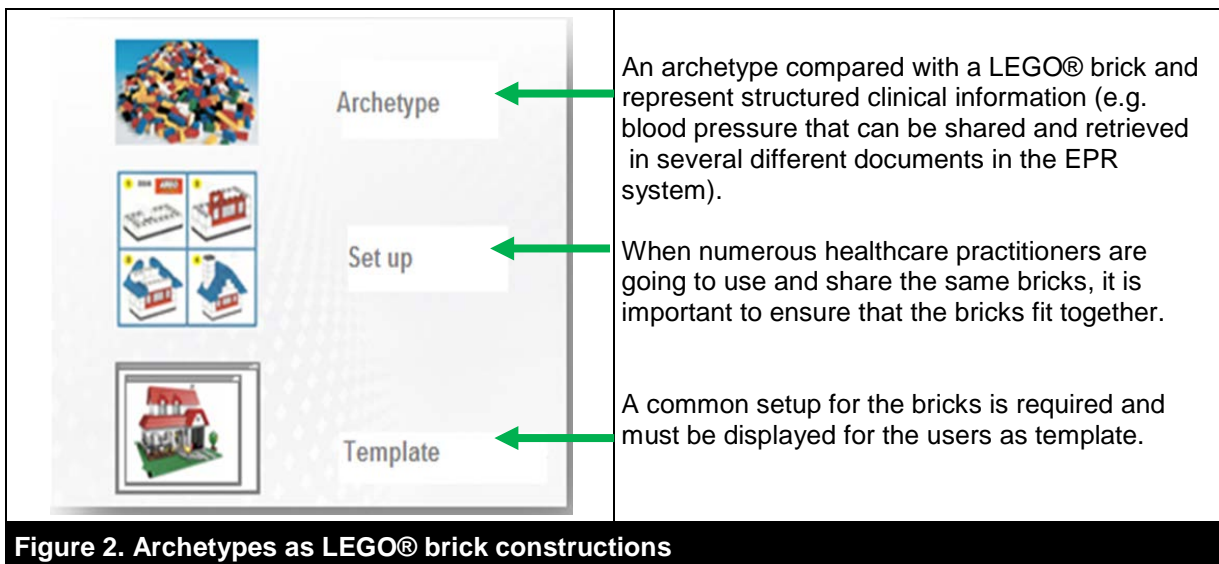
Once again, the context-bound clinical narratives became crucial in the development process by serving as a clinical backdrop for the generic “LEGO®” elements. The users welcomed the presentation of linking the two-level model concept to LEGO® constructions, and furthermore the translation of generic software into imagine local software based on clinical narratives and earlier discussions.

However, rewriting the context-bound clinical narratives into generic information to guide the vendor’s internal development process and translating the generic software back again into a clinical context added a layer of translation work for the developers to keep the development process on track. One BigVendor developer said:

It is challenging to design something general, but we ought to make the generic in the context of a specific context. In that sense, we enable locally tailored functionalities. In addition, I have to ask, if we don’t make it related to a specific context—what will we be able to present to the users?

Moreover, as the development process proceeded, the vendor placed a stronger focus on testing generic software in smaller groups of users. When testing, the users actually tried functionalities from the new EPR system to support tasks they normally did during their daily practices, but, of course, in a test-environment, not influencing the working EPR system. The users tried the software by themselves and with instructions from the vendor’s test personnel and gave feedback directly to the vendor.

Finally, the involved clinicians initiated an interesting discussion related to reorganization of the clinicians’ workflow as a response to the new evolving system that paved the way for supporting clinical work. For instance, the new system made it possible for physicians to set up an appointment for a patient in an outpatient clinic by themselves, in contrast to the limitations of the existing EPR where physicians have to send a referral to the secretary who scheduled the appointment. In addition, documenting patient information by using archetypes simplifies the documentation process (e.g., by reusing information and check-offs), and this triggered the physicians to do more of the documentation by themselves. Besides, implementing the new system calls for tailoring the system to different clinical contexts. Accordingly, the secretaries may play an important role as domain experts because they have high-level knowledge about clinical workflow conditions because of their everyday practice.



6. Discussion

6.1. Generification Strategies with a Foothold in Local Practice

From the outset, it is easy to believe that designing a generic system implies building it from scratch. In our case, for example, the vendor emphasized building the new system in accordance with the emerging openEHR framework and asked the users to forget about their existing functionality and think of something completely new. However, it is important to have in mind that the vendor controlled the principal existing information infrastructure in the hospital, including thousands of associated users. In such a perspective, the commissioned new openEHR-based system represented an extension and a development of the existing installed base of EPRs in the North Norwegian hospitals.

The decision to apply the OpenEHR framework spawned a set of generification strategies. In the first workshops, the users were invited to forget about their existing EPR system and asked to formulate user stories describing generic functionality with a clear reference to the OpenEHR framework. Unfortunately (alas as expected), this did not work out because it did not provide any meaning for the users to think in conceptual terms not bound to a specific context. In this regard, several studies have pointed out how a local foothold is essential in developing information infrastructures (see, e.g., Berg & Goorman, 1999; Star & Ruhleder, 1996). Our case illustrates how detailed and context-bound insight appeared to be a much better way of identifying what the users' actually needed.

An interesting finding from our case is how the users not only reflected on needs supported by the new system, but also on the current state of their local practice and how it might change. As technical advancements and new functionality was presented to the users, their feedback to the vendor emphasized the need for adjusting, changing, and improving current work practices: physicians could do more writing, ordering of tests, and examinations, and then secretaries and nurses who had done these tasks earlier could do other things. A suggestion emerging from the reflections was that of training the secretaries to be clinical domain experts. This indicates and underscores how the design of generic software occurs in co-construction with local practice (Monteiro et al., 2012), a striking contrast to the ideals of a two-level modelling openEHR approach.

While openEHR represents a relatively complete model of healthcare, it is interesting to note that a shared conceptual understanding between users and designers gradually emerged through insight from local practice and the installed base. An illustration is the long narrative about the patient with the urine disorder. The narrative was used repeatedly for developing a conceptual understanding of what a clinical process actually is: how different health personnel engaged with each other in various stages of the process, what kind of process and decision support was needed during the process, and by whom. As a generification strategy, this suggests that local processes of learning and the subsequent development of shared concepts are quite powerful compared to just applying ready-made models such as the openEHR, even if these are thoroughly worked out. For example, from the outset, users and designers interpreted the key concepts decision support and patient pathways quite differently, but, through interaction in the workshops, they negotiated and reached a shared understanding. This also indicates why the initial focus on short user stories vanished because these failed to capture the bigger contextual picture—the infrastructural interdependences across the various practices. The developers instead needed longer descriptions of current practice in which the users reflected on the support they received today and the improvements they would like to have. The vendor increasingly understood the infrastructural interdependences and organized the development teams according to contextual areas. In this way, concrete results, as the translation of generic software, were presented and discussed with specific user groups.

6.2. Generification by Translation: Archetypes, Templates, and Building Blocks

In Section 6.1, we discuss a range of generification strategies that circle around a shared understanding and that sometimes imply a change in the users' practice. However, it is also clear that, due to its global foundation, generic software creates a tension with local practice that is hard to reconcile. Star and Ruhleder (1996, p. 114) argue that "An infrastructure occurs when the tension

between local and global is resolved". In our case, we see users' work in daily practice as local, and the design in accordance with the international openEHR framework as global. On one side, the users in local practices have their specific needs, and, on the other side, the openEHR model prescribes design to be done in a certain way, that put restrictions on the design according to how the customizable components of the generic software should be modelled and developed. We believe that the notion of translation (Carlile, 2004) helps to resolve the global/local tension and see it as an essential generification strategy because the developers used translation as a means to maintain and sustain several perspectives simultaneously. Still, as our case describes, the translation processes created a lot of work for the developers.

The vendor found itself in a middle position between the users and the technical limitations within the international openEHR framework (the open source library, the clinical process model, and two-level modeling approach). These two positions were difficult to align in the development process. Because the designers developed the software in accordance with the archetype model, the consequence of contextual user input was that the designers could not use the user stories or workplace descriptions into the design work directly or unreserved. The designers had to translate the context-bound user stories or workplace descriptions into technical or conceptual counterparts that could inform the design of the customizable components in openEHR—an extremely complex and cumbersome task. As one of the vendor's developers mentions: "We got a lot of experience with the work processes at the university hospital and see things we could solve quite straightforwardly, but then "the generic train" goes in a complete opposite direction... This is very challenging for us".

Later, when the designers should present the developed software (i.e., the generic components), they had to explain how the new features of the customizable components/generic building blocks could be tailored to a particular context. A developer notes:

We make it generic, but we try to make it in the context of the specific in a way that we always enable the specific, but this has been challenging (...) if we don't manage to concretize it for a specific context, what should we present otherwise?

Increasingly, the vendor was not able to present working software for the users and therefore had to compensate by explaining how the archetype-based framework might support customization for experienced users. This represented a translation process between IT used in the users' existing practice and IT used in an imaginary future practice. BigVendor frequently used metaphors such as the ability to build a LEGO® city of LEGO® bricks. In turn, the participants in the BigInvestment project created their own metaphor by using PowerPoint as an illustration: "BigVendor offers us a PowerPoint, but we have to make the presentation by ourselves". In this way, both the vendor and the project management wanted to appeal to the users' imagination of how the system might be customized and used.

While the users welcomed the presentation, it still represented a gap between possible functionality and working functionality. In some stages of the development process, the designers had very little working functionality to present to the users. Similarly, the developers increasingly questioned whether the generic functionality they were developing was useful or requested by the users.

6.3. Generification by Widening the Distance to the Users

Several studies have pointed to the shortcomings of traditional design methods characterized by a clear distinction between design and use (Hanseth & Lyytinen, 2010; Karasti et al., 2010; Pipek & Wulf, 2009). In particular, Hanseth and Lyytinen (2010) promote several guidelines for intervening in large-scale information infrastructures. Some of these are stepwise design and short iterations: design for usefulness, make things simple, and produce working software from the very first release. Today, many of these guidelines have been incorporated in agile design methodologies and expressed through the agile manifesto: "Individuals and interactions over processes and tools, working software over comprehensive documentation, customer collaboration over contract negotiation" (Beck et al., 2001).

However, this strategy does not necessarily pay off in the design of generic systems. Our case illustrates that 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.

The two-level modelling OpenEHR architecture required implementing support for a number of different functionalities often not relevant at the current stage in the development process. In addition, designing a tool (e.g., the building blocks) instead of a tailored product meant that the designers had to invest a huge amount of work in-house to lay the groundwork for, and to carve out, the generic elements of the software. This suggests that the design strategy of large-scale generic software tends to head in the opposite direction of agile development because it increasingly requires a lot of planning and up-front design.

In one way, this resembles a traditional design strategy that splits designers and users. However, framing the process as a traditional design strategy would be a mistake because our study illustrates the necessity of a close and transformative design/use interaction. We rather see this as a generification strategy where the vendor needs to take a step back and strategically plan how to conceptualize and develop the generic system. A characterization of this process is that it widens the gap between designers and users, which makes the actual development process increasingly "resilient" in proportion to various user input. Accordingly, the process of developing a generic system has questioned the traditional agile development methodology, but confirmed the importance of a user/developer collaboration in one way or another. This seems to carve out some characteristics of the relationship between design and a developed information system. An agile design tends to offer a flexible design process, but may lead to a system with fewer customization capabilities. Agile design clearly puts the user at center stage, and it requires the developers to be adaptive to the users' changing and emerging demands. Accordingly, software has been closely tailored to a specific local practice, which for the same reason may be more difficult to use in a different practice. On the other hand, heavy up-front design of a generic system may allow few actual changes in the design process, but will offer (if the promises come through) more customization capability of the completed generic system for the users.

7. Conclusion

Not surprisingly, our case is yet another example of solving socio-technical challenges during the development process of a large-scale EPR system. However, this paper particularly focuses on how the generification process plays out in the formative stages of generic systems by illustrating the socio-technical key mechanisms at play in the initial phase. The promoted idea of a two-level modelling approach is a more distinct boundary between technical development and clinical particularities, and, as a striking contrast to the idea, our case demonstrated how the design of generic software occurred in co-construction with local practice. Furthermore, the evolving co-constructive collaboration captured the socio-technical key mechanisms at play. These mechanisms are the vendor's generification strategies of solving the local/global tension by translation and adjusting the design strategy from lightweight methodology to a modified up-front design.

Our findings have implications for practice: First, the vendor realized that the development process entered new terrain, which meant the vendor had to experiment with its design strategy. Accordingly, we suggest that designing a generic system calls for a flexible vendor willing to change and adjust its development strategy along with the evolving project. Moreover, in our case, it is important to notice how the vendor managed to resolve the global/local tension by translation in the meaning of allowing several perspectives to be maintained and sustained simultaneously. The vendor made a significant effort to keep the user-developer collaboration on track, and, by the effort, the vendor accentuated the necessity of the users' involvement during the process. 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 software design and raising their skills in making precise contextual narratives. Because designing generic process- and decision-supporting software addresses a need for contextual information that reveals all the particularities and concerns in a

specific work process. Consequently, the users should make the clinical contextual knowledge available for the designers by describing what every professional role in a work process actually do, how professionals perform the activities, and importantly—but often forgotten—why they act the way they do. Additionally, it is a well-known issue that clinical personnel often do not have time or do not want to spend time in projects with no direct influence on their everyday practice. Third, even if the case did not put a particular focus into the BigInvestment management's role, the management's engagement in recruiting clinical personnel and in making it possible for the clinicians to participate in a project is important.

Regarding implementation, it is tempting to announce a new dimension of the local/global tension likely to come into play; namely, the clinical specification of the customizable components—the openEHR archetypes. The new dimension of the local/global tension addresses a need, on one hand, to tailor openEHR archetypes to a specific local practice, and, on the other hand, to make sure that the tailored local archetypes adhere to the standardized framework to ensure interoperability. Accordingly, local user tailoring can cause risks to vendors because they have to ensure backward compatibility on a system that they don't totally control anymore. In addition, local/global tension raises other interesting issues related to which socio-technical challenges will emerge in the transition from free text documentation to a structured process- and decision-supporting EPR system. Consequently, the implementation of the new generic EPR system calls for further research.

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Paper 2

The Biography of Participation

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ABSTRACT

While it is an overall understanding that user participation is important in the design of new information systems, it is still an open question how to best organize participation in large-scale development projects. Based on an ethnographic-inspired study of a large-scale Electronic Patient Record project, this paper explores this issue in detail. By applying the Biography of Artefacts and Practices perspective, we identify three different “moments” of participation in the project so far. We argue that it is necessary to analyze development processes over time and place to understand the varying nature of participation

Author Keywords

User participation, Electronic Patient Records, design, evolving

ACM Classification Keywords

K.6.1 [Project and People Management] Life cycle, Staffing and Systems development

INTRODUCTION

The Participatory Design (PD) research community has always emphasized the crucial role of user participation in the design of new information systems (IS) (Simonsen and Robertson, 2012). Through participation, users are supposed to inform the developers of needed functionalities and at the same time learn about new technical possibilities and what is achievable from the designers’ point of view.

However, in the recent years, we have seen the rise of many large-scale information systems that challenges our understanding of how to integrate users in their development. The systems are expected to encompass entire organizations and include practices that may differ from each other quite considerably, resulting in varying type of user needs and requirements (Mackay et al., 2000). This is in contrast to earlier decades of IS projects where systems often were developed and implemented on a very local basis and the users for this reason were more homogenous and thus easier to cope with.

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. This implies that

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user participation in different phases of a project may spell out very differently. This questions findings in former localized studies, which only capture discrete moments of the design process. This also takes us beyond the “good (participation)” and “bad (not participation)” dichotomy of the phenomenon. Hence, while it is an overall understanding that participation is important, it is still an open question on how to best *organize* participation in different phases of large-scale development projects, i.e. whom to include, when and where to include them. In order to respond to these questions, we lend on the concept of Biography of Artefacts and Practices (BoA) (Johnson et al., 2013; Pollock and Hyysalo, *forthcoming*). BoA underscores the importance of moving beyond episodic studies of settings of technology design or organizational implementation to the evolution of workplace technologies over multiple cycles of design and implementation. It also reflects the necessity to engage more coherently with the ways in which broader context shape innovation processes and outcomes (Johnson et al., 2013). This derives from a concern to reassemble the macro and micro levels of analysis. The biographic perspective offers a way to clarify the connections between the individual and the socio-historical in reaction against the flat ontologies of postmodernism (*ibid*). 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 Information Systems as an extended field of practice (*ibid*). Thus, BoA is not a method per se, more a commitment to take on a historical perspective in knowledge of the outcome. With this focus, our paper aim to contribute to the PDC 2014 call “Reflecting connectedness” on what it means to design for a multilayered and heterogeneous network of users. As systems encompass entire organizations and involve numerous practices, the nature of participation is difficult and has to be modified during the development process. The BOA perspective may explain the changing strategy of user involvement in longitudinal development processes across various practices.

Our biography of participation is grounded in an ethnographic-inspired study (Klein and Myers, 1999) of an evolving large-scale Electronic Patient Record (EPR) project managed by the North Norwegian Regional Health Authority. The analysis was guided by a provisional understanding of the nexuses in which the artefact, attendant practices and knowledges were being created. Specifically, we present three “moments” in the

project where user participation spell out considerably differently.

THE EMERGING BIGINVESTMENT PROJECT

In 2011, the North Norwegian Regional Health Authority issued a call for tender, asking for new clinical ICT systems for all 11 hospitals in North Norway. The cost of this project hereafter dubbed the BigInvestment project amounted to 82 million EURO for the period 2012-2016, making it one of the most ambitious healthcare-related ICT projects in Norway at the time (Silsand et al., 2012). One important goal for the Regional Health Authority was to acquire a process- and decision supportive EPR. Hence, the bid for tender asked for an EPR with high level of interoperability and configurability to contribute to standardize treatment and workflows within the region. The largest EPR vendor in Norway (here named BigVendor) was commissioned to develop the new EPR infrastructure based on the openEHR architecture (Beale and Heard, 2007). Due to the high level of configurability associated with an openEHR-based EPR, it was expected that it would have the potential to support collaboration and workflow of flexible patient pathway processes across departmental as well as institutional boundaries.

Nevertheless, the ambitious goals of the project required extensive collaboration between users and designers in the development process. In this regard, BigVendor had over some years successfully applied agile software engineering methods characterized by short development cycles and by continuous releases of working software. This method had enabled users to regularly assess and give feedback on the functionality of the system throughout the development process (Johannessen and Ellingsen, 2012). As part of agile methods, the users (clinicians) produced user stories, which were small descriptions (3-4 lines) of work situations. The developers then used the user stories as a basis when developing the new functionality.

Moment one: With this as a backdrop, BigInvestment recruited users from all the 11 hospitals within the region for workshops managed by BigVendor. BigInvestment held it as very important to engage clinicians from every hospital in the region in the project. More than 150 users were involved in different development tracks. Hence, the regional workshops had to take into account different existing contexts of patient care and treatments in the hospitals. Thus, the workshops became an arena for the users from the different hospitals to understand and reflect on how diverge practices actually were, and they had to negotiate and compromise in order to agree upon standards and trajectories across organizational boundaries (Silsand et al., 2012). For instance, in the first workshops, much time were spend to discuss the divergent use of concepts between the hospitals. The role “coordinator” in the operating department had quite different meaning for the users from the smallest local hospital with 2 theatres, than it had for the users from the university hospital with 16 theatres. Still, they had to decide upon some core activities for this role. It seemed to be important for the users and designers to gain a unified understanding as a basis to be able to create user-

stories, subsequently also understanding how the EPR was supposed to work.

Even if such extensive user participation was welcomed in the hospitals, it proved difficult for the users to allocate time to participate regularly in the workshops. This lead to discontinuity in attendance, and new clinicians adding new perspectives along the development process, making it difficult to move forward. New attendances that had not participated in the negotiations brought in user stories that did not cohere to the ones that the developers already were working on. The lack of coherence was problematic for the developers. A developer from BigVendor stated:

“The developer teams worked pretty quickly at diverging lines that sometimes crossed, but also went in completely different directions.”

Yet another aspect that complicated the relation between developers and users was the high degree of configurability that was to be built into the EPR. This turned out to be demanding for the developers:

“...there must be a technically advanced system with a dramatically higher degree of complexity than before... We are not going to develop specific local functionality in for example surgery planning, but rather generic functionality that makes surgery planning possible.”

Hence, the development took more time than BigVendor anticipated, and it was necessary to work out more technical solutions before the context represented by user stories could be taken into account. Thus, the users were not presented the “result” of their user- stories, but rather a technical solution that was hard to relate to their work practices. The users perceived this as if their contributions had not been noticed and the motivation for attending the workshops decreased.

However, during the year of collaboration the regional users and developers had tried, tested and failed – and accordingly gained a common understanding of the complexity of clinical practice as well as the possibilities and limitation of the novel system.

Moment two: After approximately one year of developing, it was apparent that the agile approach didn’t work out sufficiently. Since a very important aspect of the new EPR was to enable interoperability in terms of flexible patient pathways across departmental and institutional boundaries, it became necessary to picture just how such care processes fold out. The context was again important to bring into the development process, represented by longer narratives on clinical pathways. A surgeon was invited to describe the pathway for a patient with blood in the urine, from the referral was received at a local hospital to the patient had surgery for cancer at the university hospital. The surgeon described the subsequent steps in a several-pages document, and the process revealed that steps were performed by different professionals; sub-specialized physicians, nurses and secretaries. Initially, the developers had focused only the physician’s role, but this turned out insufficient:

“I don’t know what happens after I have seen the patient in the out patient clinic and made my assessment, I just

know that the patient turns up in the operating theatre” (surgeon)

There were much more collaborative activities than the developers had perceived, and they needed to bring in a more integrated perspective to envision the care process.

For the patient to turn up for surgery, it was necessary that the surgeon’s assessment and instructions went into an electronic workflow managed by secretaries. So far such workflow hadn’t had any attention. From what users were presented at this stage, it seemed that surgery plans were made as the physician made his assessment. However, the surgeon’s decision was only the “trigger” of surgery planning, and much work by secretaries and coordinating nurses went into the planning process.

«...you have forgotten to describe all the work in handling the referral, allocating resources, and putting up a schedule for surgery...not to mention all the preparations that nurses do at the ward before surgery” (coordinating nurse at workshop)

This multidisciplinary perspective was absent at that time, but had to be taken into account. A developer stated:

“We need to talk to all these people and ask them what they do and how they do it. We need to understand how they overlap and hand over assignments. How is the workflow that the system must support?”

The users were invited to describe pathways for other conditions as well, and the focus turned from single user-roles to work processes, moving the development towards process supportive abilities. This was a necessary step towards software for supporting clinical pathways across departmental and organizational boundaries.

Moment three: Having identified several inter-organizational patient pathways, it became apparent that the designers needed more specific insights for the development process. As some of the users had been working extensively with work process improvement within the university hospital, they invited the developers to take part in some of their hospital-internal projects. The university hospital had over several years aimed to modernize the internal processes through a so-called Lean methodology. Lean is a quality improvement philosophy, which implies a continuous focus on organizational improvement in the healthcare organizations. Health care personnel themselves are to map their work processes to reveal and identify bottlenecks and areas for improvement. The Lean-project in Gastro Laboratories was just about to kick-off, and the developers were put in right from the start.

In the first meeting, the developers were presented the context of the project; a section encompassing 3 rooms for scope examinations, differently equipped for gastro or endo entries. An average of 5000 examinations was performed per year. Nurses were allocated to the section in a roster reaching 3 months ahead and the physicians were allocated one month ahead. That meant the secretary could plan for one upcoming month at a time.

The mapping of the patient pathway for scope examination showed lots of “waste” in the information flow early in the process, starting at the point where the hospital receives the referrals for treatment. Literally sitting on the secretary’s lap as she did the planning of

patients, rooms and physicians, the developers had lots of questions for her and really dig into the details: *Why do you put the patient in that room instead of the other, why do you open the referral to pass it on.* They were confused by the fact that they were not able to predict how she would place the patient in the plan, from what seemed to be the obvious choice. The answers revealed yet another layer of details that must be taken into consideration in the planning process:

“I must consider where the patient lives, and how long it takes him to travel to the hospital. In our geography, that means considering timetables for ferries, busses and airplanes. A patient living 4 hours traveling time away from the hospital cannot be scheduled at 0800 in the morning. Another factor might be if the patient has co-morbidity. Then maybe I have to use a better equipped examination room then the actual procedure itself requires. I map out these things as I work on the referrals and set up the plan”. (Secretary)

To the developers, the complexity of the work practice was surprising since they were pictured that planning the activities in GastroLab would be rather simple. Confronted with all the details at different levels, a workshop with the developers and the health care personnel decided to work on IS support for the coordinating secretary. They agreed to focus on two functionalities as a first step, and some of the findings in the Lean project were now turned into the language of the developers: user stories. In contrast to the user stories from the regional workshops, the user stories from the Lean project were congruent and specific in their requests. Hence, they could easily be translated into technical functionality. Moreover, the developers had observed the clinicians’ work practice and had an understanding of the context in which the user stories belonged.

CONCLUDING DISCUSSION

Applying the BoA perspective, we analyze and discuss user participation in relation to the evolving large-scale ERP system during three “moments” of the development process (Monteiro et al., 2013).

Moment 1:	Moment 2:	Moment 3
Aligning of users from all hospitals	Inter-organizational patient pathways	One-site users
A focus on details	Multidisciplinary perspective	Agile methods reintroduced based on broader contexts
Agile methods fails		

Figure 1: Characteristics of the three “moments”

The case illustrates how the evolving software required changes in the panel of users and their contribution to the development (Mackay et al., 2000). As described, the project started out by inviting users from different locations, professions and clinical practices to participate “on the vendor’s ground”. The vendor managed the user-developer collaboration and applied an agile approach like in earlier development projects (Johannessen and Ellingsen, 2012). However, the system to be developed was conceptually new, and made the development much more complex (Markus and Mao, 2004). Due to the scale and complexity of the project, the developers could not use the requested user stories conforming to the agile

approach. It is tempting to characterize the first development phase as a failure since the preferred approach was not applicable for designing the novel system. Still, looking at the development process in a BoA perspective, the first phase was significant in terms of trying and failing in order to find a way about. Subsequently, for the users and developers to gain a common understanding of what a process- and decision system actually is (Mackay et al., 2000; Pollock and Hyysalo, forthcoming). Also, the phase represented a kind of training for the users to imagine how an EPR tool actually could support their clinical work. The initial collaboration managed to set the course for the upcoming development process by exploring the complexity of interdependencies necessary to enable support of clinical work practices. Particularly, the collaboration was necessary for the vendor in terms of reconsidering their “set of arrangements” for managing the coming collaboration (Johnson et al., 2013).

As the technical solution of the platform evolved, the developers needed a wider perspective on clinical processes. The issue was solved by asking the users for elongated contextual information, narratives, in contrast to the earlier requested user stories. In an extended perspective the phase folds out as a cumbersome process due to all the complexities within clinical work that was necessary to take into account when designing a process supporting system. The developers had to get hold of all the details to be able to present working software, thus the evolving development process called for yet another extension of the “set of arrangements” to manage the user collaboration (Johnson et al., 2013). Hence, the development process was hooked on a Lean project and the developers “moved” into “the users ground”. Following the evolving development process, it is interesting to note how the users were put in the driver’s seat as the developers entered the users’ context. As the developers became a part of the organizational improvement project, they were integrated in the process of contextual mapping and gained a thorough understanding of work processes, which served as a backdrop for the next stage in the development process. Yet an interesting aspect was the reintroduction of agile methods when working in close collaboration with a user group from a single sited clinical context.

User participation is not simply a matter of participation, but has to be entangled with the product to be developed (Markus and Mao, 2004). In BigInvestment, the technology was new, both to the developers and the users, hence the users contribution was not clear. Some trying and failure in the process seems quite fair. Also, as the systems encompass entire organizations and involve numerous of different practices, it is not surprising that the selecting of users is difficult and has to be rearranged during the development process. From a socio-technical point of view, systems supporting clinical processes will more or less move beyond organizational borders, which makes it difficult to differentiate the system from the other aspects of changes. Since hospitals are organized into medical disciplines, not to say sub-disciplines, clinicians work in narrow fields. Thus they may lack the

broader picture of cross-boundary clinical pathways and what support is needed to coordinate such treatment and work. As an implication for upcoming configurable system design, we will suggest that the initial development process of large-scale projects will benefit from users with considerable organizational knowledge, such as patient pathways coordinators and managers. Bringing these users early in the project could have helped identify the necessary functionality of a cross-boundary process-supportive EPR, before diving into the details of different clinical pathways where clinicians are the expert users. However, when we argue that more organizational knowledge is needed in large-scale projects, we simultaneously recognize that this represents a dilemma for the PD community. Inevitably it may undermine the end-users’ direct influence on the system and the fulfillment of their specific needs. The request for detailed user stories in the first phase, and its failed outcome illustrates exactly that. There were so many other concerns that also needed to be taken into account due to the scale of the project. Therefore it is important to maintain the core of the PD perspective where ordinary users have a say. The request for broader organizational knowledge should therefore be carefully balanced with sufficient user influence.

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Paper 3

Complex Decision-Making in Clinical Practice

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ABSTRACT

Clinical Decision Support (CDS) Systems are considered crucial for diagnosis, treatment and care of patients. However, practical benefits of such systems have been far below expectations. This paper explores how the evolving interdependencies in organizational, clinical, political, and behavioral terms influence the design and implementation of CDS. The paper discusses how these interdependencies complicate clinical use of CDS where cross-departmental patient pathways increasingly dominate approaches to dealing with patients with complex conditions.

Empirically, we report from an acute geriatric patient pathway project. The aim was to design and implement a decision-support form for triage of elderly patients in the emergency unit. The study emphasizes the intertwined collaborative nature of healthcare work, and the resulting need to consider the whole context when designing and implementing CDS tools. The contribution is to emphasize the “extended design” perspective to capture how workplace technologies and practices are shaped across multiple contexts and prolonged periods.

Author Keywords

Decision support; healthcare work; patient pathways; ethnography; information infrastructure.

ACM Classification Keywords

H.5.3 [Information Interfaces and Presentation]: Group and Organization Interfaces – Computer-supported cooperative work.

INTRODUCTION

While decision support systems in health care are considered crucial for diagnosis, treatment, and care of patients [26], the practical benefits of such systems have proven to be far below expectations [6,8,11,26]. Clinical Decision Support (CDS) systems are used to integrate clinical and patient

information to provide support for decision-making in patient care as well as to generate case-specific advice [8,12,21].

In 2007, Aarts, Ash, and Berg [2] reported that less than 10% of US hospitals had implemented the decision support system “computerized physician order entry” (CPOE), which allows a physician to enter medical orders and monitor their results. This tendency seems to be representative of western healthcare organizations in general and Norway in particular, as several studies and reports indicate low uptake of electronic decision support systems in hospitals in recent years [6,12,17,33,37,40]. Moreover, the lack of diffusion of CDS systems is associated with the complexity that arises from the nature of decision making, the intellectual challenge of creating knowledge, technical dimensions of delivering CDS, and social aspects of incorporating changes into clinical care [8,11,17,34,37].

These discouraging results indicate that we need a different approach to managing the challenges of decision support systems. As a response, we suggest that a socio-technical approach is needed for shedding light on the dynamics between decision support systems and the specific nature of the work these systems are intended to support. In particular, we want to explore how the evolving interdependencies in organizational, clinical, political, and behavioral terms influence the design and implementation of CDS systems. Further, the paper discusses how these aspects complicate the adoption of CDS systems where cross-departmental patient pathways increasingly dominate approaches to care of patients with complex conditions [17,34]. In this paper, we conceptualize patient pathways as planned and pre-booked steps combining both administrative and clinical prescriptions, as distinct from typical medical guidelines, in order to manage patient trajectories [28].

From this perspective, we ask the following research question: What are the key challenges of designing and implementing decision support systems in clinical practice?

With this, we challenge the way many decision-support systems have traditionally been designed, namely for one particular profession (i.e. physicians) in one particular setting. Accordingly, the contribution of this paper is to emphasize an “extended design and implementation” perspective of decision-support systems, to capture how

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workplace technologies and practices are shaped across multiple contexts and over extended periods.

To conceptualize the dynamics of how various healthcare professionals, activities and decision-support tools are interwoven in the support of the patient's trajectory through the healthcare system, we draw on a work practice perspective from the CSCW field [4,10,13,22]. However, we supplement this perspective with the concept of information infrastructure, which has been used to study the design, implementation, and use of large-scale information systems [15,19,38].

Empirically our study is based on the "acute geriatric patient pathway project" established in September 2011 by a university hospital in Norway. In the initial phase of the project, a decision-support form was introduced for triage of patients in the emergency unit. The first version was a paper form, which was replaced later in the process by an electronic form in the Electronic Patient Record (EPR). This allowed detailed insight into how a clinical decision support tool gradually evolved in practice.

The rest of the paper is organized as follows: The next section describes the theoretical framework for this paper. The method section briefly introduces the setting and the paper's methodological foundations, followed by an explanation of the methods for the empirical research. The section named "CASE" contains the empirical findings presented as the history of the design and implementation of the decision-support system. These sections are followed by discussion of the findings in relation of the chosen theoretical framework, and followed by the conclusion.

CONCEPTUALIZING DECISION SUPPORT

Like other complex organizations, the healthcare sector has an increasing need to implement ICT systems that can support clinical and organizational decision-making activities. Health ICT systems are expected to serve organizational goals to fit into work processes, and to be usable and safe. Generally, the move toward Electronic Patient Record (EPR) systems has led to the development of guidelines, care paths, and decision-support devices providing reminders and recommendations within the EPRs. In particular, well-designed CDS systems have the potential to improve healthcare quality and patients' outcomes, as well as to increase efficiency and reduce healthcare costs [2,5] [12,20,26,29]. Along with the growth of standardized patient pathways, a key issue concerns the decision to initiate a pathway combining both administrative and clinical prescriptions for a particular patient. Accordingly, the use of patient pathways addresses a need to identify the patients who will benefit from a particular pathway, due to limited resources within the healthcare service in general [17,28]. Hence, sorting patients becomes important before initiating a pathway and often starts as triage of patients at the emergency unit. Triage is the process of sorting patients based on their need for immediate medical treatment in relation to their chance of benefiting from such care, and may

seem to be a straightforward activity for healthcare personnel based on standardized classification schemes. However, previous studies [7,28] emphasized the collaborative process of sorting patients, and investigated how different formal and informal sorting mechanisms are in play. While we appreciate the thorough investigations by Møller & Bjørn [28] and Bjørn & Rødje [7], our study differs because we explore the design and implementation of a decision support tool.

Today, there is an array of different clinical decision support (CDS) systems in healthcare practice. CDS systems can be defined as 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 CDS systems based on, for instance, available best evidence, which is represented in guideline recommendations. Many different types of clinical tasks can be supported by CDS systems, for example use of patient-monitoring devices such as Electrocardiogram or pulse oximeters that warn of changes in a patient's condition [21]. However, the scope of this paper is limited to the design and implementation of a CDS form to be integrated in an Electronic Patient Record (EPR).)

One example of CDS integrated in EPRs is the system for computerized physician order entry (CPOE), designed for use by physicians, which can send reminders or warnings for deviating laboratory test results and can check for drug interactions, dosage errors, and other prescribing contraindications such as a patient's allergies [3,21].

Another example of CDS is electronic systems or forms, integrated in EPRs, used to provide support for decision-making in patient care as well as to generate case-specific advice at various stages in the clinical process. For complex cognitive tasks, for example diagnostic decision-making, the aim of the CDS can be to assist, rather than to replace, the clinician. When a patient's case is complex, or the healthcare practitioner making the diagnosis is inexperienced, a CDS system can help in formulating diagnoses and can give treatment and care suggestions based on patient data and the system's knowledge base [6,8,12,21,26]. Accordingly, in this paper the decision-support form can be *compared* to the latter example of use, as the form was intended to provide support to junior physicians assessing elderly patients in the emergency unit.

Despite widespread agreement on the importance of systems supporting clinical treatment and care processes, the development and implementation of these systems have failed to achieve their potential when the systems were put into practical use. It is not easy to suggest a cause-effect explanation of the low uptake of electronic decision support systems in hospitals. Several studies point to the complexity that arises from the nature of decision-making, the intellectual challenge of creating knowledge, technical dimensions of delivering CDS, and social aspects of

incorporating changes into clinical care [6,8,11,17,34,37]. Moreover, CDS systems are still not widely accepted within clinical practice, especially if use of CDS exacerbates the increasingly time-pressured patient care process, which may occur [3,6,8,11,37]. However, relatively little sound scientific evidence is available to explain why systems fail. Hence, there is a need for realistic complex studies that examine the user-CDS interaction and its impact on the clinician, the workflow, and other organizational processes and outcomes [6,17].

This suggests we need a better understanding of the sociotechnical challenges of designing and implementing decision support systems where we manage to grasp the dynamics between the systems and the specific nature of work to be supported. Health care work is far from clear-cut, and far from the glossy pictures where individual physicians assess diagnosis and prescribe treatments of patients [26]. We need a broader approach where we take into account the patient's trajectory through the healthcare system, the various professionals involved along the way and the particular activities necessary to assist the patient along the journey. Accordingly, the CSCW field is especially relevant to explore and understand decision support in clinical use.

The CSCW field has contributed extensively in providing how information systems or artefacts can support distributed collaborative work among groups of users, and in mapping the complexities of coordinating daily activities and documentation practices among healthcare staff [4,10,13]. In short, findings from CSCW research suggest that designing, implementing and using technology or artefacts involves complex, diverse and locally situated socio-technical challenges and intended and unintended organizational consequences [16].

The CSCW field has proved to be a strong framework for conducting and analyzing workplace studies and single site design and implementation. However, while providing the tools for focusing on the micro-mechanisms of collaboration in a specific context, the "here and now", it has somehow lacked the broader picture of understanding the collaboration of many and various professionals, material, and systems across different contexts, during development, implementation, and adoption [22,29]. The "here and now" or "local sensibility", understood as smaller scale interactions for design restricted to particular settings and timeframes, has been important to the historical research agenda of CSCW, for good reasons [29]. However, "local sensibility" contrasts with today's need for understanding cross-organizational workflows over time and space.

Monteiro et al. [29] note that several researchers point to how important influences from other levels and moments of technological design and implementation may be ignored when one focuses on one specific local or time period. An important ambition of CSCW is geared towards improving the design of computer-based systems by acquiring a deeper understanding of the *collective and collaborative character*

of work processes and how they may be better supported by more appropriately designed systems. To capture the intertwined and complex work processes, often stretched across space and time, in the design and implementation of technology, it is necessary to supplement the "local sensibility" with an "extended design" perspective [29].

Therefore, we enhance the CSCW perspective with the notion of information infrastructure, which has been used to study design, implementation, and use of large-scale information systems [19,29,30,38]. Information infrastructures are never seen as standalone entities, but are integrated with other information systems and communication technologies, and with non-technical elements across many local settings. Therefore, analyses of information infrastructures need to consider a broad range of socio-technical issues shaping the design and implementation process [15].

A basic principle is that an information infrastructure is never built from scratch; rather, it evolves from the installed base of existing systems and practices in a specific contextual setting. As a part of this, information infrastructures are characterized by openness to a number and types of users and interconnected contexts. Accordingly, the infrastructure shapes and is shaped by the work practice in an on-going co-construction process between technical and social elements stretched across space and time [29,38].

In this regard, many studies do not refer to infrastructural design as construction, but rather conceptualize it as an "evolving socio-technical system" [19] or infrastructuring [25,30] that needs to be carefully cultivated [1]. Hence, information infrastructures cut across many local settings and in this sense represent a broad definition of a patient pathway.

METHOD

The research site

The paper reports from a patient pathway project, named "the acute geriatric patient pathway", at a university hospital in Norway. The project was "owned" by the Internal Medicine Clinic, which includes the Specialist Acute Geriatric Unit (SAGU). The Internal Medicine Clinic's director was the top-level leader of the project. However, a *project manager* who worked as a clinical adviser led the daily organization of the project. The project manager had extensive clinical competences as an expert nurse, as well as formal project manager competences. The project steering group consisted of clinicians from different professions such as physicians, nurses, and secretaries from the Internal Medicine Clinic, mainly SAGU, and from the Emergency Unit. Project meetings were held regularly, but there were also ad hoc meetings when necessary. In addition, there were meetings with the project steering group and clinicians who were introduces to the CDS form in their clinical practice.

The university hospital is a specialist hospital providing advanced medical treatment and care, and currently has

around 6000 employees. The university hospital consists of 10 different clinics for patient treatment and care, each with their own administrative and clinical management. The Emergency Unit, which is part of the Emergency Medical Service Clinic, is the gateway to the hospital. Accordingly, patients with all kinds of illnesses requiring acute medical or surgical care are admitted and assessed at the Emergency Unit, and then discharged or transferred to a specialist ward for treatment and care. When patients arrive at the emergency unit, traditionally a nurse makes the initial assessment (triage to sort the patients according to their immediate need for treatment) and consults a physician based on the patient's condition and its severity. Mainly, junior physicians conduct further examinations, with back-up from more experienced physicians. If the patient is hospitalized, the (junior) physician decides which specialist ward is appropriate according to the patient's medical condition.

The Emergency Unit receives approximately 1000 patients per month, and strives to keep the waiting time as short as possible to ensure the patients subsequent treatment and care from the correct specialist ward. Accordingly, the clinicians work under high pressure to assess a large number of patients in a minimum of time. Moreover, a quarter of the 1000 patients assessed per month are aged over 75. A large proportion of the elderly patients have a medical condition that requires surgical treatment, or specific organ symptoms that enable a streamlined process of admission to the correct specialist ward. However, a significant proportion of the elderly patients have to be admitted to a specialist ward with a tentative diagnosis because their medical condition is difficult to determine. Because of their age, most of these patients are admitted to SAGU. SAGU is an eight-bed ward for elderly patients with acute confusion or acute functional deterioration. The ward is a defined medical unit with an interdisciplinary team approach (e.g. specialist nurses, geriatrists, speech therapists, physiotherapists, occupational therapists). A major part of the healthcare practitioners working in the ward are specialized in geriatric care to provide increased attention to patients' level of functioning and specific treatment of diagnoses common in older people.

Research approach

The study adheres to an interpretive research approach [27,39] where the epistemological belief emphasizes the understanding of social processes by getting involved inside the world of those generating them and viewing an empirical phenomenon from different perspectives. This implies that different sources of field data are all taken into account in the interpretation process. The method includes a relatively detailed case story, which allows the readers to gain insight in the field data, followed by an examination of the data for potential analytical themes presented as headlines in the discussion. The analysis was based on a hermeneutic approach. To improve the understanding of the empirical data, the data was continuously presented and discussed in informal meetings with the project manager, physicians, and

nurses involved with the project, the second author and members of the research group. This was an iterative process between issues to be interpreted, the context, the authors' preconceptions, and the theoretical perspectives chosen for this study. Our understanding at one stage thus became the preconception for understanding the next stage in data [27]. It should be noted that the first author had previously worked as a nurse at the hospital's internal medicine clinic, and accordingly had significant insight into visible and invisible norms and guidelines of clinical practice within the clinic.

Methodologically, we find the concept of biography useful for framing our research [31,32]. The biography approach focuses upon socio-technical processes in innovation, and studies the accumulated history of artefacts in its historical context and across its life cycle. The life cycle of the product involves many stages from "birth" through implementation, in which the biography focuses on the transformations and translations that a product goes through during its life cycle [31]. 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. The biographic perspective offers a way to clarify the interdependencies between the individual and the socio-historical, and reflects the necessity to engage more coherently with the ways in which the broader context shapes innovation processes and outcomes. This derives from a concern to reassemble the macro and micro levels of analysis [23].

Data collection

The empirical data were collected from February 2012 to April 2015. The first author conducted the data gathering process primarily through participant observation in project meetings, workshops with physicians, at the emergency unit, and participating in informal meetings with project members, in total 75 hours of fieldwork. Moreover, the first author has conducted 10 in situ interviews with project members and clinicians involved and has collected project documents from the initial phase of the project and throughout the research period.

The emergency unit was central during clinical observation (one week of day shifts), in which the first author observed the clinical work in general – for instance 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.

The permission for the first author to be an observer created opportunities 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, allowing the first author to share her office one day a week. Working in physical proximity to the project manager gave the first author an opportunity for rich discussions about the evolving project and its obstacles,

participating in ad hoc meetings, formal as well as 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.

CASE

The need for decision support

Four underlying factors supported the acute geriatric patient pathway project.

First, the population aged 74 and above in the hospital's catchment area is expected to increase by 20% over the next 10 years, which will likely represent a significant demand for acute geriatric medical admissions in years to come.

Second, the clinical problems and needs of older patients are often substantially different from those of younger patients. Older people's needs are more complex with potentially coexistent medical, functional, psychological, and social care needs. The clinical picture for older patients with acute or sub-acute medical illness, often presented in a non-specific manner, may emerge as functional deterioration or acute confusion within hours or days. This makes diagnosis, treatment and monitoring of older patients more complex and difficult than for younger patients [36].

Third, it is extremely important to act early and provide appropriate treatment for elderly patients, because they generally have a lower functional reserve than younger adults do. Accordingly, frail elderly patients admitted to hospital as an emergency should have access to a specialist geriatric medical unit [36].

Fourth, there was also a concern related to the utilization of the multi-disciplinary approach, because age was often used as the main criterion for admission of elderly internal-medicine patients to SAGU. Consequently, the eight beds were often occupied, but not always by acute geriatric patients. The overbooking reinforced a negative cycle because patients in need of the multidisciplinary team were admitted to other inpatient units. Therefore, the management of the internal medicine clinic emphasized that age could not, and should not, be the only admission criterion for SAGU. Moreover, the internal medicine clinic's management and the SAGU's specialist geriatric physicians asked for criteria to help the junior physicians in the emergency unit to identify the elderly patients who would benefit most from the geriatric multidisciplinary approach. Overall, there was no doubt among the healthcare practitioners, in both SAGU and the emergency unit, about the importance of selecting the correct elderly patients for admission to SAGU.

Designing the decision-support form (November 2011 – April 2012)

Designing the decision-support form was considered the first step in generating an acute geriatric patient pathway. The aim of the form was to support the physicians with no geriatric specialization, working in the emergency unit, when assessing elderly patients with unclear symptoms. The

discussions among the clinicians during project meetings underscored the importance of making the form easy to use in terms of distinct criteria for triage of the elderly patients, and easy to fill in because of the hectic working conditions in the emergency unit. The initial challenge in designing the form was the absence of existing criteria or guidelines to distinguish geriatric patients with acute confusion or acute functional deterioration from elderly patients with acute organ-specific illness, e.g. low-hemoglobin, urinary tract infection or cardiac insufficiency, but presented with unclear symptoms. Of course, there are geriatric approaches to examining geriatric patients for various conditions, but the clinicians considered these assessment tools to be too comprehensive and time-consuming to use as a first-guidance tool in demanding circumstances.

However, the process of defining and agreeing upon the correct criteria was performed by specialist geriatric healthcare personnel, evidence-based literature, interviews with specialist geriatric healthcare personnel in other hospitals, and feedback from the physicians in the intended user group. Still, it was a cumbersome process lasting approximately 5 months. During this period, several meetings were conducted with the project steering group and clinicians to discuss which criteria should be used, how to interpret different concepts within the form, and how to make the form intuitive to use. The project steering group made the final decision about the form's layout.

Putting the decision support into action (April 2012 – June 2012)

Even though the hospital had used an Electronic Patient Record system (EPR) for nearly 15 years, the first version of the form was paper-based (Figure1). Based on the cumbersome process of agreeing upon the form's layout, the project steering group anticipated several changes that would be easier to manage "on paper" than changing a form in the electronic patient record system. On the other hand, to validate the form's functionality, the project steering group depended on physicians actually using the form.

Acute geriatric decision supporting template		
Applicable to	<ul style="list-style-type: none"> • Internal medicine patients • Age ≥ 75 years 	
Exclusion criteria	Yes	No
Patients in obvious need of treatment from a non-geriatric specialist unit. If Yes, no further registration is necessary.	<input type="checkbox"/>	<input type="checkbox"/>
Inclusion criteria:	Yes	No
The status "acute geriatric patient" demand Yes in criteria 1 or 2.		
1. Acute confusion of unknown pathology: occurred last 2 weeks.	<input type="checkbox"/>	<input type="checkbox"/>
2. Acute illness of unknown pathology: occurred last 2 weeks, and with two or more additional criteria a-f.		
a) Acute functional impairment (guidelines pkt.2a back page)	<input type="checkbox"/>	<input type="checkbox"/>
b) Suspicion of drug side effects/interactions	<input type="checkbox"/>	<input type="checkbox"/>
c) Nutritional deficiency		

Figure 1. Segment of the paper form

Moreover, the project steering group thought it was important to support the use of the form by other healthcare professions working in the emergency unit, as well. Consequently, the project steering group had to map the general workflow in receiving acute patients in the emergency unit, to tailor the form into existing routines.

The pilot study lasted for two months from the end of April 2012 to the end of June. The introduction of the paper-based form in practice took place as follows: Despite the presence of a hospital-wide EPR, the emergency unit used an interdisciplinary paper-based pre-record during the patient's stay in the emergency unit.

The purpose of the pre-record was to gather necessary bedside information about the patient's observations, examinations, medication, and recommended follow-ups in a single document, making it easy to access for all involved healthcare practitioners in the emergency unit. Moreover, a copy of the pre-record was sent with each patient to the relevant inpatient ward in order to inform the next healthcare practitioners in line about the patient's condition. The pre-record bridged the time span from the patient's arrival at the hospital to when healthcare practitioners, physicians, and secretaries had completed the electronic documentation. However, the first step of preparing for a patient's arrival in the emergency unit was to tag the pre-record with the patient's barcode of personal information, and put the pre-record in a front cover. A nurse or a secretary performed this task. When the patient left the emergency unit – discharged or admitted to an inpatient clinic – the secretaries scanned the pre-record into the EPR. If the patient was hospitalized, the nurses ensured that a copy of the pre-record and other papers belonging to the patient were gathered in the front cover and accompanied the patient.

When the new acute geriatric decision-support form was introduced into the described workflow, the secretaries were assigned the responsibility for putting the form into the patient's folder before (s) he arrived at the emergency unit. Secretaries were on duty from 07:30 to 22:00 from Monday to Friday. Therefore, nurses had to be involved in putting the paper in the folder at night (from 22:00-07:30) and at weekends. Hence, when a physician assessed the patient, the decision-support form would be on top in the familiar folder, and it was easy for the physician to remember to use it. After filling in the form, the physician put it, along with the pre-record, into the front cover. The physician or a nurse handed the patient's front cover (with the form inside) to the secretaries' office, where all the papers were scanned into the EPR. Because the aim of the pilot study was to test whether the chosen criteria supported the physicians in sorting the elderly patients correctly, the forms had to be put on a marked shelf at the secretaries' office. This allowed the group manager to collect the completed forms and, in cooperation with the physicians who had used the forms, the project steering group could analyze how the form had been completed. In addition, the project steering group could

compare to what extent forms were filled in, in relation to the number of patients aged over 75 who arrived at the emergency unit during the pilot study.

The result from the pilot study indicated that the form was appropriate as a decision-support tool. The physicians reported to the project steering group that they were satisfied with the form's functionality – and even asked for the form in cases in which the form had been left out of the patient's folder by mistake. In project meetings, the physicians said that they used the form at the patient's bedside when assessing patients, but they also reported filling in the form after the examination of the patients was done – especially in cases where it was obvious that the patient did not need specialist geriatric treatment. During the pilot study, 160 forms were handed in and 327 patients aged over 75 were assessed in the emergency unit. Accordingly, the project steering group received enough completed forms to evaluate the tools usability.

Still, analysis of the used forms demonstrated some weaknesses that needed to be addressed. A minor revision of the form's layout was conducted before the form was transformed into an electronic version.

Transforming the paper-based form into the EPR system (August 2012 – November 2012)

By November 2012, the electronic form (Figure 2) was ready to be implemented in the EPR system. Converting the paper-based form into an electronic version made the layout more user-friendly, according to feedback given by the physicians who had used the form in clinical situations. In the electronic form, the instructions on how to use the criteria were minimized as a response to comments such as “too much to read – it won't be used...”. In addition, a new option, “Do not know”, was included for each sub-criterion for use when specific patient information was difficult to obtain. Although the layout was improved, taking the electronic form into ordinary use revealed different kinds of contextual challenges.

The electronic version of the decision-support form was very much like a plain document archived in the EPR. The physicians had to upload the form through an array of steps in the EPR before getting access to the form: First, by logging into the EPR system; second, accessing the patient's record by searching for the particular patient's name or date of birth; and third, opening the document folder and choosing the correct form for acute geriatric decision support. The software did not support triggers such as “pop-up alarms” when patients aged over 75 were registered at the hospital.

Acute geriatric decision support template

Applicable to

- Internal medicine patients ≥ 75 years, and with
- Acute illness of unknown pathology occurred last two weeks.

Not applicable for patients in obvious need of treatment from non-geriatric specialist unit.

a) Acute confusion	<input type="text"/>	CAM recommended as screening tool Answer Yes if changes in one of the options: personal hygiene, mobility, ...
b) Acute functional impairment	<input type="text"/> <input type="text"/> <input type="text"/>	

Figure 2. Segment of the electronic form

In practice, the electronic form made it difficult for the secretaries and nurses to provide a direct reminder corresponding to the one they had generated when they placed the paper-based form into the front cover of the patient's folder. The secretaries and nurses could no longer directly remind the physicians about using the electronic form because the physicians had to log into the computer with their own password to their own user account to find the electronic form. Accordingly, the physicians were more or less left on their own in remembering to use the form and when to use it, in contrast to the network supporting the paper form. Moreover, the forms were meant to facilitate the next step in the acute geriatric patient pathway, and to serve as a "ticket" to SAGU. However, the form was put into clinical use before the overall pathway was established.

Accordingly, the physicians in the emergency unit spent time filling out the form, even though the form did not ensure the acute geriatric patients the necessary "ticket" because beds were not always available in SAGU. As a result, the use of the form did not play a major role for the physicians in the emergency unit in terms of ensuring the acute geriatric patients the optimal treatment and care.

Another situation that occurred related to the discrepancy between demand and supply of acute geriatric beds was that patients were "tagged" as acute geriatric patients and then enrolled in random inpatient clinics – the one with an available bed. This led to a significant increase in "satellite" acute geriatric patients all over the hospital's wards. This, in turn, led to growing dissatisfaction among the specialist geriatric physicians because they became responsible for several more patients all around the hospital, a significant increase in the number of patients compared to their resources. Moreover, they had to perform doctor's rounds in unknown wards, cooperating with unknown healthcare personnel, who were not trained to take care of acute geriatric patients.

"A great number of acute geriatric patients became visible through use of the form, but the hospital did not have the capacity nor the organizational structure to take care of the patients moving to the next step of the pathway" (Quote, Doctor).

Despite further improvement when the paper form was converted to an electronic version, the physicians complained that the electronic form was difficult to use "at hand", mainly because it was time consuming to access through the EPR system. The project steering group was confronted with this statement and made an effort to analyze the problems involved in using the form. Even if the form could be uploaded and retrieved from the EPR system in different situations, the system did not support multi-disciplinary use. It did not allow the secretaries to upload the form and attach it to the patient's EPR as they had done with the paper form. In a way, the electronic form disappeared into the EPR. Moreover, after the pilot, the project manager stopped visiting the emergency unit to collect completed

forms on a regular basis. The visits might indirectly have reminded the clinicians to use the form. When the form had been introduced into ordinary use, the clinicians in the emergency unit had to be prompted to use the form by mechanisms other than the activities of the pilot study.

Moreover, by the time the electronic form had been taken into ordinary use there had also been a change of junior physicians in the emergency unit. The clinical education of junior physicians involves a rotation schedule, and accordingly the new doctors' "clinical backpack" did not contain the history of the form, or the pilot study, which included training in using the form. Because the form was "hidden" in the EPR system, use of the form depended very much on instructions to every new physician at the emergency unit about when and how to use it. It is also important to mention that by this time, it was not a formal task for the project steering group or the project manager to inform new physicians and train them to use the form, as well as informing other clinicians involved with geriatric patients. At this stage, this important task had more or less been handed over to the management at the clinical units involved.

Back to basics (November 2012 to March 2015)

During the first year of using the electronic form, the anticipated number of used forms decreased dramatically. The acute geriatric form, despite the requirement for filling in the form as a "ticket" to SAGU, had been used for only 40% of all patients admitted to SAGU. In meetings between the project steering group and clinicians from the clinical units involved, several complicating issues were reported. An explanation for the radical decline was the challenges of implementing the acute geriatric form into the physicians' workflow at the emergency unit. There were also reported organizational challenges; e.g., elderly patients with complex health-related problems and symptoms from multiple organs had to be moved between several organizationally separated wards because there was no coordinated patient pathway underpinning the care and treatment of this particular patient group. This required extra coordination from other healthcare professionals because first, they had to find a bed for the patient in an appropriate ward, and second, the healthcare personnel had to coordinate the patient's transfer between wards, like a piece in a board game, waiting for an available bed in SAGU. Negotiation about how to distribute responsibility for patients when the appropriate ward was full was unfortunately the situation for many patients. However, given the complex and often vague presentation of frail elderly patients' medical condition, this was not acceptable for the patient group. As previously described, if the patient was "tagged" acute geriatric and SAGU did not have an available bed for this patient, the situation involved a significant workload for the physicians who had to do their doctor's round in several other departments. Because of all the unintended consequences, the project steering group and the superior leader of the project made an overall evaluation and withdrew the electronic acute geriatric form from the EPR. From

November 2013, the form reverted from an electronic form in the EPR to a paper-in-pocket format that served as “guiding prioritization criteria. It is fair to say that the hospital was “back to basics” in relation to the daily challenges of receiving a large group of internal medicine patients with unclear symptoms or a non-organ-specific clinical picture.

However, managers and healthcare professionals at the internal medicine clinic were still motivated to improve the healthcare services for internal medicine patients who did not fit into the existing structure of strictly organ-specific departments. Looking at the stranded implementation of the acute geriatric form in a broader perspective, the hospital initiated two new projects in 2013/2014. The first project’s mandate, released in late 2013, was directed towards an organizationally aligned clarification of the responsibility for internal medicine patients with an unclear condition or a clinical presentation in a non-specific manner, mainly encompassing patients over 80 years old. The first project’s management recommended an organizational restructuring to make sure that the particular patient group was given appropriate treatment and care despite the current organ-specific organizing of services. In this effort, the prioritization criteria for geriatric patients with acute conditions were again sought to support physicians who had no geriatric medical specialization when assessing elderly patients.

The second project, called “patient-centered healthcare services”, started in early 2014. The aim was to assess and support patients with complex and/or chronic illnesses in an early stage of a medical disorder to prevent hospitalization or to support their discharge from the hospital to prevent readmission. This project crossed the traditional organizational boundaries to ensure continuity of care. Nursing coordinators manage the patient-centered healthcare services, and tailor an individual pathway for each patient. In hospital, all departments are very specialized, and these patients often have multiple conditions – so they often need assessment from several medical specialties. Currently, electronic tools do not support the coordination of patient-centered healthcare services. *“In the beginning there is more than enough work to establish appropriate links for collaboration across organizational boundaries. We are so accustomed to work within our own borders, so it can be difficult and associated with uncertainty when you start working over borders. So, in the beginning we must work slowly and gently – it requires a change of attitude – more than tools”* (quote, nurse coordinator).

DISCUSSION

Using an information infrastructure perspective, we will discuss the design and implementation process of a small local CDS tool, and how the process was influenced by evolving interdependencies in organizational, clinical, political, and behavioral terms. The evolving process revealed several interdependencies related to the use of the

decision-support form, all of which were deeply rooted in the existing clinical practices, systems and the hospital’s management policy.

The paradox of designing and implementing decision-support systems

A compelling question is where and how to start the design of decision-support tool envisioned to support the patient’s trajectory through complex health practices and which users to include. In our case, it seemed right to start with identifying the patients needing specialized treatment and care as well as the role of the physicians [7,28]. The reason is that clinical decision-support tools are often more easy to “sell in” to the clinicians because the aim of the tool was to support their clinical work. In this case, the clinicians even had the opportunity to develop the form and influence its design themselves. Because the first version of the form was a paper sheet, making changes in the form’s content and layout was an agile process. A side effect of putting the clinicians in the “driving seat” of designing was the way that the discussions aligned the clinicians’ understanding of how to use the form and the necessity of the patient pathway. Moreover, the discussions contributed to improving clinical knowledge, especially that of the junior physicians, in assessing elderly patients. Making the physicians “chief designers” of the form was useful in order to mobilize a powerful profession [3,10,13,18].

However, the strategy of including the physicians as designers also limited the focus to tasks that only the physicians do. Accordingly, the project “fell into the trap”, in terms of designing a tool tailored for a specific group (i.e. the physicians) with less focus on including other healthcare professions. In the initial phase of the project, the insufficient attention to other healthcare professions was “concealed” because the paper form was visible in the collaborative workflow, and the secretaries and nurses compensated for the design defects by performing invisible work. They made an effort to ensure the form’s clinical destiny, even if they did not play a particular role in the actual use of it. This echoes much of the CSCW literature that emphasizes the collaborative nature of ICT [14,35] as well as a lot of hidden work and workarounds implicated in it [4,10,13,16].

Surprisingly, the simplified layout of the electronic form, revised and adjusted in order to be more intuitive in use, was not perceived as convenient to use by the physicians. While the form was clinically relevant, conforming to its purpose and designed in collaboration with the intended users, it became invisible in the coordination process (workflow) in the emergency unit compared to the paper- version – it “disappeared” into the EPR. The physicians did not receive the invisible support provided by nurses and secretaries as they did when using the paper form [5].

This underpins the importance of a CSCW approach in the design of artefacts to support patient pathways. CSCW plays an important role toward the design of artefacts by producing

rich pictures of the collective and collaborative character of work practices in particular settings. However, our data suggest mapping of the “local” context several times, an “extended design” perspective, according to the adjustment of the artefact in design, which has to include every profession and practice involved with the patient’s trajectory [29]. The single-user artefact has to be placed in a heterogeneous, interdependent context, which is not necessarily visible in the initial design phase. It is important that every project becomes aware of the ever-changing interdependencies along with design, implementation, and adoption. Focusing exclusively on the initial design phase may relegate important actors and factors in the shaping of a technology to the background. Accordingly, the responsible organization for each innovation project has to make sure that the project management get enough time and resources to handle the challenges of the ever-changing interdependencies [22,29].

How decision-support tools shape organizational politics

The electronic form played a role distributed over time and space. In the local setting, the emergency unit, the form was convenient to use “bedside”, but did not ensure the “tagged” patient a bed in the acute geriatric specialist ward. This, in turn, led to negotiations about which ward should receive the “tagged” patient when all beds in SAGU were occupied. Unfortunately, negotiations dealing with *where* to admit patients because all beds in the appropriate ward are occupied are a well-known situation for healthcare coordinators. Moreover, as a backdrop for the particular discussions, older patients with complex conditions very often have longer stays in hospital and often need a multidisciplinary treatment approach, which organ-specific wards cannot necessarily offer. Accordingly, healthcare personnel not trained in geriatric medicine often find such patients challenging to manage. So, as long as the form “tagged” the patient, the collective responsibility for ensuring best treatment and care based on available resources in a way dissolved into negotiation about where to put the patient “on hold” until a bed at SAGU became available.

Even more, in the EPR system “tagging” of patients as “acute geriatric” evolved into an organizational question because “acute geriatric” meant that these patients belonged to SAGU – regardless of *where* the patient was admitted. Generally, if the specialist ward was occupied, the patient would be admitted to a collaborative ward, and, more important, this ward was assigned the responsibility for the patient until transferal or admission. Consequently, the “organizational” tagging of acute geriatric patients became a clinical “bottleneck” for SAGU’s physicians because it triggered an additional workload. The geriatric physicians were assigned medical responsibility for patients dispersed over several different wards.

In short, the form was still convenient to use at hand, but in a wider perspective, the decision-support form could not be

seen as an enabler for gaining efficiencies and quality of treatment and care for geriatric patients with acute conditions. The small local artifact had broader organizational consequences not possible to predict in the initial design phase [15,29,30]. An essential point is that electronic tools shape and are shaped by several contexts simultaneously, and therefore interact with healthcare practitioners and influence healthcare practices in more intertwined and invisible ways than a visible paper artefact [4,5,19,28,29].

How local decision-support systems scale to infrastructural dimensions

As a huge number of information infrastructure studies has demonstrated, it is difficult to point at a single specific cause explaining why promoted designed artifacts do not necessarily materialize with the envisioned effect on healthcare collaboration, treatment and care [25,29,30,38].

We have observed and identified fragmented interdependencies of organizational relations as reasons for a result far below the project’s expectations. Nevertheless, we need to move a step further, and provide input to prospective patient pathway development processes, particularly addressed to the health care service itself.

Putting the case in a 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. Along these lines, as pointed out in the last part of the case, the implementation of a small-scale artifact in local practice turns into – or implicates – a large-scale reorganization process [19,22,23,25,29].

In short, the form was useful at the bedside, but the use of the electronic form depended entirely on the memory of every single physician, in contrast to the collective support of using the paper form. Moreover, the electronic form influenced the organizational responsibility for the acute geriatric patients, which led to an increased workload for the specialist geriatric physicians.

The case demonstrates how the implementation of a local, situated system created interconnections and interdependencies with other contexts (“tagging” the patient) and how a change in one system evolved in terms of creating bridges between clinical practices and local systems in different departments. These issues are difficult to anticipate or plan for, but analyzing and discussing the empirical data in an information infrastructure perspective identify and illustrate some implications for design and implementation of electronic systems for clinical decision support [15,29].

Yet another interesting issue, barely described in the last phase of the case, was the willingness to change workflow and work practice: “[...]...we are so accustomed to work

within our own borders, so it can be difficult and associated with uncertainty when you start working over borders. So, at the start we must work slowly and gently – it requires a change of attitude". As we have already argued, evolving complexities are inherent in designing devices to support patient trajectories and call for reorganization processes. According to the case, reorganization processes challenge well-established working routines and address attention to issues recapitulated as habits, power and politics – which are more difficult to map, but must be given particular attention.

From an information infrastructure perspective, designing and implementing decision-support tools is an activity distributed in both time and space. Further, infrastructures are not designed from scratch, but in this case, it was necessary to zoom into the locally situated practice at the emergency unit as a point of departure. However, bringing one specific period into focus may relegate important actors and factors in shaping of work practices to the background. Because, information infrastructures evolve, they shape and have to be shaped by existing practices and systems [23,25,29]. Therefore, studying and evaluating evolving infrastructures in "short-term temporal aspects" will not capture the essential interconnections and interdependencies that occur over time [15,25,29].

CONCLUSION

We have demonstrated 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. Moreover, the design and implementation's interdependencies need to be solved by large-scale re-organizational processes. The CSCW framework supports the empirical strategy of the acute geriatric patient pathway project by starting the design in a local setting. It was considered useful to trace out the local interdependencies as a point of departure. To promote initial use, it is important to design a first version of the new artifact so it can deliver necessary value to the users, and motivate adoption. However, as the decision-support form was transformed, the "electronic outfit" did not create the anticipated value for the users, nor for the local physicians in the emergency unit or the distributed users in a wider context. Moreover, we found the chosen perspectives from information infrastructure theory useful to dismantle the evolving complexities: organizational, clinical as well as human/politics/behavior interdependencies, which are the key challenges for design and implementation in clinical practice. Generally, as we have argued, designing and implementing decision-support tools are inherently complex processes and they shape and have to be shaped by existing practices and systems like evolving infrastructures [9,16,24,29]. Hence, supported by the theoretical framework, the preferred way of making infrastructures "grow" is by using the existing infrastructures [14,15,19,29,38]. Unfortunately, in this case, the decision-support form became an obstacle in the installed base. No overall agreement was established for the CDS tool's wider

contextual use and how it could influence cross-organizational practices and clinical work. In turn, what characterizes the design and implementation of decision support systems in clinical practice is the need to zoom in and out, in contrast to the tendency to focus on "short-term temporal aspects" in local contexts [23,29,31].

Our paper identifies, illustrates and discusses important interdependencies in clinical practice, which all have significant influence on the design and implementation process. Moreover, the paper has a longitudinal narrative embedded in real-world clinical practice, which highlights the difficulties of making changes in pressured and constrained clinical settings. Accordingly, the contribution of this paper is to emphasize the "extended design" perspective, when designing and implementing decision-support systems, to capture how workplace technologies and practices are shaped across multiple contexts and over extended periods. Empirically, this means that wide contextual implications are not implications to be solved by the defined project management mandate only, but have to be addressed by the hospital management as well.

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Paper 4

Governance of openEHR-based information infrastructures

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Abstract

Governments and healthcare organizations worldwide have increased their attention towards Electronic Patient Records (EPRs) that have the potential to support better patient experiences through quality and satisfaction, better health outcomes of populations and reduction of per capita cost of health care. To meet these ambitions, the EPRs originally dedicated to support healthcare staff in their core activities, now also have to support managerial ambitions of increased efficiency and patient throughput. This presupposes common interoperable standards to ensure that information is understood and interpreted consistently across various contexts. In this regard, the openEHR specification seems promising as it offers 'interoperability standards' (archetypes) that put the users in the 'driver's seat' of the standardization process. This paper focuses on the underlying process of developing and using a broad range of archetypes over time as well as the need to formalised organisational structures (i.e. governance) to support the process. A key insight of this study is that such a process requires a well-working and partly overlapping governance structures on different organizational levels. The development process comes around as a carefully coordinated balancing act between different perspectives. Empirically, our case is an

interpretive case study that draws on the development process of a new openEHR-based EPR system in the Health Authority Northern Norway in the period January 2012 to December 2017. Theoretically, the study draws on the concept of information infrastructure.

Keywords: Governance, User-driven standardisation, openEHR, archetypes, Electronic patient records, information infrastructures

1 Introduction

Governments and healthcare organizations worldwide have given considerable attention to the proposition that accessibility, efficiency, and effective sharing 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 (IHI, 2017). Digital health information systems have the potential to support the triple aim, particularly electronic Patient Records (EPRs) dedicated to support healthcare staff in their core activities to also include support of managerial ambitions of increased efficiency, and patient throughput. This presupposes common interoperable standards to ensure that information is understood and interpreted consistently across various use contexts (Bowker and Star, 1999; Star and Ruhleder, 1996). However, standardization within healthcare has proven difficult to achieve, and a considerable body of literature has demonstrated empirically as well as analytically that organizations are different and have diverging needs. A crucial cause is that standardization processes traditionally have had a top-down approach for which little (or no) attention has been paid to users' work practices (Bowker and Star, 1999; Hanseth et al., 2012; (Timmermans and Berg, 1997; Timmermans and Berg, 2003).

As an alternative, the openEHR specification seems promising as it offers 'interoperability standards' (archetypes) that have the potential to serve different stakeholders' needs as well as it puts the users in the 'driver's seat' of the standardization process. The empowering of the users is made possible through the openEHR specification as an open health-computing platform that separates the responsibility of users and designers. While the reference model of an EPR (technical issues) is the responsibility of designers, the clinical information model of

the EPR, i.e. the archetypes (organisational issues), are the users' responsibility. This is an important difference from traditional systems where the information model is controlled by the vendor (Beale and Heard, 2007; Garde et al., 2007). A rough estimate from an international openEHR course is that it is necessary to define approximately 1000–2000 archetype standards, to constitute a working EPR system (Ulriksen and Pedersen 2016). Altogether, the collection of defined archetypes constitutes a backbone of interoperable EPR systems that lend on the openEHR architecture. In this way, the complete set of archetypes represents a large-scale information infrastructure (Bowker and Star 1999; Aanestad and Jensen 2011; Hanseth and Lyytinen 2010).

Although giving the users “complete” control of standardisation processes is practically and democratically appealing, it begs many questions on how this can be accomplished on a large-scale. The openEHR specification have addressed the need for a formalized role related to 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). Subsequently, even though the clinicians are promised to be in the “driver’s seat” of the archetype development process, someone needs to take a formalized role of controlling and governing the process.

While such a formalized role of governing domain knowledge is defined conceptually, we don't know how this can be organized in real life. We therefore pose the following research questions: What is the best way to organize governance of large-scale information infrastructures such as the openEHR framework? How is it possible to balance local users need for functionality versus global need for interoperability? And finally, what type of user control is really possible to achieve in an openEHR based setting?

The contribution of this paper is to provide empirical insight into the longitudinal process of establishing a user-driven standardization approach within openEHR based EPR systems, and the necessary governance and organizational structures.

Empirically, we have studied the development process of a new openEHR-based EPR system and in the Health Authority Northern Norway. The project started in 2012 and was originally planned to be completed by the end of 2016, but is now extended to 2021. The development process started out as a collaborative effort between an EPR vendor and the health authority, but evolved later to also include several other stakeholders on a national level. We have

followed the escalation of the process, for which we have also followed a national initiative of building a national repository of common archetypes for collaborative EPR systems (Christensen and Ellingsen, 2016).

The rest of the paper is organized as follows: Section 2 describes the theoretical framework. Section 3 introduces the paper's methodological foundations. Section 4 presents the empirical setting, followed by three vignettes presenting the empirical findings. In Section 5 we discuss the empirical findings in relation to the theoretical framework, which is the basis for providing concluding remarks in Section 6.

2 Theory

In response to the goals of integrated care, standardized patient pathways, and evidence-based treatment and care, healthcare organizations have increased their focus on a semantic interoperable process-oriented EPR systems that has the ability to exchange clinical information between vendor-independent EPR systems. Accordingly, EPR systems are evolving from systems designed for information storage to user-centered work tools (Christensen and Ellingsen, 2014) as well as systems that conform to managerial ambitions of increased efficiency and patient throughput. This presupposes the establishment of interoperable standards to ensure that information is understood and interpreted consistently across various use contexts (Bowker and Star, 1999; Star and Ruhleder, 1996; Timmermans and Berg, 2003). However, standardization in healthcare has often proven difficult to accomplish because much of the structuring of the EPR content translates into the need for standardizing clinical routines and practices as well (Ellingsen et al., 2007; Timmermans and Berg, 1997). Taking into account the repurposing of systems, this calls for flexible standards that may comply with a lot of different needs.

In this regard, the openEHR platform¹ seems promising as it serves as a framework for an EPR that has the potential to be flexible to serve many different purposes. A crucial aspect of the openEHR platform approach is that it gives users in clinical practices the opportunity as well as the obligation to design archetypes, which is an important difference from the

¹ The openEHR architecture was developed by the openEHR foundations and standardised by CEN and ISO in the EN/ISO 13606 standard series.

development of traditional proprietary system where information models are integrated and controlled by the vendor (Beale and Heard, 2007; Garde et al., 2007). The openEHR’s archetypes are clinical information models, which represent a description of all information a clinician might need about a clinical concept, its sub-elements, and a technical well-defined data model. For example, a blood pressure (BP) archetype represents a description of all the information a clinician might need or has to report about a blood pressure measurement in a patient’s EPR. The actual blood pressure value is accompanied by additional data regarding who (who measured the BP), how (which type of equipment was used, and if the patients was sitting/bed resting), when (related to datum and time of day), and where (refers to the location on the patient’s body [e.g. intra-arteria BP, right/left arm or leg etc.]) as a way of describing the context of the blood pressure measurement (Kalra, 2006, p. 138). Accordingly, the openEHR clinical information models are designed as ‘meta-standards’ independent of use context, which make it possible to support clinical work processes as well as reuse of data for ‘secondary’ purposes such as administrative and management needs.

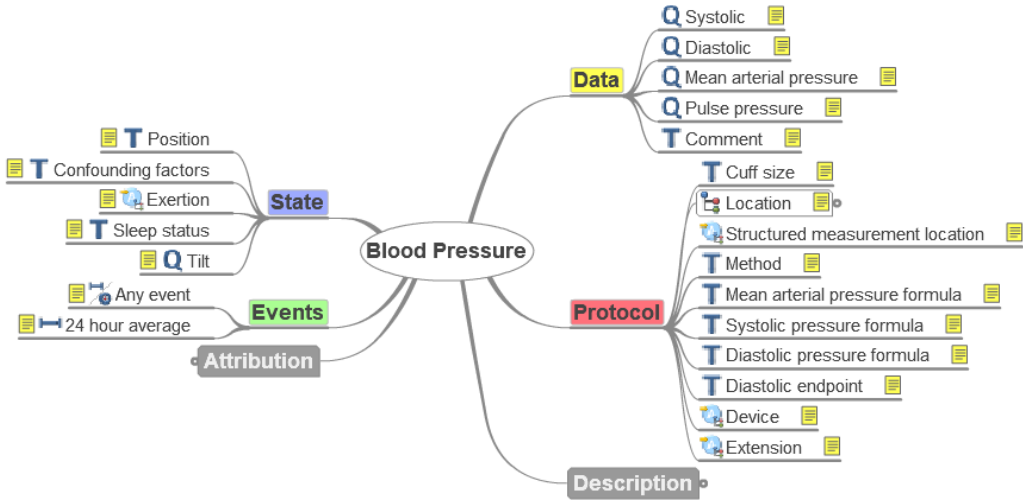


Figure 1: openEHR Blood Pressure archetype (openehr.org)

The openEHR specification is an open health-computing platform approach that separates the technical design of a system’s reference model from the archetypes. This gives the users in clinical practices the opportunity to design the archetypes and the technical reference model is designed by software-developers. The process of developing a new archetype starts with the users describing their need for recording clinical concepts that can be standardized for share- and re-use purposes during a clinical process or patient pathway. Experienced

practitioners argue for good practice in archetype development processes (Santos et al., 2012; Kalra, 2006). This means that subjective influences such as personal context and background of the actors involved in the local development process, need to be balanced by facilitating participation from 'global' actors who will give input from their context and backgrounds (Conde and Berry, 2010). In doing so, the clinical knowledge within an archetype will scale up to the 'meta-standard' level and making the archetype useful in every clinical context. However, archetypes as 'meta-standards' imply that will not be necessary to record all the information represented in an archetype in every clinical context. Therefore, after the archetype is developed, the users or expert users need to tailored the archetypes back to the local use-context by removing or mandating data from the 'meta-standard' (Garde et al., 2007, p. 333).

OpenEHR based EPR systems are "empty" systems where the users need to determine and design up-front the archetypes representing the clinical information they expect to create and record during clinical processes (Beale and Heard, 2007). Of course, it is possible to supply the system with new archetypes when it is taken into use, but if no archetypes exist up-front, then free-text need to be used for documentation purposes. Transforming clinical concepts to archetypes in accordance to the openEHR specification implies an increased level of abstraction because the openEHR idea is aimed at producing an understanding of how information systems can support the creation of information during a generic care delivery process. To enable this, clinical information is separated into different classes: Observations, actions, instructions, and opinions/evaluations (see Fig. 2), in addition to 'composition'-, 'cluster'-, 'admin' classes. However, the selection between the different classes requires an increased understanding of the archetype designer-tool and the methodology for designing archetypes.



Figure 2. A generic care delivery process

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) where highly skilled users (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, healthcare personnel must participate in consensus processes when archetypes are in the ‘design-loop’ (Silsand and Ellingsen, 2014; Ulriksen et al., 2017). However, the openEHR specification does not provide a list of archetypes or a complete CKM repository as part of the standard. The strategy of user-driven standardization through the openEHR framework implies developing an evolving repository of standardized clinical information models (archetypes) based on requested needs from the clinical communities (Atalag et al., 2016; Garde et al., 2007).

Archetypes designed in accordance to the formalized process and published in the international CKM is supposed to be used across different openEHR conformant EPR systems. Nonetheless, the result of the interoperability within and between systems and organizations, depends on archetypes that are designed in accordance to the formalized process, systematically organized in accordance to the design principles from the openEHR community (Atalag et al., 2016; Garde et al., 2007). While the openEHR approach is supposed to put that healthcare personnel in ‘the driver’s seat’ of the standardization processes (Garde et al., 2007), the extended use-contexts of the archetypes call for governance routines to ensure that interoperability is obtained across different organizations and user-needs.

Based on what we have outlined above, the development of archetype to support the realization of openEHR-based EPR systems are taking information infrastructure characteristics (Ulriksen et al. 2017). The archetypes can be conceptualized as ‘interoperability standards’, which are expected to support sharing and reuse of information for various purposes within and between EPR systems in different organizations, heterogeneous users, and different stakeholders. Accordingly, the archetypes are not some kind of purified technology, but a technological element that can’t be separated from social processes of design and clinical use (Hanseth and Lundberg, 2001; Monteiro et al., 2012; Star and Ruhleder, 1996). Hence, we find the notion of information infrastructures useful to explore and understand the complexities and mechanisms involved in the archetype-development process.

In an information infrastructure perspective, the archetypes can be characterized by their supporting or enabling function as they are designed to support a wide range of activities, e.g. the support of clinical work, administrative and governance purposes in different organizations. The enabling function of an information infrastructure is intended to open up a field of new activities, not just improving something existing, which often affect the distribution of responsibilities, hierarchies, and introduce new roles and routines (Vikkelsø, 2005).

The archetypes as a component of a large-scale information infrastructure is shared by a larger community, and will change and grow in relation to the ever-changing health domain’s need for granularity of clinical information in different use-contexts. Taking into account the described process of developing archetypes, starting with local needs and scaling up to ‘meta-standards’ that need to be tailored to local clinical use context, this implies many layers of the same standard with several stakeholders involved in the process. In addition, composing local tailored archetypes into templates for different purposes within different organizations scales the complexity of the standards to ensure that interoperability of the information infrastructure is obtained. Hence, from the repository of a developed archetype, grows a network of sub-repositories of customized archetypes and templates. This reflects that the openEHR repository take on installed base characteristics (Ulriksen et al. 2017), in which newer versions or customized archetypes need to be carefully introduced or adjusted, to

replace previous versions, in order to maintain backward compatibility (Bowker and Star 1999).

The network constituted by the archetype development process consisting of data elements, use practices, openEHR specification and development practices affects what can be changed, how and by whom (Hanseth and Lyytinen, 2010; Star and Ruhleder, 1996). It also challenges the prominent role ascribed the users in openEHR-based information infrastructures where users are assumed to be in control of the process (Christensen and Ellingsen, 2017, p. 51). This raises the general question of how and to what degree an information infrastructure in general and openEHR-based archetypes in particular can be managed at different levels of healthcare. In the information infrastructure literature, several authors have used the notion of infrastructuring (see, for instance, Pipek and Wulf 2009) in order to emphasize the proactive engagement with large ICT portfolios. While these insights are relevant for understanding the mechanisms for change; however, there has been less focus on the more formal governance of organizational structures and configurations of information infrastructures. There is a need to establish ICT governance organizations that make decisions, as well as monitor results and performances (Beratarbide and Kelsey, 2009) at different healthcare levels.

Since most information systems have had in-house governance until the mid-1990s, governance has often been exercised from an internal perspective (Sambamurthy and Zmud, 1999). It is thus challenging to establish inter-organizational and local/national governance that can manage goals, processes, people and technology related to large-scale information infrastructures. In this regard, Star and Ruhleder (1996) state that the configuration mechanisms of governance are typically a mixture of various structures, processes and relational aspects. In this regard, Constantinides and Barrett (2014) suggest a polycentric governance approach in which different stakeholders are engaged in dynamic and adaptive governance processes. Polycentric governance includes organizing a number of governing units at diverging levels instead of one monocentric governance unit. In such governance model, there is a distribution of decision- making across organizational layers and among a broad range of stakeholders, where each layer deals with associated subjects at a gradually larger scale and less-detailed level (McGinnis, 1999). Along these lines, openEHR archetypes appears to require a new dimension of governance related to the distributed standardization and customization processes driven by the users and domain experts. And actually, how the

ascribed prominent user role in the openEHR approach will play out, is not easy to foresee given the information infrastructure's unbounded scale, uncertain functionality and several unforeseen socio-technical interdependencies (Perrow, 1984). This motivates to explore how one should govern the processes of designing archetypes, in terms of how to mobilize and coordinate multiple new actors that take part in user-led standardization processes (Aanestad and Jensen, 2011).

3 Methodological approach

This study is an interpretive case study (Klein and Myers, 1999; Walsham, 1995) with the aim of providing empirical insight about the longitudinal process of establishing the user-driven standardization approach within openEHR based EPR systems, and the following implications for governance. Interpretive research has emerged as an important strand in information systems research over the past decades, and led to the adoption of empirical approaches focusing particularly on socio-technical interdependencies of information system design (Walsham, 1995; 2006). Research in the information system field investigates the phenomena that emerge when an information system and a social system interact through social constructions such a language, consciousness/observation, shared meanings, and documents. However, in this paper, it is not the design of the openEHR based system as such that is the object in focus, but rather the underlying process of developing archetypes. Accordingly, we apply an interpretive research approach to produce an understanding of the context for developing archetypes and the process whereby the development of archetypes influences and is influenced by the context (Klein and Myers, 1999, p. 69; Walsham, 1995, p. 4–5).

The epistemological foundation in interpretive research emphasises that gaining knowledge for understanding the context of developing archetypes means getting involved in the world where the developing process occurs, and not by hypothetical deductions or predefined variables. The approach also assumes that social realities are not discovered, but interpreted (Orlikowski and Baroudi, 1991). 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 researchers that construct and make sense of the reality. Accordingly, setting up and carrying out fieldwork is the fundamental basis for any interpretive study (Walsham, 2006). This implies that the 'field' site is constructed reflexively by every

choice that the involved researchers make in selecting, connecting, and bounding the site through interaction with people (Blomberg and Karasti, 2013).

We have traced the development process of the new EPR system – and thus the process of designing archetypes - through its evolution from the initial start with user-vendor workshops on the local level in January 2012, to implementation in a clinical setting in May 2016. In addition, we have followed a national initiative of building a national repository of common archetypes for collaborative EPR system. The data collection ended in December 2017. Data were collected through qualitative methods (Klein and Myers, 1999; Walsham, 1995). Concretely these were:

- Participant observation in workshops with the vendor and users when designing the new EPR system, software module testing, meetings and seminars on archetype strategy, and formal and informal project meetings. Estimated to 400 hours of observation.
- The first author has conducted twenty-six semi-structured interviews of developers, project managers, and clinicians, each lasting 40–60 minutes. Note, the second author participated in four of the interviews, all these four with developers. A digital voice recorder was used in all the interviews, and the interviews were transcribed.
- Document studies of the ongoing project and reports from National ICT Health Trust² on ICT architecture and archetype strategy were performed.

The interpretive approach calls for detailed case descriptions, followed by an analysis of the data for potential analytical themes guided by the philosophical perspective of hermeneutics and the chosen theoretical framework. The hermeneutic perspective implies the consideration of the entire data collection in an iterative and interpretive process. Therefore, our analysis has been a back-and-forth process between observation, case descriptions, and the use of the relevant literature and document studies mentioned above to generalize the findings from the empirical case and make the findings interesting for other organizations and

² National ICT is a separate health trust responsible for coordinating ICT-related initiatives in the Norwegian specialized health care services (National ICT 2011). The four health authorities in Norway provide the mandate for National ICT. National ICT is a central actor in realizing national ICT efforts and strategies in Norway.

contexts. Moreover, informal talks with stakeholders and research fellows have played an essential role in the interpretive process.

The first author has worked as a nurse for several years, and in different roles as being ‘on the floor’ to administrative roles e.g. holding a part time position at the Governance Department for Clinical ICT systems at the University Hospital. This background plays a role when it comes to the interest for issues within the empirical process to be explored. The second author has a long history of studying the implementation and use of ICT in healthcare, particularly regarding EPRs in hospitals.

4 Case

4.1 The empirical setting

The Northern Norway Regional Health Authority decided in 2011 to invest in new clinical ICT systems for all 11 hospitals in Northern Norway. The regional project was then established with a cost likely to exceed €100 million for the period 2012–2016, and it is currently one of the most ambitious healthcare-related ICT projects in Norway. A key aim of this project was to replace an existing, largely free-text-based EPR with a new openEHR based EPR system offering extensive decision support, interoperability capabilities, and easy reuse of data for clinical research and organizational governance. The procurement conformed to the reports from the Norwegian National ICT Health Trust, which had explored the use of openEHR archetypes as a starting point for developing national interoperability standards.

DIPS, the principal vendor in the Regional project, currently holds approximately 86% of the hospital-based EHR market in Norway. During the last 25 years, its system developers had accumulated high-level expertise in developing ICT systems in this domain. Because of the healthcare domain’s complexity, DIPS started to experiment with a so-called Model-Driven-Development methodology as early as 2006. This culminated in 2011 with the decision to use the openEHR architecture for its future EPR system. DIPS regarded the openEHR architecture as the perfect strategy to handle an increasingly complex healthcare market:

“Very much of what we had developed in the period 2008–2011—was good functionality, but all the screens and modules were hardcoded, and every tiny change to our software had to be done by our developers and that was an overwhelming task

(. . .) [in comparison] openEHR is a very good domain model of the healthcare sector (. . .) and building a system where it is possible to model things and change structure afterwards would be very efficient for us” (system architect, DIPS).

Through this adherence to the openEHR framework, DIPS could concentrate its efforts on developing the technical part of the new EHR while the users were expected to model the clinical content of various healthcare domains through archetypes in accordance with the national strategy (National ICT, 2008).

The regional project started out in early 2012 with several workshops in parallel, in which developers and managers from the vendor, the clinicians, and the members of the regional project cooperated to plot the course of the system to be developed. In this process, more than 150 clinicians from all 11 hospitals in the northern health region were invited to workshops to define their expectations and requests for a new EPR system.

In this paper, we have limited our focus to the development of a new surgery-planning module within the new EPR system, which was identified as one of the most important components due to the need of improving efficiency in a very costly area, namely the surgery-planning process. In the following, we present three empirical vignettes that illustrates the cumbersome path to establish the necessary governance bodies to support the establishment of working archetypes.

4.2 Vignette 1: Developing an archetype-based EPR from scratch

As elaborated above, DIPS regarded the openEHR architecture as the perfect strategy to handle an increasingly complex healthcare market. One of the managers stated:

“The profit by using the “archetype approach” is that it allows us (the developers) to live in “our own little developers’ world”—though, not the developers who implement the system. (...) the designers don’t need so much clinical contextual knowledge, and the domain experts don’t need extended technical skills—but we have to know a little bit of each other’s domains” (Manager, DIPS).

Through adherence to the openEHR framework, DIPS could concentrate its efforts on developing the technical generic reference model of the new EPR while users were expected to model the clinical information necessary to support various healthcare domains through

archetypes. In turn, the vendor's running software would process and interpret the archetypes to generate user interfaces, workflow, and process support.

In the initial phase of the development project, the clinicians were enthusiastic about the possibility of gaining flexible structured clinical information, which could be reused during clinical processes and serve as a premise for process and decision support. In this regard, building software in accordance to the openEHR specification was a striking contrast to the traditional software design where the vendors' have complete control of the development process. Traditionally, the clinicians' requirements are gathered via the well-known "use case" methodology; whereupon systems are built from this and followed by testing and deployment of the software. Based on openEHR approach, the vendor was supposed to concentrate on developing the technical part of the new EPR while the clinical content—the semantic interoperable data elements—were expected to be modelled by the clinicians.

Anyway, at this stage of the development process, the vendor did not have any working software to present to the clinicians, but needed feedback from the clinicians about how the software should process archetypes dynamically into the prospective user interface. According to the developers, they would not develop a specific local functionality (e.g., in surgery planning for a local hospital), but rather generic functionality that could process archetypes and then make it possible to plan surgery tailored to the local context (Figure 3). Related to this a developer from the vendor explained:

“We are going to build a LEGO® city, but at this stage we are making the description of how to put the single bricks [archetypes] together”.

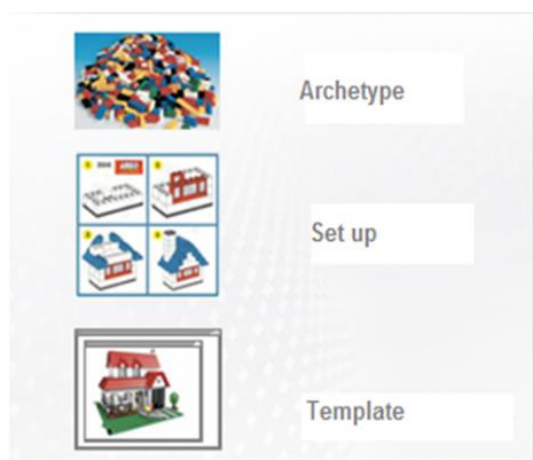


Figure 3. The Lego analogy

However, grasping the potential of a completely new technology was challenging for the clinicians and similarly, getting the clinicians' feedback was challenging for the developers. An essential problem was that the users were supposed to give feedback on an abstract level related to a generic process of care delivery supporting the creation and recording of information during a general clinical process. Nonetheless, for the system developers it was of great importance to get the clinicians' opinions to carry out the design of the reference model. At this point, the clinicians were not held accountable for the responsibility of developing archetypes. From the vendor's side, archetypes were something that needed to be developed, but not absolutely necessary early in the process of designing the reference model. Still, with no working archetypes to process in the generic reference model, it was difficult for the clinicians to see what a functionality would look like. And subsequently they had difficulty of understanding the potential of the new EPR with its promised local customisation possibilities. The only thing the developers could do at this point was to present 'static' suggestions of user-interfaces and this was insufficient.

4.3 Vignette 2: The need for national governance

During the first year of the development process, it became clear that the new EPR would be difficult to develop and would not be operative without the presence of a broad range of archetypes to represent the clinical surgery-planning process. The vendor had expected the Northern Norway Regional Health Authority to organise relevant user forums for modelling archetypes. However, the management of the regional project had no mandate to do so, and they also realised that building a repository of archetypes would be a task too huge for the smallest health region in Norway. Accordingly, an increased understanding of the need for a broader national initiative to do this work led to the establishment of an editorial group (two full-time positions) for building and governing a national archetype repository (a clinical knowledge manager) in January 2014. The initiative was developed through National ICT and the vendor. In February 2014, the editorial group launched a Norwegian CKM, aiming to govern Norwegian archetypes by the same principles as the international CKM.

The introduction of a national repository of archetypes was an important step towards sharing clinical information over institutional boundaries, and the archetypes were designed in accordance with the design principles from the openEHR specification. To obtain a basic catalogue of archetypes quickly, the archetype governance program saw it as effective to start

the process of filling the repository with observation-type archetypes already developed and approved internationally. The intention of an evolving archetype repository was to develop archetypes through a “do-ocracy”, for which clinicians, allied health workers, and other experts propose which clinical information that need to be archetyped based on local needs— or, for example, national initiatives—as quality standards for healthcare. Moreover, the requested archetypes had to be reviewed, in which the editorial group supported by regional archetype groups was responsible for recruiting reviewers (healthcare personnel) to national consensus processes. If the requirements - such as having the right number of clinical specialists for the specific archetype - were met, the editorial group provided the final approval. The process of translating international archetypes or defining local ones, recruiting reviewers, and often several rounds with the consensus process before finally approval, proved to be a very time-consuming process.

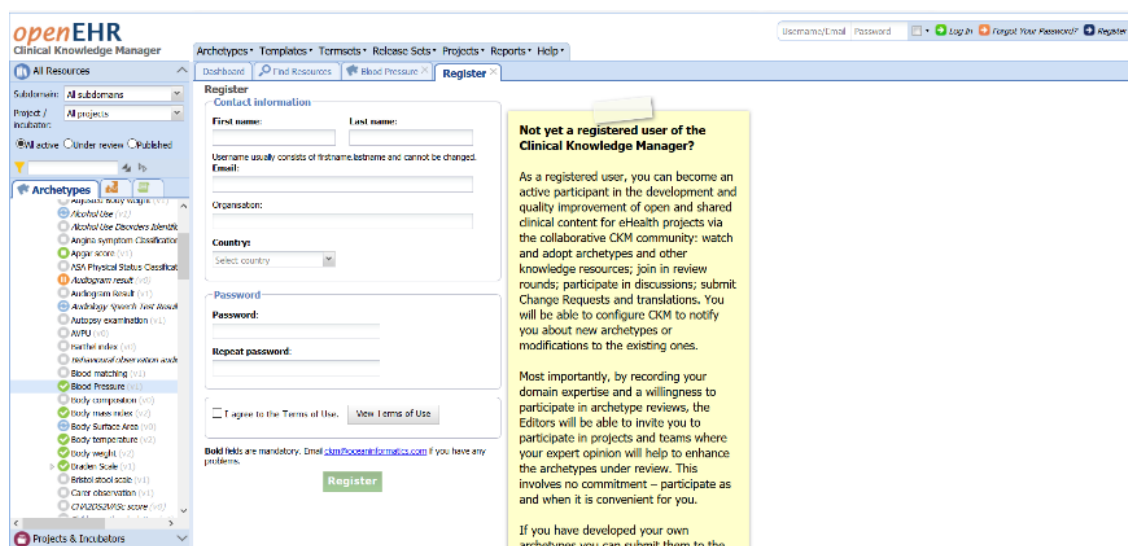


Figure 4. Illustration of the registration site to become an archetype-reviewer

From the vendor’s point of view, the initial process of modelling nationally approved archetypes moved too slowly. The vendor was heavily engaged in the development of the surgery-planning module, which traditionally combines structured data from the EPR with logistic data and resource overview data from other systems to create a schedule for surgery activities. Accordingly, the surgery-planning module needed a certain number of working archetypes. However, as long as the national editorial group was in the formative stage, and there existed no regional ‘archetype group’ by that time, the vendor found it impossible to

deliver an empty system that would require the users to spend years building the archetypes necessary to make the new EPR work. Consequently, the vendor took the responsibility of defining and creating the initial archetypes for the surgery-planning module in cooperation with international stakeholders and the national editorial group. While the openEHR specification clearly states that it is the clinical communities' responsibility to propose and create archetypes, both the vendor and the national editorial group were aware that developing vendor-based archetypes was far from the ideal of national approved archetypes initiated through the 'do-ocracy'.

Furthermore, when the National Editorial group was getting momentum in their archetype-modelling work, they found it still difficult to recruit clinicians to participate in the consensus processes. This was unfortunate since the openEHR specification required a number of clinical specialists for every specific archetype to meet the needs for a 'meta-standard'. The problem of recruiting clinicians to participate in the consensus work, seemed to suffer from several causes, but particularly the following: First, the clinicians did not see the practical and functional effect from contributing in modelling archetypes as long as the new EPR was not implemented. Second, the clinicians did not want to use their spare time to do the archetype-work, which was expected to be voluntarily, and they did not have time for the archetype-work during ordinary clinical practice.

4.4 Vignette 3: The rise of the domain experts

As described in vignettes 1 and 2, developing an archetype-based EPR system revealed how organisational dependencies and structures were missing by the time the development process started. The archetype development process did not follow the official channels of users' proposing their need for clinical information that needed to be archetyped, and the lack of archetypes were an important bottleneck for the evolvement of the open platform. Nonetheless, in April 2016, the surgery-planning module was ready to be tested in clinical practice, but restricted to a specific setting of surgery performed on a limited group of patients in an outpatient clinic of the University Hospital of Northern Norway. After more than four years of development and testing of the new EPR system, the implementation of the surgery-planning module was prolonged and welcomed by clinicians, project management, and the vendor.

The project group responsible for implementing the surgery planning module had mapped thoroughly the work processes for all of the healthcare personnel involved, and tailored the work processes to the new functionality up-front. Moreover, during the test period, the project group almost «sat on the clinicians’ lap» while using the new system to be sure that nothing went wrong or that patient’s safety was threatened. So, what did the first month of clinical testing reveal? The clinicians had expected that they could tailor the archetype-based schemas in the new EPR, in terms of constraining or expanding the number of clinical variables within (templates) schemas to fit into their local use context. However, by the time of implementation, the vendor did not offer tools to the clinicians/domain experts enabling them to customize archetypes to local context. Hence, tailoring the archetypes was not an option for the clinicians during implementation, and the clinicians felt misled compared to the expectations they were given in the initial stages of the development process. Nevertheless, the archetypes needed to be customized, and the vendor performed the customization process itself. Another aspect of the customization process was to compose archetypes into templates, in this case corresponding to a surgery decision note, an aesthetic pre-operative assessment note, and surgeons’ assessment note. The developers composed these templates based on input and feedback from the users.

However, another worrying issue was that in accordance to the openEHR specification (Fig. 5), the user-developer collaboration missed the domain expert level supposed to process both the customization of archetypes and composition of templates. Even though the vendor did not offer tools to do this work within their system, the customization and template design can be done without these tools, but depends on domain experts trained to do this.

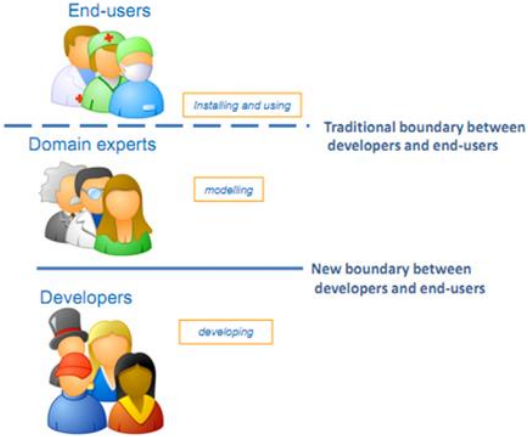


Figure 5. Different roles within the openEHR approach

Another concern related to the absence of domain experts was where, to whom, and how could local clinicians address their needs of clinical information that could be designed as archetypes during implementation and use? An illustration of such a local need was stated by a clinician in the test period:

”It is ok with reuse of clinical information like blood pressure, weight, and height, but what would be of real added clinical value is if a clinical procedure, e.g. a surgery procedure, automatically initiates a list of new procedures, measures, or actions that you have to consider and make a decision in relation to the patient condition. Then, we are talking about a new dimension of process- and decision-supporting systems”.

However, during the test period, requests described by the clinician was not given specific focus because it was the technical integrations between the new and existing EPRs that was of concern. Nor were there established a ‘domain experts group’ in the region trained to handle such tasks. While the need for new archetypes were addressed, the bridge between clinical practice and the national editorial group was missing. To summarise the initial clinical use of the new EPR system, the clinicians were mostly positive about the new user interfaces and functionalities. On the other hand, accessibility, efficiency, and effective sharing of clinical information by archetypes as a critical component to increase the surgery-planning process and quality of treatment and care to the patients was limited. The test period revealed that the responsibility for developing archetypes had not been given specific attention neither from the clinical community or at the regional management level during the development of the surgery-planning model. The responsibility needed to be addressed to comply with the regions goals of extensive decision support, interoperability capabilities, and easy reuse of data for clinical research and organizational governance.

5 Discussion

This paper focus on the longitudinal process of establishing the distributed network of users, domain experts and an overall governance organization to conduct the development, distribution, and governance of openEHR archetypes. In the following section, we take an information infrastructure perspective and discuss how these interdependencies need to be

coordinated and governed to make the distributed network of users, domain experts and designers to ‘walk-in-line’.

5.1 A distributed an interdependent governance

Comparing the openEHR approach with design of proprietary EPR system, designing the latter one implies that the vendor is responsible for the ‘entire’ development process of hardware, software, and information models. In contrast, the openEHR approach separates this process between designers and users where the user group have got responsibility for developing the information models, i.e. the archetypes.

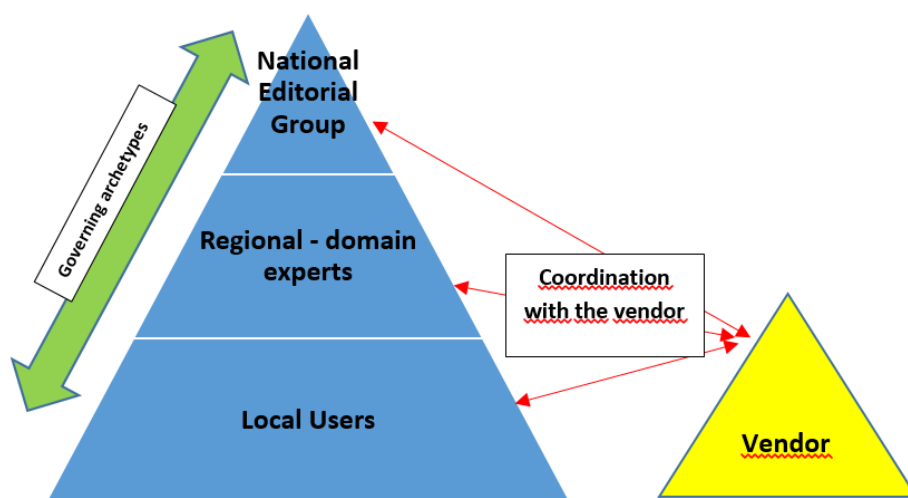


Figure 6. The different levels of Governance of the archetype development process

Moving away from a traditional designer/user relationship, towards a landscape that stretches out vertically (nationally, regionally and locally) as well as horizontally (many hospitals and vendors) in a distributed manner, clearly reflects an extremely complex information infrastructure. The various stakeholders and components are interdependent of each other and if one of them breaks, it will have severe consequences for the whole information infrastructure (Perrow, 1984).

In turn, such a wide-reaching information infrastructure calls for a distributed governance setup similar to a polycentric governance approach (Constantinides and Barrett, 2014) where stakeholders are engaged in adaptive governance processes at several levels. However, it is also clear that an essential problem was that from the outset there were no governance of

archetypes at all: There didn't exist any national editorial group (level 3) that could coordinate the process, nor were there any domain experts (level 2) and users (level 3) participating in the start-up process. From a traditional information infrastructure perspective, this shouldn't necessary constitute a problem since infrastructures are an emergent phenomenon where the installed-base are carefully cultivated (Aanestad and Jensen, 2011).

However, a problem in this case was that the openEHR architecture presupposed too much formalised governance established up-front in order to coordinate the development of a technology that was too disentangled from the EPR (the installed base). Our case obviously illustrates that in order to maintain a smooth development process of archetypes it required that you already have the three level of committed stakeholders as illustrated in the figure above. This three-level organisation was in turn supposed to suggest, negotiate and agree on archetypes that should serve as a foundation for the new EPR system. And the new EPR was depending on these archetypes to work. In an information infrastructure perspective, this comes around as problematic since the users were expected to participate in this collaboration without really getting a working software in the foreseeable future (Ulriksen and Ellingsen, 2017).

Our case also illustrates, that while an openEHR-based infrastructure prescribes a distributed governance, the responsibilities between the levels and the stakeholders is not clear cut as outlined by the openEHR framework. Instead some overlap of the areas should be expected. While the openEHR approach prescribes that users and designers should work interdependently, in practice is not possible. Technical and organisational issues interlock and therefore users cannot work solely on the information model and the designers on the technical part. The design of archetypes reflects rather a co-construction process (Bossen, 2011; Ellingsen et al., 2007) between users, designers, domain experts and the editorial group, where the developers do the technical design of the reference module and the users do their share for designing archetypes (Fig. 2).

5.2 The domain experts - dealing with the local/global tension

It is by now well established in information infrastructure studies that standardization involves a negotiation between the "global" and the "local" (Timmermans and Berg, 1997), and that there are implicated trade-offs and dilemmas (Bowker and Star, 1999). However, there is

scant evidence on exactly how these negotiation spans out empirically, and particularly in an openEHR context.

In our case, this is illustrated by the different (yet still interdependent) levels of governance. The concrete dilemma that needed to be solved played out along two dimensions. First, how the need for structured data in clinical practice (local level) had to be translated into and context-free archetype useful across several contexts (global level). Second, how the users had to state their requirements for what they wanted with the new EPR functionality, which subsequently the designers had to translate into a generic reference model.

Both these issues were difficult to solve. Along the first dimension, clinicians were generally reluctant to participate in the archetype work because it both required that they had to invest a lot of resources into it. For instance, since an archetype were supposed to be used across various health care domains - e.g. a nursing archetype for an oral assessment should be applicable to other medical domains as well – the users had to negotiate with other clinicians to agree on a context-free archetype. In addition, clinicians that did take part in the development processes found it extremely challenging to design abstract archetypes where the implications for working software was not possible to see until the vendor had embedded these archetypes in the new EPR system. Along the second dimension, the users found it very hard to conceptualize their work practices in generic terms, which the designers could apply to develop a reference model that in turn could be populated with archetypes.

However, while this process was characterised with many challenges, the emerging infrastructure enabled the rise of a new user/designer role that appears to balance the tension between local and global needs. This role was the domain expert (level 2 in the figure). Although, the domain experts and their position in the governance structure conforms to the formal organizational structures in the openEHR community to coordinate activities within and between domains (Garde et al., 2007), the role of this group became much more prominent than was initially anticipated. The domain experts needed to operate on the local level where the developers and users cooperate in design and implementation of new system modules. In this setting, the domain expert needed to guide the users into the archetype modelling process, in co-operation with the developers, and enable the users to address their need for standardization of clinical information. In this regard, the domain experts had to engage in extensive co-constructive work along the two dimensions elaborated on above.

However, this is not the kind of co-construction where the developers get input from the users' and transform these inputs into working solutions. The co-construction of the reference model and the archetypes argues for an abstraction, in which the developers need to design a generic reference model and the archetypes need to be designed as 'meta-standards'.

5.3 The nature of user control

The relevance of engaging users in the development of information systems is well recognized. On the one hand, users are expected to provide designers with valuable insight into the users' work practice. In small-scale projects this is pretty straight forward to achieve. In contrast, this is considerable more difficult in large-scale information infrastructures with associated governance structures. The question in these circumstances would rather be what form of user control can be supported and to what extent. Since the openEHR framework, promises extensive user participation and control (Garde et al., 2007), this is of particular interest in an information infrastructure perspective where users are just one of many stakeholders (Hanseth and Lyytinen, 2010).

Taking a closer look into our case, appears to challenge this particular lead user role in openEHR since the users are part of a broader infrastructural ensemble or socio-technical network (Latour, 1987). In this way, the users are both part of, and shaped by a formal governance organisation. Basically, the users' participation and engagement are under substantial control of the standardization regulations and rules promoted by the openEHR community. The users must follow certain rules and they must be thoroughly trained to be able to do so. The level of abstraction requires an increased understanding of the archetype designer-tool gained by experiences and support from openEHR communities. All of this has to be done to ensure that the archetypes are interoperable within the national information infrastructure. Consequently, the users have to 'walk in line' (Silsand and Ellingsen, 2014; Pollock et al., 2007) with the given specifications for archetype and template design. Overall, this may sound discouraging. The type of user participation in the openEHR approach demands a degree of competence, engagement and adherence to openEHR regulations, in which many users are not prepared to offer. The users have to commit themselves to a quite large extent if they want to shape the process.

Despite this, there are some interesting and positive possibilities for participation. For instance, the users may in on-line archetype discussions in a quite flexible way. These

discussions can be accomplished independent of time and space (although within the timeframe of the specific consensus process). In addition, if the users learn to adhere to the framework that the openEHR specification prescribes, there are great opportunities for the users to shape functionalities, interoperability and reuse within new EPRs. Only time will tell if the users see these benefits to such a degree that they are willing to invest sufficient amount of resources into the process, and if the management in the different healthcare organizations offers the means to support this participation. In this sense, the degree of participation should not be assessed in isolation, but rather be considered as a balancing act recognized in many information infrastructural studies (Star and Ruhleder, 1996; Hanseth and Lundberg, 1991).

6 Conclusion and implications

This paper has particularly focused on the underlying process of developing archetypes promoted to be done through a user-driven standardization approach. An important insight of the study is that developing archetypes to be the 'interoperability standards' of large-scale information infrastructures require a well-working governance structure on different organizational levels. However, it is not enough to promote user-driven standardisation of openEHR based information infrastructure as something the users can do by themselves because developing archetypes implies a network of different use practices, the openEHR specification and a regulated development practice, the relationships to other infrastructures, and the data model itself. The multifaceted network constitutes a myriad of links between all actors, which affect and can be a risk for the overall goal of interoperability (Hanseth and Lyytinen, 2010; Star and Ruhleder, 1996). Accordingly, it is of importance to make the actors of the network to 'walk in line', in which the user-driven standardization approach plays out as a need for governance of the standardization process, as well as of the large-scale openEHR based information infrastructure.

We draw the following implications from our study: First, while on the one hand the openEHR framework is characterized with extensive flexibility, it also is characterized by a formalized governance bureaucracy. In order to avoid that this governance results in a static top-down approach, it is important that its role maintain supportive and enabling rather than demanding and controlling. This should be carefully monitored. Second, the crucial domain expert role calls for the establishment of some form for 'domain expert education'. Accordingly, the

archetypes enable 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 depends on the support from the management level. The management level need to take their responsibility to recruit domain experts, organize the necessary domain expert education, and adjust for the users' participation in the archetype development processes. Third, the user role is extremely important in information infrastructure studies. It is clear from this study, which promised extensive user control, that this is illusory. The focus for future studies on user control should rather be on what type of user control can be achieved under the current circumstances and what can we do to improve it.

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Paper 5

The ‘Holy Grail’ of Interoperability of Health Information Systems: Challenges and Implications

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Abstract. Enabling integration between heterogeneous health information systems (IS) across different institutions is attracting growing interest from national and regional governments. “Interoperability of health information systems” is an overall goal to strive for. This empirical paper addresses the challenges of integrating heterogeneous health information systems with the goal of achieving semantic interoperability of patient information within and between all hospitals in a health region. The paper describes a complex development and integration process, and looks into a promising strategy of using openEHR archetypes as an architecture to reach the goal of interoperability.

Keywords: Health information systems · Integration · Interoperability · Healthcare processes

1 Introduction

Today, people have more mobility and longer lives, while healthcare services are increasingly shared between care providers and different jurisdictions. In addition, healthcare institutions tend to combine different information technologies, modules or subsystems, following a best-of-breed approach. Accordingly, integration of information systems (IS) is essential to support shared care and to provide consistent care to individuals [1–3].

Health IS and technologies have the potential to support a smart, sustainable and consistent healthcare service, in which accessibility, efficiency and effectiveness are key concepts. Enabling integration between heterogeneous health information systems (IS) across different institutions is attracting growing interest from national and regional governments; “interoperability of EPRs” is an overall goal to strive for [4, 5]. However, to integrate fragmented portfolios of health IS in such a way that communication and clinical information used for healthcare delivery will improve, address many different issues [9, 13, 20].

First, integration of health information systems involves complex processes due to diverging needs from healthcare practitioners, heterogeneous groups of patients, and diverse procedures and approaches to medical treatment and care. Accordingly, it is important to understand the characteristics of the healthcare processes the systems are

going to support. Second, it is important to understand the concept of interoperability, in which smart and consistent healthcare services address a need for information shared by systems to be understood and processed by the receiving system (semantic interoperability). This is a premise for advanced process and decision support.

Prior studies have explored processes of IT integration in the context of healthcare and identified factors facilitating successful processes, for example, integration of new systems with existing work processes or necessary reorganization of clinical as well as organizational workflows when implementing a new EPR [6–8]. This paper addresses a different empirical situation: the challenges of integrating heterogeneous health ISs with a goal of achieving semantic interoperability of patient information within and between all hospitals in a region. Empirically, this study reports from a large-scale regional project to replace an existing, largely free-text-based electronic patient record (EPR) with a new semantically interoperable EPR base on the openEHR approach, and simultaneously integrating a new electronic charting and medication (ECM) system with the EPR in change. The project started in 2011, and took place in the Northern Norway Health Region.

Against this backdrop, the following research question is posed: *What are the key challenges when integrating heterogeneous health ISs to enable semantic interoperability?*

To conceptualize the dynamics of how various healthcare professionals, activities, stakeholders, and technology are interwoven during the integration process, the study draws on the notion of information infrastructure (II). II literature addresses the socio-technical challenges of realizing large-scale technological systems, and is relevant for analyzing the regional integration process [9–12]. In doing so, the study contributes with important empirical insights about introducing vendor-independent clinical information models [15], exemplified by the openEHR archetypes, as an approach to realizing the goal of semantic interoperability within and between heterogeneous health ISs on a regional scale.

The rest of the paper is organized as follows: Sect. 2 describes the theoretical framework for this paper. Section 3 briefly introduces the empirical setting and reflects on methodological issues. Section 4 presents the case and elaborates on important steps of the evolving development and integration process. In Sect. 5, the case is discussed in relation to the chosen theoretical framework, followed by Sect. 6, with the concluding remarks.

2 Theory

Integration of health ISs are complex processes due to the different needs of healthcare practitioners, different patients’ needs, and diverse procedures and approaches to medical treatment and care. Integration of heterogeneous health ISs in such a way that communication and clinical information used to support these complex processes of healthcare delivery will be improved addresses various issues [9, 13, 20]. First, it is important to have a common understanding of what characterizes the healthcare processes the systems are going to support [13].

2.1 The Characteristics of Healthcare Processes

In Lenz and Reichert [13], healthcare processes are characterized as a cooperation of different organizational units and medical disciplines, which depend heavily on both information and knowledge management. They have identified different levels of process support in healthcare, and distinguished between organizational processes and the medical treatment process. In short, the organizational process patterns help to coordinate collaborating clinical personnel and organizational units (e.g., handling of a medical order and result reporting), and the medical treatment processes are linked to the patient.

In hospitals, organizational tasks often burden clinical personnel. For example, surgery planning procedures – like the empirical case – have to be planned and prepared, including scheduling appointments with different service providers, in-house transportation of patients, 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 canceled or may require latency time. Integrated process support, information management, and knowledge management on different levels are needed. The current situation of heterogeneous healthcare ISs, where patient information is often spread over different unintegrated applications, does not meet these requirements [13].

However, in recent years a number of integration and interoperability standards have emerged, which provide the basis for health ISs to support organizational and medical treatment processes in healthcare.

2.2 The Concept of Interoperability

Interoperability in health information systems is often referred to as the ‘holy grail’, in which the goal is to make clinical information available across different healthcare institution to provide a smart, sustainable and consistent healthcare service [1, 14]. Accordingly, it is important to understand the concept of interoperability, and in this paper, the review of HL7’s EHR Interoperability Work Group is used to frame the concept [14].

Technical interoperability is the ability of two or more systems to exchange information so that it is readable by the receiver, but cannot be further processed into semantic equivalents by software.

Semantic interoperability is the ability to share information between two or several systems so that the meaning of the exchanged information is understood in exactly the same way by both systems and can be processed by the receiving system.

Process or social interoperability is a requirement for successful integration of computer systems into work settings. It describes the methods and strategies for optimal integration of computer-supported communication of clinical information into an actual work setting [14].

Successful process interoperability relies on successful technical and semantic interoperability because the preferred information must be successfully transmitted (technical interoperability) and properly understood (semantic interoperability).

A promising strategy for dealing with the challenges of supporting inter-organizational healthcare processes involves health ISs conforming to a vendor-independent health computing platform architecture, in this paper exemplified by the openEHR approach [15].

The openEHR approach separates the technical design of the system from detailed organizational and clinical issues. A standardized reference model represents the first level, which is a generic model for all kinds of health information. For example, a blood result from the laboratory would be stored in the same general-purpose data structure. The second level is represented by openEHR archetypes, in terms of reusable, formal definitions of domain level information. Archetypes are not part of the software or database of a system. An archetype represents a description of all the information a clinician might need about a clinical concept – a maximum definition. For instance, a blood pressure (BP) measurement is traditionally represented by systolic and diastolic pressure. As an archetype, the BP is accompanied by data describing the context of measurement such as who (who measured the BP), how (which type of equipment was used, did the patient rest/sit/stand, where on the patient’s body (left/right arm or leg), and when (related to date and time of day). Accordingly, it is important that clinicians are involved in creating the knowledge inherent in archetypes, and a fundamental aim of the openEHR approach is to engage clinicians in the archetype design [16, 17]. The openEHR’s approach offers a high degree of advanced semantic interoperability because the clinical and other domain semantics are defined above the software and database schema level, in which archetypes are an important means to achieve semantic interoperability between the different health ISs [17–19].

Accordingly, interoperability of health ISs is closely related to the healthcare context the systems are going to support. The goal of making clinical information available between different health ISs and across different healthcare institution addresses a need for a relationship between systems and human factors.

2.3 Information Infrastructures

To conceptualize the relationship between systems and human factors, the study draws on the notion of Information Infrastructures (II). II literature addresses the socio-technical challenges of realizing large-scale technological systems, and is relevant for analyzing the empirical case of integrating health ISs into a common health information infrastructure [9–12, 20].

The following characteristics describe an II [21–23]:

- Shared, by the members of a community, including vendors, users and staff
- Evolving, not “designed”, but evolves continually, as growth and innovation expand it
- Open, based on the principle that there is no limit on the number of users
- Standardized, rests on standards, which allow scaling and interoperability

- Heterogeneous, consists of different elements such as technology, users, organizations, in large networks
- Installed base, such structures are seldom created from scratch, but grow from existing practices and infrastructures.

Accordingly, these systems are never seen as standalone entities, but are integrated with other information systems and communication technologies, and with non-technical elements [11, 20, 23]. With the rise in the fragmented portfolio of health ISs used in and between different hospitals across wide geographical distances, both the need for common standards and the need for situated, tailorable and flexible technologies grow stronger.

Star and Ruhleder [12] offer a socio-technical and relational understanding around the following dimensions of when an II emerges:

- Embeddedness; an II is “sunk” into, inside of, other structures, social arrangements and technologies.
- Transparency; II is transparent to use.
- Reach or scope; II has reach beyond a single event or one-site practice.
- Learned as part of membership.
- Links with conventions of practice.
- Embodiment of standards.
- Built on an installed base.
- Becomes visible upon breakdown.

Building II takes time, and all elements are connected – and in addition, the II has to adapt to new requirements as time passes. Accordingly, an II occurs when the tension between local customized use on the one hand and the need for standards and continuity (global) on the other hand is resolved.

Consequently, analyses of II need to take into account a broad range of socio-technical issues shaping the implementation or integration process, as the nature of an II is beyond a single event or one-site practice [11, 12, 20, 21, 23].

3 Method

3.1 Research Site

The paper reports from a large-scale ICT project initiated in 2011 in the Northern Norway Health Region, in which the Regional Health Authority decided to invest in new clinical ICT systems for all the 11 hospitals in the region. The Northern Norway Regional Health Authority is responsible for all 11 public hospitals, which have approximately 12,500 employees altogether. The FIKS program¹ was established with a budget of EUR 90 million for the period 2012–2016, and was one of the most ambitious healthcare-related ICT projects in Norway.

¹ A Norwegian acronym, in English “Common Deployment of Clinical Systems”.

A key aim of the procurement was to replace an existing, largely free-text-based EPR with a semantically interoperable EPR enabling advanced process and decision support within and between the hospitals in the region. An additional aim was to integrate a new electronic charting and medication (ECM) system with the EPR in change. DIPS ASA was the vendor for the existing EPR, and was chosen as the principal vendor for the new EPR system as well. The vendor currently holds approximately 86% of the hospital-based EPR market in Norway. In 2011, the vendor decided to use the openEHR architecture for its future electronic medical system portfolio. This decision was in line with the reports from the Norwegian National ICT Health Trust², which explored the use of vendor-independent standardized clinical information models and the openEHR archetype as a starting point for national interoperability standards [24, 25].

The reports concluded that separating the clinical information models from the systems' internal data models was a preferred approach to enable sharing and reuse of clinical information within the healthcare domain independent of the current heterogeneous portfolio of health ISs. The recommendation required development of national vendor-independent standardized clinical information models, but no official resolution was made concerning the openEHR archetypes as a preferred approach [1, 2].

3.2 Research Approach

The study is an interpretive case study positioned within the constructive paradigm, aimed to provide insight about the key mechanisms at play when developing and integrating heterogeneous health information systems [26, 27]. The epistemological belief in interpretive research emphasizes the understanding of social processes by getting involved inside the world of those generating them, and not by hypothetical deductions or predefined variables [28].

'Growing' an information infrastructure is a time-consuming process that tends to include many different phases in its evolution, and call for research approaches that encompass both short-time dynamics and longer-term evolutions [29]. The data have been collected from the initial start of the FIKS program in January 2012 and through different phases of the projects to January 2017. The author has collected the empirical data by becoming involved in the development process through different settings such as user-designer workshops, observing healthcare personnel, video-conference meetings, participant observation at the vendor's site, formal and informal discussions with project members, and formal semi-structured interviews. A digital voice recorder was used during the interviews, and the interviews were transcribed after recording. In addition, the author explored documents and studies of reports from the ongoing program, and reports from National ICT on ICT architecture and archetype strategy (Table 1).

² The National ICT Health Trust is responsible for coordinating ICT-related initiatives in the specialized health care services. It is a central agent in bringing about and realizing national efforts and strategies for ICT. The mandate is given by the Regional Health Authorities.

Table 1. Data collection.

Activities	Source and extent
Participatory observation	Informal meetings, workshops (EPR/ECM), observing healthcare personnel and developers (DIPS) at work, trials and pilot tests, seminars on archetype strategy. In total 470 h
Interviews	31 semi-structured interviews of healthcare personnel, developers and representatives from DIPS, archetype editors, project managers (FIKS). Each lasted 45–90 min
Document studies	Project documents (FIKS), official reports from National ICT on ICT architecture and archetype strategy, minutes from steering group and project meetings
Informal talks	FIKS management, vendor (EPR/ECM), regional ICT management, product manager at vendor (EPR), Healthcare personnel involved in the projects

The interpretive research approach calls for detailed case descriptions covering the development and integration process, which allow the readers to gain insight in the empirical field, followed by an analysis of the data for potential analytical themes guided by the chosen theoretical framework (Sect. 2). The analysis is presented as the four key challenges in Sect. 4 – discussion. However, the philosophical perspective implies considering the entire data collection in an iterative and interpretive process (the hermeneutic circle), and accordingly the analysis has been a back-and-forth process between collected data, case descriptions, and the use of relevant literature emphasizing the interoperability in complex healthcare processes and the concepts of information infrastructure. The author has discussed the data, case description, and analysis with other members of the IS research community in healthcare. To improve the understanding of the empirical case, the data were continuously presented and discussed in informal meetings with members of the FIKS program, the National Administration Office of Archetypes (NRUA), and healthcare personnel involved [4, 26].

The first author has worked as a nurse at a university hospital for several years. Accordingly, the empirical data is gathered from an “insider perspective” based on the knowledge of the healthcare field.

4 Case

4.1 The New EPR Required Standardized C

The overall goal of investing in a new semantic interoperable EPR was to improve the quality of treatment and care by improving the availability and accessibility of all relevant patient information regardless of where, when and by whom the information was created. This would form the basis for advanced process and decision support of clinical treatment processes in general and specific standardized patient pathways.

“The FIKS program is a major investment in the Northern Norway Health Region, and it’s based on the paradigm shift where EPR systems primarily played a role as a tool for documentation of treatment, results, and clinical assessments, over to look at the systems as process

supporting tools that maintain the clinical information process - which in turn will support the clinical workflow processes”.

(Manager, the Northern Norway Health Region)

The first software module developed during the EPR project was made for supporting the surgery planning process. The idea was that easier access to relevant clinical information would improve the clinical decision-making and overall quality and safety for surgery patients. Moreover, the clinicians would spend less time looking up necessary information about the patient – and gain more time to do clinical work.

However, the new semantically interoperable EPR required standardized clinical information models – so-called archetypes, which were going to be developed by the user community, in accordance with the openEHR approach. As mentioned, the official resolution to use openEHR archetypes as standardized clinical information models on a regional or national level was not carried out, and the necessary repository of agreed-on archetypes was not established. Consequently, this situation was demanding for the vendor, but the Regional Health Authority also played a role in this situation because the openEHR framework encourages clinical communities to be in charge of modeling archetypes. However, the vendor was the principal EPR vendor in three of four health regions in Norway, and the responsibility to contribute to the archetype development process was in that sense beyond the scope of the Northern Norway Health Region. This was a complex situation, which culminated in establishing the national consensus-based repository of archetypes – the Norwegian Clinical Knowledge Manager (CKM) – but still, no official resolution was made to use the openEHR archetypes as national clinical information models.

4.2 National Repository of Standardized Clinical Information Models

In 2013 the National Administration Office of Archetypes (NRUA) was launched, aimed at coordinating the development of archetypes in Norway, both handling the national consensus process of reviewing and approving the clinical information models to ensure a high quality and a high degree of interoperability. To design optimal clinical information models, it was necessary to give the clinicians a key role in both developing and approving the archetypes. The clinicians should propose needs of clinical information to be modeled as archetypes and participate in the consensus process by using a web-based tool for distributed collaboration across the country. Nevertheless, the distributed collaboration also addressed a need for recruiting clinicians from different specialties and training them to use the web-based tool to participate in the consensus process. Even though the national repository of archetypes was established, filling the repository moved slowly due to challenges with recruiting the necessary clinicians, and NRUA had only three part-time employees to facilitate the work. In April 2017, the Norwegian CKM inherited 51 approved archetypes and approximately more than 90 were in process – but the slow progression of filling the repository during 2013-2014 influenced the progression of the semantic interoperable EPR system.

“Unless we get a repository of archetypes that we can process – making sharing and reuse of clinical information possible, the semantic interoperable EPRs are nothing but a good idea”
(manager, DIPS).

4.3 Clinical Use - Transcending the Interdependency of Other Health Information Systems

In April 2016, a surgery planning module from the vendor's new EPR was ready for clinical use. The existing clinical workflow and the new surgery planning tool were adjusted to each other, and formalized into new routines. Accordingly, clinical roles and responsibilities cohered with filling in different documents (Fig. 1) - the surgery decision note (1), aesthetic pre-operative assessment (2) and the surgeon's assessment notes (3). The surgery planning process was initiated by a physician when assessing a patient in the out-patient clinic. If the assessment led to a decision on surgery, then the surgery decision note was filled in and completed, and became the trigger for the other two documents to be created as the next steps of the surgery planning process.

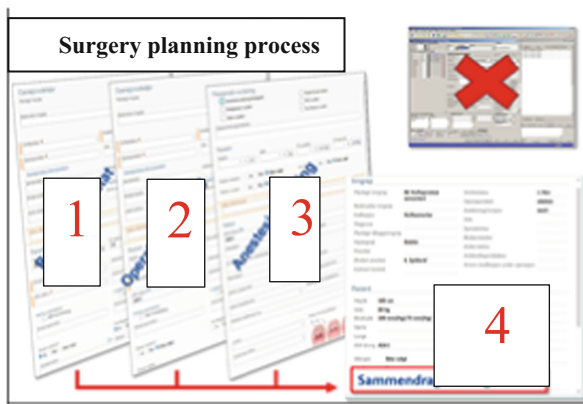


Fig. 1. Reuse of clinical information triggers follow-up activities

Parts of the clinical information within these documents were based on archetypes that could be extracted and reused between the documents, and compiled into a section of the summary document (4) to be used by surgery nurses in the surgery theatre. In addition, the surgery decision note gave instructions to the secretaries to allocate time for surgery to the patient. Nevertheless, to be able to fill in and complete the surgery decision note, the physician needed an overview of the patient's clinical condition. To obtain this, the physician collected clinical information from several different information systems e.g. radiology, laboratory, different specialized clinical subsystems, and the Medical Charting system. The latter was a paper-based system with information about the patient's medication and different clinical variables such as temperature, pulse, and blood pressure measurements.

The initial use of the surgery planning module revealed challenges related to the technical integrations between the existing free-text based EPR and the new archetype-based EPR. For example, if the physician needed information from documents recorded in the "old" EPR while filling in the surgery decision note – then the documents in the "old" system could not be uploaded on the screen while the physician

was simultaneously filling in the surgery decision note in the new EPR. Moreover, filling in the surgery decision note depended on the necessity of clinical information from other health ISs as well – and, in particular, information from the existing paper-based Medical Charting system. In addition, there were unresolved issues related to the reuse of archetypes between the surgery planning documents. The challenges influenced the existing clinical workflow and did not optimize the overall quality of the surgery planning process. Two months after the initial implementation, the surgery planning module was “put on ice”.

4.4 The New Electronic Charting and Medication Systems

As mentioned, the FIKS project embraced the development, customization, and implementation of a new Electronic Charting and Medication (ECM) system, which was going to be an integrated part of the new EPR. In December 2014, the procurement of the ECM was announced, and “MetaVision” was going to substitute the existing paper-based charting and medication system in all the hospitals. The new ECM system offered all necessary functionality to support all clinical settings, e.g. intensive care, out-patient consultations, and general in-patient wards. In addition, the ECM system offered automatic data capture, and accordingly clinical process and decision support based on the system’s inherited clinical information models.

“The Electronic Charting and Medication system will be an integrated and comprehensive solution that can be applied across organizational and professional boundaries. The ECM will provide relevant documentation of a patient’s clinical condition and treatment given, functionality for continuous medication within and between different wards as well as different hospitals – and accordingly provide advanced decision support to the clinicians”

(Project manager, ECM project)

The ECM project evolved fast and the implementation was planned to start during autumn 2017. The customization was arranged through workshops with engaged clinicians from different medical specialties and geographical locations in the region. During the customization process, a significant concern was raised by the clinicians involved:

“How to agree on which system to record the different clinical variables [Measurements, examinations, blood tests, medication, etc.] and descriptive information – should we use the ECM or the EPR, or are we supposed to record the same information in both systems, like we more or less do now [the paper-based charting and medication systems and the EPR]?”

(Group of clinicians, ECM project workshops).

Accordingly, the ECM addressed a new interdependency in reaching the goal of availability and accessibility of all relevant patient information because the two systems needed to share clinical data in a form that both systems could understand and process (Fig. 2).

4.5 Puzzling the Interdependencies

In January 2016, a new subproject “under the FIKS program’s umbrella” was launched, the Regional Patient Pathway project. The goal of the new subproject was to form

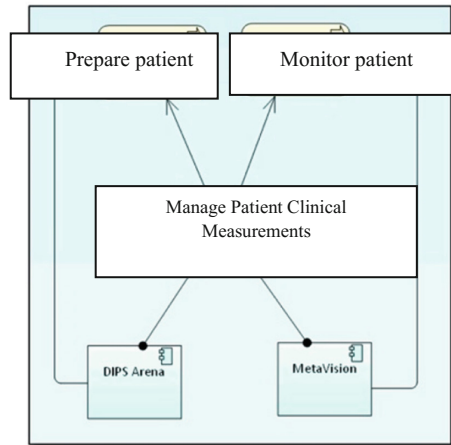


Fig. 2. Examples of clinical information necessary in EPR and/or ECM

appropriate interactions between the EPR and the ECM to enable the overall goal of availability and accessibility of all relevant patient information - regardless of where the information was created and recorded. The project manager stated:

“We (the Regional Patient Pathway project) are going to define the interaction between the Electronic Charting and Medication system and the Electronic Patient Record system in the Region. The interaction between these two systems will support the clinicians in making clinical decisions and planning treatment and care tailored for each patient. The point of departure for the interaction is the clinical workflow in the hospitals”.

However, the Patient Pathway project was well aware that integrating the systems was not a straightforward process. First – the existing EPR was primarily a free-text based system, second – the new EPR was based on openEHR archetypes and their clinical information model, and third – the ECM system used standardized clinical information model hard-coded into its software and database model.

However, the first step of integrating the systems was done in close collaboration with the Regional Health Authority’s ICT department. The project and the ICT department mapped the present clinical workflow and the interaction with different health information systems, both electronic and paper-based, to get hold of necessary clinical information during the different steps in the chosen patient pathway (Hip Prosthesis). The goal was to harmonize the different systems and overlapping functionalities, to avoid uncontrolled data redundancy and double documentation of similar information because of the heterogeneous health ISS. Nevertheless, with systems using different information models – the new EPR processing openEHR archetypes and the ECM system with clinical information hard-coded into its software and database model – the Regional goal of integrating the EPR and the ECM into a semantically interoperable health information infrastructure supporting inter-organizational work processes was not solved.

5 Discussion

In this study, the characteristics of an II have been important when “catching” all the diverging issues of human, organizational and technical characters challenging the development of the new openEHR-based EPR system, and the integration between the existing and new EPR, in addition to the new ECM system. When analyzing the empirical case in light of the presented theoretical framework, it accumulated into four key challenges in the quest for semantic interoperability within and between heterogeneous health ISs.

First, in the empirical case, the first step of reaching interoperability seemed an easy target by replacing the existing highly free-text based EPR with the new innovative archetype-based EPR system. The replacement was supposed to make the goal of semantic interoperability within and between the hospitals’ EPR systems reachable. In doing so, the vendor DIPS in cooperation with the Regional Project started the replacement as an evolution from the installed base, in terms of tailoring the new EPR to the existing EPR system in a specific clinical context of clinical routines and processes [11, 12, 20, 21, 23]. The integration was technically a success, but made the clinical work processes more cumbersome. For example, the physician needed to “jump” between the interfaces of the two systems when filling in the surgery decision note and this shift made the “clinical train of thoughts” more vulnerable to interruptions. Accordingly, the technical integration was not embedded into the clinicians’ working routines because it did not rest on common standards allowing seamless scaling and interoperability [12, 21].

Second, the integration between the two EPRs was only an interim solution because the archetype-based EPR was going to replace the existing systems successively. As elaborated in the case, the vendor needed a repository of archetypes developed by the clinicians to speed up the development process of the new EPR. The “breakdown” of the vendor’s development process brought in yet another perspective pointing at the need for common standards to make the new EPR evolve and replace the existing system – in comparison with an evolving II. The new angle addressed the necessary collaboration of clinicians to enroll, structure and standardize the clinical information (archetypes) supporting their healthcare processes [12, 14, 17]. In this sense, the evolving II had reach beyond the scope of the FIKS program’s development process, in terms of beyond a single event and one-site practice [12]. This situation addressed an organizational interdependency, the establishment of NRUA, as well as a relational understanding because the archetype development process depended on the clinicians’ engagement and collaboration. However, establishing NRUA with limited resources and the dependency of involvement from distributed clinicians was not a straightforward process. It is tempting to believe that the establishment would benefit from an overall resolution to use national or at least regional vendor-independent clinical information models as basis for a health information infrastructure [10, 12, 20, 22].

Third, in this empirical case – two best-of-breed systems are going to support the same healthcare process, the systems offer overlap in their functionality, partly providing the same or only slightly differing functionalities. This makes integration more difficult because archetypes represent maximum definition of clinical concepts, which

is not applicable for traditional health ISs, such as the ECM, to receive and process. To solve this delicate situation, there will be a need for mapping clinical information e.g. a blood pressure measurement, between the two systems' different information models because much of the clinical information will be necessary for both systems to process. However, a consequence will be that the comprehensive information in archetypes will not be exchanged because the ECM does not use information models described as maximum definitions. On the contrary, exchanging clinical documentation recorded in the ECM to the new EPR will hamper the flexibility and possibility of contextualization inherent in archetypes as maximum definitions. Accordingly, the tension between local customized use and the need for standards and continuity (global) to support the same clinical process by two different systems in the same clinical context is not solved [12].

Fourth, successful integration of health ISs, in terms of a transparent II that supports clinicians with contextual clinical information necessary for instance in coordinating surgery planning processes, requires access to all relevant patient information regardless of where the information was created (the EPR or the ECM). However, comparing the new archetype-based EPR system with the new ECM (and the majority of today's health ISs), the latter was developed in such a way that the clinical information models are hard-coded directly into its software and database models. This situation challenges the transparency of the evolving II, and it was exactly the challenge that separating the clinical information models from the systems internal data models was trying to overcome. A platform of standardized vendor-independent clinical information models was meant to enable sharing and processing of clinical information, despite the situation of heterogeneous health ISs [15]. However, this brings to the surface that archetypes do not solve the goal of semantic interoperability by themselves. Even if there exists a repository of agreed-upon archetypes, the regional or national health authorities need to decide which clinical information models can act as interoperability standards and serve as a platform between heterogeneous health ISs [14, 15, 21–23].

6 Concluding Remarks

The overall goal of integrating health information systems is not a simple question of technical or semantic interoperability, or harmonizing the health ISs to the healthcare processes. The key challenges in integrating heterogeneous health ISs to enable semantic interoperability encompass a diversity of socio-technical issues and in particular political and policy barriers that need to be addressed.

To summarize the four explicit points discussed in the previous section, it is obvious that an archetype approach does not solve the holy grail of interoperability by itself. In light of the increased interest from national and regional governments to enable a smart, sustainable and consistent healthcare service, the potential within use of vendor-independent standardized clinical information models seems to be promising – but not solved. Vendor-independent standardized clinical information models, for example archetypes, are promising as an architecture to reach 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. Moreover, this potential for deploying vendor-independent standardized clinical information models prepares the ground for further research.

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