

Socio-technical Challenges of Large-Scale EPR Standardisation in Healthcare

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Abstract

This thesis presents a qualitative interpretive study addressing the development of an open electronic health record (openEHR)-based electronic patient record (EPR) system in the North Norwegian Health Authority. The motivation for this study is the promising ambitions of standardisation efforts at different healthcare levels in Norway to establish a more structured EPR system, supporting interoperability and improved communication across healthcare organisations in line with Whitepaper 9, ‘One Citizen, One Journal’. The openEHR-based DIPS Arena conforms to a two-level modelling approach, separating the design of technical and clinical requirements and enabling users to be the lead developers of the clinical archetype standards. The main objective of the thesis is to provide empirical insight into the socio-technical challenges of large-scale standardisation within healthcare related to developing an openEHR-based EPR system. Understanding such processes requires including all involved actors; focusing on collaboration across professional and institutional boundaries; and balancing the requirements between technological, organisational, and user-related requirements in large-scale information infrastructures (IIs). In addition, it is important to stress the power balance between the actors and the need for extensive user involvement and high-quality governance for such standardisation efforts to succeed.

With this research spanning four years, the focus stretched longitudinally across different settings and scales, providing an extensive overview of the ongoing processes. I used an action researcher approach including interviews, participatory observations, and document studies to gain a broad understanding of the research field. The hermeneutic circle was used to analyse the empirical data in relation to the theoretical framework and the research questions. The thesis is a contribution to the information systems (IS) field, and II was the overall theoretical framework, emphasising infrastructuring processes of establishing national archetypes, DIPS Arena, and the standardised regional EPR system. Moreover, I included the socio-technical computer-supported cooperative work (CSCW) as a supplement to II to zoom in on the details of the interrelation between technology and practice. Standardisation theory was also important since standards constitute the ‘backbones’ for interoperability in large-scale IIs, and openEHR represents a standardisation effort per se.

One of the most important overall findings in the thesis is the need for close interrelation between the information and communication technology (ICT) system, local practice, and the users in the infrastructuring process of developing and approving national archetypes, which contradicts a fundamental belief in the openEHR architecture – namely, separating technical and clinical work. I found that it is not possible to fulfil the potential of the openEHR-based EPR system without archetypes, and it is nearly impossible to design archetypes without being able to try them out for clinical practice.

Other implications from the study relate to the formalisation of the archetype work, user-involvement power relations, and governance structure. My study indicates the importance of formalising the

governance organisation, the steps of the consensus process, and the modelling patterns. However it is crucial that the actual consensus work be informal and flexible both for enabling clinicians to attend when they have the time and to allow for discussions and negotiations alongside the standardisation process. The clinical knowledge manager (CKM) is useful for online asynchronous collaboration and communication in such large-scale standardisation work, enabling numerous users to contribute. I have however stressed the need to formalise and anchor the recruitment of archetype reviewers since the users are the ones that know the clinical practice and the requirements for a new system; hence, they need to have an extensive role in the archetype work. It was unreasonable to expect clinicians to attend the national standardisation of the archetypes for free since this was an important effort to enable interoperability and collaboration within Norwegian healthcare. Yet including so many system users in large-scale healthcare standardisation generates complex time-consuming consensus processes, hence introducing reference users was a means to limit the number of participants in the archetype standardisation and speed up the production of national archetypes in Norway. Still, it is important to have enough representatives from each medical field to reduce the clinician's workload and prevent the consensus work from stopping. It is also necessary to define expert user roles and to educate those filling them to work as intermediary translators since archetypes includes both technical and clinical requirements as well as different healthcare levels. The close interrelation between the EPR system, the archetype standardisation, and users generates a complex relationship of positions, interests, and power plays. The larger the II gets, the more important the role of power plays becomes in the standardisation processes, generating a need for constant negotiations amongst the actors involved. The most important tensions detected in this study were amongst the different actors in the archetype consensus, between regional and local requirements in the regional standardisation, and between the installed base and the new EPR as well as between different healthcare levels in the archetype work. It is important to have a well-functioning governance organisation both regionally and nationally to handle the tensions in the archetype standardisation. Establishing a fragmented governance model where different organisations at several healthcare levels govern parts of the same EPR generates complex processes and the risk of losing total oversight of the processes and the EPR system.

The main contribution of this thesis is in addressing the need for closer interrelation between the archetype standards and the EPR system than the two-level model presents. It is also important to find a balance between user involvement and the efficiency of the development process; in addition it is crucial to decide on how to including enough end-users for such standardisation processes to be successful and to consider the power relations between the actors in the standardisation process and how this influences the outcome of the work.

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Abbreviations

CEN	Comité European de Normalization
CIM	Clinical information model
CKM	Clinical knowledge manager
CSCW	Computer-supported cooperative work
EPR	Electronic patient record
FIKS	Standardisation of the Regional ICT Portfolio Project
FRESK	The Future Systems of the Clinic
FSE	Regional clinical EPR governance organisation
HICSS	Hawaii International Conference on System Sciences
HIS	Health information system
HL7	Health Level 7
HOD	Ministry of Health and Care Services
HOS	Standardisation of practice project
IARIA	International Academy, Research, and Industry Association
ICT	Information and communication technology
II	Information infrastructure
IJSODIT	International Journal of Social and Organisational Dynamics in IT
IS	Information system
KITH	Norwegian Centre for Informatics in Health and Social Care (part of NDE now)
LOINC	Logical Observation Identifiers Names and Codes
MIE	Medical Informatics Europe
NDE	Norwegian Directorate of eHealth
NICT	National ICT
NRUA	National Editorial Group for Archetype Development in Norway
NSD	Norwegian Centre for Research Data
NSE	Norwegian centre for e-health research
NST	National centre for integrated care and telemedicine
openEHR	open integrated care electronic health record
PAR	Participatory action researcher
SNOMED CT	Systematized Nomenclature Of Medicine – Clinical Terms
UNN	University Hospital of North Norway
World CIST	World Conference on Information Systems and Technologies

Papers

- Ulriksen, G-H., R. Pedersen, and G. Ellingsen. 2017a. “The Politics of Establishing ICT Governance for Large-Scale Healthcare Information Infrastructures.” *International Journal of Social and Organizational Dynamics in IT (IJSODIT)* 6 (1): 48–61. (A former version of the paper is published in the proceedings of the 49th Hawaii International Conference on System Sciences [HICSS], 2016.)
- Ulriksen, G-H., and R. Pedersen. 2016. “Structuring the EPRs: The National Development of Archetypes for Core Functionality.” *International Journal on Advances in Life Sciences* 8 (3–4): 243–256. (A former version of the paper is published in the proceedings of the Eighth International Conference on eHealth, Telemedicine, and Social Medicine [eTelemed], Venice, 2016.)
- Ulriksen, G-H., R. Pedersen, and G. Ellingsen. 2017b. “Infrastructuring in Healthcare through the openEHR Architecture.” *Computer Supported Cooperative Work (CSCW)*, 26 (1–2): 33–69.
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- Ulriksen G-H., and G. Ellingsen. 2018. “Balancing Local-Global Tension in Large-Scale Healthcare Standardization – the OpenEHR Case.” Submitted to the journal *New Technology Work and Employment (NTWE)*. (Submitted in august 2018).

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1 Introduction

1.1 Motivation

1.1.1 My overall motivations

My interest in ICT systems at hospitals, and the extensive need for interaction between systems and users, started when I worked as a bioengineer in the blood bank at the University Hospital of North Norway (UNN), and we implemented a new laboratory system. I noticed how this new system influenced the work practice at the blood bank and how long it took the system users to trust and be satisfied with this new system. Another important issue was the relation between the new system and the other parts of the ICT portfolio at the hospital and how cumbersome the information flow was between the different systems. It took a great deal of time and effort to make the system a part of the infrastructure at the blood bank, partially due to the lack of system flexibility and partially due to the limited role the users had in the development and implementation process. From 2012 to 2014 I worked in the ‘Standardisation of Practice Project’ (HOS) and in the ‘Standardisation of the Regional ICT Portfolio Project’ (FIKS), which focused on standardising the use and setup of the existing electronic patient record (EPR) system. All 11 hospitals in the health region used the same EPR system from DIPS AS; however, they all had different setups and versions of the system adjusted to local conditions, making it impossible to exchange and compare data between them. One of the most important goals of standardising how to set up and use the EPR system at a regional level was to establish interoperability and integrations between the hospitals according to a ‘best practice’ approach. A regional EPR solution enabled easier information exchange across the 11 hospitals of the health region, and it also improved the workday of the healthcare personnel and the quality of patient treatment through enhanced communication and collaboration between the actors involved. It was very interesting to observe the changes in the complex relations between the different stakeholders as well as the socio-technical relations in this standardisation process.

1.1.2 Improving the role of the EPR system and healthcare services

Focusing on standardising the setup and use of the EPR systems was a result of the health authorities’ increased focus on the role of the EPR systems in improving healthcare practice over the last 25 years. However, the goals have shifted along the way. Around the turn of the millennium, efficiency and cost savings were the focus areas. Today the main focus areas are the individual patient needs and how to improve patient treatment and clinical practice through interoperability and quality improvement (HOD

2012). Hence, there is a need for systems designed to communicate across healthcare services and organisational levels to enable information to follow the patient through the patient trajectory as well as to provide advanced process- and decision support as the basis for the comprehensive, evidence-based performance of healthcare practice. To reach such goals there is a demand for more structured information and standardised workflows in clinical practice and, hence, EPR systems. To reach such goals, technological improvements are not sufficient; it is also important to include the organisational factors surrounding the technologies. Hence, my focus has been on how the socio-technical interrelation between technology and organisations influences the outcomes of large-scale standardisations and development processes in healthcare.

The relationship between ICT and organisations has been described as complex and demanding (Greenhalgh et al. 2017; Hanseth and Lyytinen 2010), and it is important to understand their interdependency to design EPR systems that fit healthcare practice. For instance, Klein and Myers (1999) described the need for including the context in which ICT systems will be embedded in order to understand what is actually taking place in such complicated processes. It is also important to remember that socio-technical healthcare infrastructures include stakeholders with different interests, competing agendas, and related technologies (Ham 2008). Hence power relations will influence the outcome of development and implementation processes, and there is a need for extensive negotiations among the stakeholders (Orlikowski and Iacono 2001; Grisot and Vassilakopoulou 2013). ICT systems are flexible, too, and dependent on the context in which they are used, and they may be used in different ways to fit diverging interests (Orlikowski and Iacono 2001). Standardisation is therefore important to decide how to use an EPR system and how to communicate between different parts of an infrastructure. An ICT portfolio, including work practice and existing procedures, both shapes and is shaped by the infrastructuring process of establishing or expanding information infrastructures (IIs). Developing software for today's healthcare organisations is highly challenging due to the complexity of the ICT portfolio, as described above, the numerous stakeholders and practices involved, and the ever-changing user requirements of heterogeneous healthcare workers (Christensen and Ellingsen 2016). The literature in the information systems (IS) field indicates that many large-scale ICT projects in healthcare fail to meet their expectations and end up as unsuccessful investments (Timmermans and Berg 1997; Berg 1999). Infrastructural arrangements, such as EPRs, are crucial to the cooperation and coordination of work processes in hospitals. Hence, considerable resources, both from the government and healthcare providers, are directed towards establishing fully integrated healthcare infrastructures (Aanestad and Jensen 2011). In Norwegian healthcare, the emphasis on interoperability and integration has resulted in several whitepapers and governmental documents, especially Whitepaper 9: 'One Citizen, One Journal', (HOD 2012), focused on establishing one unified solution for storing and sharing healthcare data for Norwegian citizens.

1.2 Research Theme

The present PhD thesis includes three different case studies related to the development of an openEHR-based EPR system in the North Norwegian Health Authority. The first study includes the regional standardisation of the existing EPR system (the installed base) to prepare for the new EPR system, and the second focuses on the development of DIPS Arena, an openEHR-based EPR system including structuring clinical information for the reuse of data and decision and process support. The third study was on the national infrastructuring process of developing archetypes, which are the standards used in the new EPR system to structure clinical data. The main objective was determining how to balance the requirements between technological-, organisational-, and user-related requirements in large-scale IIs as well as addressing the power balance between the actors and the need for extensive user involvement in such standardisation. These focus areas influenced the choice of theoretical framework for the study. I started out with a medical informatics approach in the information system (IS) field, focusing on the ways organisations need to change when introducing new technology to large-scale information infrastructures. However to address the interrelations of the numerous actors in these standardisation processes, the socio-technical approach emphasising the interrelation between technology, organisation and uses was more suitable to use.

Since this study includes both regional and national standardisation, such a large-scale scope requires an overall theoretical framework. Information infrastructure is a useful framework to conceptualise the empirical findings since the II represents a socio-technical system, where the technical issues are always related to practice (Star and Ruhleder 1996). A key characteristic of infrastructures is that the different elements are integrated through various standards (Hanseth and Lundberg, 2001). The ambitions of standardisation – to reach interoperability, improve communication across healthcare organisations, and place standards at the core of large-scale IIs – have resulted in numerous standardisation efforts at different levels of Norwegian healthcare. Standardising clinical information and clinical processes to enable more structured EPR systems with easily accessible and reusable information is a goal in line with Whitepaper 9, ‘One Citizen, One Journal’. Large-scale standardisation at regional or national healthcare levels can be defined as infrastructuring processes actively distributed in both time and space, involving numerous actors. However, an infrastructure always relates to the existing system and practices, hence the installed base will always influence the outcome of such processes (Hanseth and Lyytinen 2010).

The II is a suitable framework to analyse overall relations between actors; however, I chose to include the computer-supported cooperative work (CSCW) framework to gain an extensive understanding of how ISs can support collaboration between different actors in complex healthcare settings (Bossen and Markussen 2010). This is important for understanding the communication and power relations that

influences the dynamics of an II. The main objective of the thesis and the research questions are included in Table 1.

Table 1. Main objective and research questions

Main objective	To provide empirical insight into the socio-technical challenges of the large-scale standardisation of an openEHR-based EPR system, focusing particularly on collaboration across professional and institutional boundaries.
Research question 1	What are the challenges of balancing formal and informal standardisation processes: the case of Norwegian archetype standardisation?
Research question 2	What are the roles of the users in the emergence of Norwegian archetype standards?
Research question 3	How do power relations influence the development of openEHR and archetype standards: the case of DIPS Arena?
Research question 4	Why choose a fragmented governance structure for a regional EPR system in Norway, and what are the challenges associated with such solution?

The findings are addressed in five papers published in peer-reviewed journals and conferences. All papers contribute with empirical insight into the standardisation processes, and all except one contribute to the theoretical notions of IIs and standardisation. Table 2 provides an overview of all the papers and their relation to the research questions. The dark grey cells illustrate a full match between papers and associated research question, light grey means a partial match, and white indicates no match at all between paper and research question.

Table 2. The relation between the papers and the research questions

Papers	RQ1	RQ2	RQ3	RQ 4
Ulriksen, G-H., R. Pedersen, and G. Ellingsen. 2017. "The Politics of Establishing ICT Governance for Large-Scale Healthcare Information Infrastructures." <i>International Journal of Social and Organizational Dynamics in IT (IJSODIT)</i> 6 (1): 48–61.				
Ulriksen, G-H., and R. Pedersen. 2016. "Structuring the EPRs: The National Development of Archetypes for Core Functionality." <i>International Journal on Advances in Life Sciences</i> 8 (3–4): 243–256.				
Ulriksen, G-H., R. Pedersen, and G. Ellingsen. 2017a. "Infrastructuring in Healthcare through the openEHR Architecture." <i>Computer Supported Cooperative Work (CSCW)</i> , 26 (1–2): 33–69.				

Ulriksen, G-H. 2017, April. “How to Involve the Users in the Large-Scale Work with OpenEHR Archetypes in Norway?” In World Conference on Information Systems and Technologies WorldCIST’17, Porto Santo, Portugal: 757–767. Cham, Switzerland: Springer International.				
Ulriksen G-H., and G. Ellingsen. Forthcoming. Balancing Local-Global Tension in Large-Scale Healthcare Standardisation – the OpenEHR Case. Submitted to the journal New Technology Work and Employment (NTWE) in July 2018.				

1.3 Further Organisation of the Thesis

The rest of the thesis is organised as follows: Chapter 2 addresses ICT and EPR development in Norwegian healthcare, focusing on how demands for interoperability and integration have made it increasingly more important to improve the role of healthcare ICT and EPR systems. Chapter 3 addresses my theoretical approach, starting with elaborating on standardisation theory, including different types of standards and standardisation perspectives as well as the process and challenges of standardisation within healthcare. Then, the next section addresses information infrastructures, emphasising the installed base and infrastructuring. This section also includes power relations and organisational politics as well as governance related to the new EPR system. Chapter 4 presents the three different research settings, including an introduction to openEHR and archetypes. Chapter 5 describes the method, including data collection and analysis as well as reflections on the method. Chapter 6 summarises the findings of the five papers in the thesis and includes a summary of the papers in relation to the research questions, theory, and implications. Chapter 7 addresses the practical and theoretical implications of the study in relation to large-scale standardisation processes. This chapter also includes a section in which I reflect on the theoretical perspective chosen and outlines the limitations in these theoretical frameworks in relation to the empirical findings. Chapter 8 concludes the thesis.

2 ICT and EPR Development in Norwegian Healthcare

At the national level, the Ministry of Health and Care Services is the governmental organisation in charge of providing quality and comparable healthcare services for the population of Norway (Regjeringen 2017). The Norwegian Directorate of Health is the authority below the Ministry of Health and Care Services and is responsible for improving the health of Norwegian citizens and the community as a whole through targeted activities across services, sectors, and administrative levels in areas of health policy (Helsedirektoratet 2017). In January 2016, the Norwegian Directorate of eHealth (NDE) was established as another subordinate institution of the Ministry of Health and Care Services. The goal of

the NDE is to be the organisation governing and coordinating eHealth at the national level through close collaboration with local and regional health authorities, technical organisations, and other interested parties. This includes implementing national eHealth policy, establishing the requisite standards, and administrating the use of eHealth methodology (NDE 2017). In addition, National ICT (NICT) is a national organisation managing ICT relations within the specialised healthcare sector, including the regional health authorities, hospitals, and other healthcare actors, such as primary healthcare, the ministry of health and care services, and the Norwegian healthcare network.

2.1.1 Background on ICT for Norwegian healthcare

According to national healthcare plans and strategies, the right use of ICT, combined with organisational development focusing on interoperability and integration, is important for achieving healthcare's political goals (Riksrevisjonen 2008). There has been an increased focus on this matter in Norway, and the first national strategy concerning ICT and healthcare, called 'More Healthcare for Each BIT' (HOD 1996), was released in 1996 with the overall goal of identifying how to use ICT for healthcare services to improve quality and information for users (HOD 1996). Initiatives such as 'Say@' of 2001 (HOD 2001), 'Te@mwork' of 2007 (HOD 2007), and 'Interaction 2.0' of 2008 (HOD 2008) focused on shared and unified infrastructure, information, and data foundation. Say@ was the first ICT plan to emphasise strengthening the interconnection between healthcare, social services, and social security by establishing a secured platform for electronic interaction and messaging (HOD 2001). Te@mwork 2007 stressed establishing efficient teamwork and communication between all the actors in the healthcare sector to provide healthcare services based on the needs of the individual patients in the whole patient trajectory (HOD 2007). The Interaction 2.0 initiative (HOD 2008) presented a national strategy for electronic interaction in healthcare between hospitals and primary care to handle the increased life expectancy of citizens. In 2008, the Coordination reform identified a lack of communication and collaboration between specialist and primary healthcare (HOD 2009). Hence, the government focused on establishing a more proactive role in developing national eHealth solutions. This resulted in publishing Whitepaper 9 in 2012 (HOD 2012), underscoring the overall goal of one integrated EPR system and the improved exchange of healthcare data within and across healthcare levels.

Whitepaper 9, 'One Citizen, One Journal' (HOD 2012), is the foundation for this research project and includes recommendations for how to improve the EPR systems and the exchange of healthcare information. The main goals of the whitepaper are (1) the need for healthcare personnel to have simple and secure access to patient and user information; (2) the need for citizens to have access to simple and secured digital services; and (3) the need for healthcare data to be available for quality improvement and healthcare surveillance, control, and research (HOD 2012). Healthcare personnel need fast, easy, and safe access to healthcare information, and the information needs to follow patients through their entire trajectory of treatment, independent of where they are treated (HOD 2012). Improving the EPR

and modernising the ICT platform is crucial to achieving these goals (HOD 2012). The realisation of Whitepaper 9 is complex, and NDE has an outlook towards 2040 for fulfilling the goals of the whitepaper, including one shared ICT solution integrating all necessary systems and providing semantic interoperability across healthcare services.

Other overall documents important for the project include the National Action Plan for eHealth 2017–2022, underlining the challenges of today’s fragmented organisation of healthcare services in Norway (NDE-1 2017) and emphasising that digital services should be easy for everyone to understand and use. This includes supporting healthcare personnel in providing safe and efficient services (NDE-1 2017). The national eHealth strategy and goal are to provide user-friendly services for citizens to improve their use of healthcare services (NDE-1 2017). Some focus areas of the National Action Plan for eHealth 2017–2022 are digitalising workflow and improving the use of health data, which requires a significant modernisation of the EPR, including structuring patient data as well as process and decision support (NDE-2 2017). This also includes defining and standardising the information models and terminologies used (NDE-2 2017). In addition, NDE published a report in October 2017 addressing how to better connect research and eHealth through the knowledge needs of eHealth in Norway. This thesis answers some of the needs defined in the report, following the modernisation of the EPR system through action research in relation to ‘One Citizen, One Journal’. Developing and implementing a new EPR system and standardising the clinical information comprise an attempt to improve the coherence in patient trajectories across organisational boundaries.

Another important future factor for developing the EPR in Norway is the ongoing work with Helseplattformen in the Central Norway Regional Health Authority. Helseplattformen will have a unified vendor system providing the EPR for hospitals, primary cares, and general practitioners (GPs), allowing them to follow patients’ entire trajectories of care. This project is currently (as of fall 2018) in a bid for tender process and the outcome will be interesting for organising Norwegian healthcare in the future.

2.1.2 The status of today’s EPR systems in Norway

Improving the role of the EPR has been an important part of health policy goals and visions for Norwegian healthcare over the past 25 years (HOD 2012; NICT 2012), and this has made the EPR systems the most important actors in health informatics strategies (Kalra 2006). The hospital-wide EPR systems are complex and have various functionalities, crossing several practices and professionals (Berg 1999). EPRs feed directly into, and shape, work practices within a large, institutional-wide scope. Because they inhabit different roles in different contexts and for various actors, the outcome of the technology is extremely difficult to predict (Ellingsen and Monteiro 2006). The primary purpose of such systems is the support of continuing, efficient, and quality integrated healthcare (Aanestad et al. 2017).

An EPR is a repository of information regarding the health of a subject of care in computer-processable form. Information is stored and transmitted securely and is accessible by multiple authorised users, building on system-independent, commonly agreed logical information models. Even though there is a high degree of digitalisation within Norwegian healthcare service today, and EPR systems are implemented in all hospitals, there is a lack of integration and interoperability between the systems. Specialist systems appear mainly as isolated silos that, at best, can copy selected data between them and exchange information through messages (Aanestad et al. 2017).

Today's hospital EPRs are systems where healthcare providers successively document free text information about patients but with limited possibilities for structuring the information; hence, communication between and within the systems is challenging. The information stored in clinicians' heads is still important for the treatment process since healthcare personnel mainly use experience-based and implicit knowledge. The information within an EPR system is generated during patient encounters (diagnoses, lab results, etc.) and includes information coming directly from the patients (off-the-shelf medicine, home measurements, etc.). The EPR only supports single work tasks, not entire clinical processes or trajectories (NICT 2007). When it comes to easy access and the reuse of relevant clinical information, the standardisation of clinical information in one form or another is considered necessary (Bowker and Star 2000). ICT development in healthcare progresses slowly due to overall challenges, such as the non-exploitation of technological contingencies, the existence of many independent actors and systems, and a lack of integration and semantic interoperability between them (HOD 2012).

In Norway, the augmented focus on sharing and integrating healthcare, as well as organising information in a more structured manner (Meum et al. 2013), has raised the emphasis on standardisation and seamless communication, both within and across professional, departmental, and institutional borders (Fitzpatrick and Ellingsen 2013). Today the information about a patient is scattered not only between different healthcare providers but also in a mix of narrative, structured, coded, and multimedia entities (Kalra 2006). This makes it challenging for healthcare personnel to gather the information needed to get a total overview; especially when patient pathways cross organisational borders and healthcare levels, and constitutes a risk for compromising the quality of treatment and care.

2.1.3 Towards process-oriented EPR systems

Improving the EPR system is most likely the ICT initiative with the largest profit potential in healthcare (Riksrevisjonen 2008). Hence, the goal is to move from today's EPR, which is described as more or less a paper-based system for information storage implemented to a computer (NICT 2007), to an interactive work tool for users. The goal for the next generation of EPR systems is to build on structured, reusable information, where the work processes and patient trajectories are aided by process and decision support, following patient pathways from primary care to hospitals and back.

One alternative to fulfil these requirements is the process-oriented construction of EPR systems set to supports moving from one activity to the next in a process, such as in a trajectory of patient treatment. This contributes to achieving more continuous and comprehensive patient pathways, distributes work tasks, and coordinates healthcare personnel. The focus on integrated care where the care processes are designed around the patients' needs and are founded on emerging, evidence-based medicine as well as the development of guidelines and care paths that incorporate efficiency considerations and quality assurance, have led to an increased interest in process orientation in recent years (Berg and Toussaint 2003). Process-supportive EPRs balance standardised information exchange and good system governance to fulfil their potential (NICT 2007). Such EPR systems engage in the clinical work processes to improve the coordination between healthcare personnel and interdependent activities (NICT 2007). Recent examples of process-oriented EPR systems conform to the openEHR architecture.

NICT has produced a line of initiatives in relation to the need for improving the interactions between ICT and healthcare, implementing process-oriented EPR systems, and choosing standards for communication between healthcare systems. Action 10.1 addresses requirements for healthcare services to be evidence-based, continuous, comprehensive, and well-coordinated (NICT 2007). This brings forward the notion of process-supportive EPR systems to balance standardised information exchange and good system governance. Process-supportive EPR systems engage in clinical work processes to improve the coordination among healthcare personnel and enable interdependent activities and trajectories between the different levels of healthcare services (NICT 2007). Action 27 is a feasibility study conducted to map the need for clinical variables and integrated terminologies in the EPRs and the connected clinical systems (NICT 2009). The pilot project recommended further initiatives to pursue, translate, and use the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) in future electronic clinical chart systems to secure the use of standards to support information sharing. Action 41 suggests the use of process-oriented EPR, following the openEHR architecture using archetypes to standardise clinical information and achieve semantic interoperability (NICT 2012). NICT Action 41 further underscores the need for defining which information model to use in Norwegian healthcare, as well as the need for establishing archetype standards for the clinical EPR content if archetypes are chosen as the information models to use. Coordinating the needs for designing and governing archetypes is also addressed (NICT 2012). Action 48 addresses the further work of structuring the EPR systems in Norway. The purpose is to use archetypes and templates to acquire structured data output, enabling the use of the data elements for process and decision support within the EPR (NICT 2014a). Action 50 includes structured documentation, like description of knowledge-based healthcare, EPR systems and health registries as destinations for such information (NICT 2014b). Today, an openEHR-based, process-oriented EPR system is under development and implementation in three of the four health regions in Norway. The process of developing such a large-scale EPR system and the need for

standardising the clinical information and processes as well as the collaboration between different stakeholders are important for process-oriented systems to become successful. Analysing these processes and identifying the challenges to be overcome, requires a theoretical backdrop explaining the complexity of regional and national processes.

3 Theory

This chapter addresses the theoretical framework of the thesis. First, I present standardisation theory, defining standards and standardisation and presenting different types of standards and standardisation approaches, including the socio-technical CSCW framework. In addition, the process of standardisation and its associated challenges within healthcare are included. Second, I present the main theoretical framework of the thesis – namely, information infrastructure – focusing on the installed base and infrastructuring. This section also includes power relations and governance issues.

3.1 Healthcare Standardisation

In general, a standard refers to a point of reference (Timmermans and Berg 2003) covering several different entities (Brunsson, Rasch, and Seidl 2012). Standardisation is defined by Timmermans and Berg (2003, 24) as ‘the process of rendering things uniform’, and they define standards as ‘the means and outcomes of standardisation’. Standards have been defined based on several distinctions and categorised into technical and non-technical standards, process and outcome standards, and de jure (law) and de facto (market mechanisms) standards (Brunsson, Rasch, and Seidl 2012). Standards are constructed to make things work together over distance and heterogeneous metrics (Bowker and Star 2000), and they hold socio-technical societies together by specifying work practice and how technologies interact. Standards within ICT are designed to ensure interoperability across different technical platforms, components, and institutions (Atalag et al. 2009). It is well documented that standards constitute an important factor for macro-economic growth in advanced economies, and they play an important role in the innovation of services in digital sectors such as engineering, telecom, and ICT (Blind 2002).

Similarly, there has been an increased focus on standardisation in healthcare as a means to enhance quality and effectiveness. In addition, this is a way to achieve the desired goals of sharing and comparing health data within institutions and across institutional borders (Rolland and Monteiro 2002; Timmermans and Berg 2003; Winthereik and Vikkelsø 2005; Hanseth and Bygstad 2015; Aanestad et al. 2017). It is also a means to enable all levels of healthcare, such as hospitals, GPs, laboratories, and pharmacies, to share patient data as their IT systems must relate to defined standards (Hanseth and Bygstad 2015). Hence, there has been an increased focus on standardising EPR systems to achieve overall goals, such as establishing one common EPR for each patient, for instance, as described in the

governmental initiative in Norway's Whitepaper 9, 'one patient one journal' (HOD 2012). Standardising clinical data makes it easier to reuse and transfer necessary information within and between different healthcare levels and the numerous systems involved in patient trajectories. Hence, a best practice principle for standardisation is considered necessary to define work processes and system setups within healthcare (Timmermans and Berg 2003; Meum et al. 2013). The increased focus on process-oriented EPR systems also indicates a need for the standardisation of clinical data in EPR systems since their functionalities are based on structured data, standardised by using clinical information models (CIMs). This is a means to offer persistent services across different healthcare levels (Singh 2008) and possibilities for patient information to be easily compared and analysed across these levels (Christensen and Ellingsen 2014).

3.1.1 Different types of standards in healthcare

However, when looking at standards in more detail, the notion becomes blurry as a standard may have different meanings in different contexts and for different stakeholders. For instance, it may refer to one common way to use technology, a way of organising healthcare practices, terminologies, or clinical standards to structure data in EPR systems for reusability and interoperability purposes. A consequence of the omnipresence of standards in different forms and structures is that there may be several ways of approaching and classifying them. One way of classifying standards is to sort them at an overall level, related to organisations, as described by Brunsson, Rasch, and Seidl (2012). They present three dynamic aspects of how standards and organisations interact. First, the standardisation *of* organisations relates to how standards affect an organisation, and the way they are adopted, diffused, implemented, and altered, in the course of implementation. These are often defined as rules the organisation is expected to embrace for economic reasons or as means to improve efficiency. However, organisations are often not legally bound to adopt a set of standards, yet different types of pressures may influence the adoption of standards. Second, standardisation *by* organisations addresses the fact that most standards are products of work done in formal organisations, where the members have ideological or economic interests in the respective standards, or they represent a field of expertise associated with the standards' requirements. For instance, the standards of the International Organization for Standardization (ISO), SNOMED CT, and Health Level 7 (HL7) are developed and revised by organisations consisting of different expert groups, and the members typically have equal rights to influence the development of the standards. Third is standardisation *as* organisations; here standardisation can be defined as a way of organising society nationally and globally since there is a need for common rules within and among organisations; hence standards are included as important governance mechanisms. Standards therefore contribute to the organisation of markets by promoting compatibility and harmonisation among otherwise diverging components of a system or a society and are well suited to support institutional changes. Standards are also very important in the context of international regulation; since most state legislation remains bound

to a nation, standards are often the only type of rules possible to apply internationally. The standardisation approach presented by Brunsson, Rasch, and Seidl (2012) addresses the way standards relate to the organisation in which they are implemented without consideration of how the standards influence other factors, such as technologies. Nonetheless, Brunsson, Rasch, and Seidl (2012) address certain other issues related to standardisation that are important for this study, such as how the users are involved in the work of standardisation, the degree to which standards may be forced on an organisation, and what the challenges are for standardising an organisation.

Another way of classifying standards from a socio-technical perspective is presented by Timmermans and Berg (2003). They define four ways of standardising healthcare and EPR systems. The first type of standards are design standards, set to define detailed and structural specifications of social and technical systems to ensure compatibility, logistics, and integrations. Such standards are explicit, detailed specifications of individual components, ensuring uniformity and mutual compatibility. In hospitals, design standards include specifications such as features of X-ray devices, the size of hospital beds, and the jurisdiction of care professionals. For the EPR system, this mainly includes technical standards, such as databases, networks, and reference standards (Timmermans and Berg 2003). To illustrate, between 1998 and 2000 the standardisation department in the Norwegian Directorate of Health (formerly KITH¹) developed a fundamental EPR standard covering the basic requirements of an EPR system (NICT 2012). This was the starting point for defining several standards to cover the informational content of the EPRs and outlining the functional demands for such systems (NICT 2012). At the same time as the EPR standard was defined, an international standard for communicating the EPR content EHRCOM was completed. This EHRCOM reference model was the starting point for transforming the EPR content standard to the archetypes and templates used through openEHR architecture (NICT 2012). Numerous standards exist for establishing interoperability across various systems (Atalag et al. 2009). For instance, Hanseth et al. (2006) state that ‘An EPR can be conceptualized as a package of standards’.

The second category of standards, terminology standards, are promising in relation to reducing medical errors and increasing the quality of care as well as efficiency (Berg 2003). Some examples of such standards are the World Health Organisation (WHO)-based International Classification of Diseases (ICD) and the SNOMED (Timmermans and Berg 2003; Timmermanns and Epstein 2010) as well as HL7. The terminology standards defined by Timmermanns and Berg (2003) did not receive much attention in the IS field until recent years (Timmermanns and Berg 1997; Bowker and Star 2000). Terminology standards are designed to ensure the safe and secure exchange of information across organisational and professional borders. They are important means for enabling comparability across healthcare domains and different information systems (Garde et al. 2007), and their usefulness ranges

¹ KITH was the competence centre for IT in the Norwegian health and social sector. It established standards and was responsible for governing encodings used for Norwegian healthcare between 1990 and 2012.

from enabling local day-to-day planning to the possibility of aggregating data to provide large-scale statistical information for national health authorities. In addition, the augmented focus on process-oriented systems has made terminology standards increasingly important to address within the IS field since they are tightly embedded in work practice and organisation. Examples of other such standards for healthcare are international nursing-specific diagnoses, such as the North American Nursing Diagnosis Association (NANDA) and Nursing Interventions Classifications (NIC). Other frequently used standards for healthcare are the international coding schemes for procedures in surgery and treatment from ICD -10, codes for pathology from SNOMED RT, NORACO codes for radiology, and ISO 17025 codes for laboratories. Another important example is ISO 13606, a specification for the communication of EPR data designed to achieve semantic interoperability in electronic health record communication (García et al. 2012), and the archetypes, which are CIMs for openEHR-based EPR systems.

The third category of standards are performance standards, which are set to define outcome specifications. They do not prescribe what to do or how to do things; rather they simply outline the result of an action (Timmermans and Berg 2003). Performance standards are important for EPR systems since they are used for representing measurements by, for example, describing a maximum level of complication rate for a specific operation or a minimal score on an examination (Christensen and Ellingsen 2014). The national quality indicators defined for Norwegian healthcare are examples of performance standards set to present an overview of which hospitals provide the best quality of treatment and care as a means to secure accountability for health system performance. To enable this, there is a need for standardising according to 'best practice' and for changing practice and routines if necessary to achieve the goals defined by the standard (Hanseth and Bygstad 2015; Aanestad et al. 2017). This will enable comparing the aligned processes in relation to quality or efficiency (Timmermans and Berg 2003).

The fourth category of standards is procedural standards, including clinical guidelines, standardised procedures, clinical decision support, and care plans, which are frequent conditions for integrating different systems and practices (Hanseth and Monteiro 1997). Such standards are assumed to increase quality, predictability, and equal treatment for patients (Coiera 2003). Procedural standards defines steps to be taken when specified conditions are met, for example, how GPs should proceed when they suspect a new diagnosis, steps for a nurse to follow in preventing ulcers, and checks to perform before declaring an operation theatre ready for use (Timmermans and Berg 2003). Such standards may be written by one person or produced through an extensive process of literature analysis, cost-effectiveness studies, and consensus building. This is the highest level of standardisation and forms the heart of evidence-based medicine (Hanseth and Monteiro 1997; Timmermans and Epstein 2010).

Accordingly, there are numerous definitions and categorisations of standards. However, related to this PhD study, the two standardisation approaches mentioned above are useful for analysing data in relation to the healthcare standardisation of ISs. Brunsson, Rasch, and Seidl (2012) address standardisation from the perspective of organisation studies, and they describe its dynamic aspects and the effect it has on organisations in general. When they address the standardisation done by organisations such as ISO, they focus on how standards arise and operate and how the members influence the process. They also highlight the tension between the need to include users in the standardisation process as well as the risk of a slow process and not reaching consensus when involving too many users in such processes. Timmermanns and Berg (2003) have a goal to locate the political opportunity for social change within standardisation, and they investigate both the form and content of standardisation, including what it is, how to standardised, how things and people are included and excluded, and the degree of uniformity. For this study, terminology standards (second category) and procedure standards (fourth category) are the most important since archetypes have a clear connection to terminology standards and will increasingly reshape healthcare practices.

3.1.2 Four standardisation perspectives

Due to the complexity of standards and varied associated meanings, researchers in diverse fields have approached the phenomenon slightly differently. Four research traditions are addressed here to position the PhD study in relation to the body of standardisation literature. In this regard, I will deal with topics such as work practice, scale, and power, underscoring how the roles of the users, organisations, and technology are similar or different between the four perspectives. The boundaries between the approaches are not always clear-cut. The purpose is rather to illustrate the essence of each perspective related to the topics described above.

The medical informatics perspective

The medical informatics perspective is omnipresent in healthcare (Berg 1999; Coiera 2009; Arts et al. 2007; Leslie et al. 2009; Blobel, Goossen, and Brochhausen 2014; Moreno-Conde et al. 2015). Here, IT (like the EPR) is considered a crucial tool for collecting and integrating medical information to improve clinical decision-making (Hannan 1999), teamwork and patient focus (Nøhr et al. 2001), and meeting new demands from patients (Grimson 2001). Hence, medical informatics is the study and application of a method to improve how to manage patient data, clinical knowledge, and other relevant information in relation to patient care (Wyatt and Liu 2002). Systems developed in this tradition are mostly considered from the information and technology perspective, including bits and bytes and hardware and software (Lopez and Blobel 2009). Hence, this is a technology-positive engineering perspective, focusing on constructing systems and how a given technology constitutes the means to improve healthcare processes. This field deals with the resources, devices, and methods required to optimise the acquisition, storage, retrieval, and use of information in healthcare, and the aim is to study the general principles of

processing data, information, and knowledge, focusing on high-quality, safe services and efficiency (Blobel, Goossen, and Brochhausen 2014). It is an interdisciplinary tradition of the design, development, adoption, and application of ICT-based innovations in healthcare. From this viewpoint, technological change occurs relatively independently of human actions, and organisational change is caused by the introduction of a new technology into an established organisation. Hence, the impact technology has on organisations is preconfigured by those who are involved in the development of the technology (Leonardi 2009). There is a clear separation between the technical domains and the organisation the technology is designed for, and the technical changes are autonomous entities that exist separate from society (Leonardi 2009). Designers define the roles of the users, and how they should behave, instead of taking into consideration how they actually behave (Christensen and Ellingsen 2016); hence, the process of developing EPR systems has not been clinician-focused. The software engineers of later years have approached clinicians, trying to define and document clinical requirements and implementing those to technical specifications (Leslie et al. 2009). In addition, standardisation processes have taken place in standardisation organisations such as HL7, the European Committee for Standardisation (CEN), and the ISO (Leslie et al. 2009). It has been challenging for clinicians to participate in the work of such standardisation organisations. This work often requires a certain expertise across both technical and clinical domains, in addition to significant time and commitment, and includes attending meetings and teleconferences (Leslie et al. 2009). Information and communication technology (ICT) is a key means for achieving organisational goals in clinical practice. These goals are typically associated with improved organisational efficiency (Toussaint and Berry 2013), such as standardised patient pathways, decision support, and governance possibilities as well as better quality in the treatment and care of patients (Christensen and Ellingsen 2013).

An example of a medical informatics view on healthcare ICT developments is the process-oriented openEHR-based EPR system (the empirical focus of this PhD study) set to improve the interoperability and work processes in hospitals. This services-oriented architecture is made to standardise how applications communicate with systems and how systems exchange information with each other (Chen et al. 2009). This architecture is designed to provide system-independent and flexible standards for data content structure and terminology existing outside of technologies and applications through information models in the form of archetype standards (Chen et al. 2009; Beale and Heard 2008; Garde et al. 2007). Conforming to this technology, the EPR system will shift from being a storage of information to an interactive work tool for clinicians, providing them with process and decision support as well as structured clinical data. The idea of this technology-positive approach focusing on the possibilities of the openEHR architecture is that the necessary organisational changes follow the requirements of the technological solution. The goal is to promote and facilitate high-quality EPR systems to support the needs of patients and clinicians everywhere and to ensure interoperability and design flexibility for users

(Garde et al. 2007, Beale and Heard 2008). For example, a study by Garde et al. (2007) concerns the modelling of clinical content of EPR systems and how clinical content is made available using archetypes and templates from OpenEHR and ISO 13606. There has, however, also been an increased focus within the medical informatics field the later years, to include more socio-technical relations and organisational issues the later years and not focus only on the role of the technology.

The organisational perspective

As a reaction to the medical informatics view focusing on the technology, an organisational perspective evolved. Here the objective is to use the organisation, where standards or technologies will be used, as the focus point for the analysis of data. From such perspective the technological requirements and the user involvement follow the needs of the organisation. According to Brunsson, Rasch, and Seidl (2012), standards have three defining characteristics. First, a standard can be defined as a specific type of rule (see e.g. Blind, 2002); for example, the ISO organisation defines standards as consensus-based documents approved for common and repeated use (ISO 2001). Hence, they are important tools for regulating behaviour and social order (Brunsson, Rasch, and Seidl 2012). Second, the adoption of standards is voluntary and cannot be forced upon organisations; however, those that do adopt them can make them part of their binding rules, in this way making it mandatory to adhere to them (Brunsson, Rasch, and Seidl 2012). Third, most standards are meant for common use (Rasche 2010) even if some organisations set standards exclusively for their own activities; in this way standards contribute to regulating general behaviour (Ortmann 2010). Orlikowski and Iacono (2001) outline that the field of information systems (IS) has not deeply engaged its core subject matter – namely, the essence of information technology (IT). IS research has tended to take information technology for granted, positioning the theoretical attention elsewhere, for example, on the context in which the technology is used, without defining the actual technological solution or how this will influence the organisation in which it is implemented and used. Hence, it has become necessary to include the ICT artefacts as well in the studies of technology to advance the theoretical understandings of them (Orlikowski and Iacono 2001). Taking technological artefacts for granted is not restricted to the IS field but has been addressed in numerous studies on technology, sociology, and organisational studies (Bijker and Law 1992).

However, the lack of attention to the technology makes it necessary to engage more seriously and explicitly with the material and cultural presence of the information technology artefacts (Orlikowski and Iacono 2001). ICT artefacts are not neutral, universal, or given; they are dynamic entities, consisting of a number of fragile and fragmentary components interconnected through integrations. Orlikowski and Iacono (2001) also state that ‘Even after a technological artefact appears to be fixed and complete, its stability is conditional because new materials are invented, different features are developed, existing functions fail and are corrected, new standards are set, and users adapt the artefact for new and different uses’.

Environmental factors, such as new technologies, have the power to alter the structure of an organisation, but the relationship does not work in reverse, according to Leonardi (2009). One of the reasons why technology has received less attention may be the organisational challenges of healthcare. According to Jacobsen (2012), the hospital organisational structure is loosely connected, and consequentially what happens in one part of the organisation has little influence on what happens in another part. This makes it difficult to gain an overview and may lead to large problems when it comes to developing systems that require organisational changes. It might be challenging to get all the loosely connected departments to pull in the same direction. Several subcultures and professions exist in hospitals that make it challenging for employees to see the need for changes (Christensen et al. 2010). The organisational structures in hospitals are divided in parallel hierarchies, the medical and the non-medical. The hospital has a decentralised organisational structure, including many autonomous specialties (Vinge 2005). Furthermore, consideration is needed in regard to how to improve cooperation between health and non-health stakeholders (e.g. technology partners) (Broens et al. 2007). Implementing and embedding new technologies of any kind involves complex processes of change at the micro level for professionals and patients and at the meso level for the healthcare organisations themselves (Mair et al. 2012). It has become evident that system development not only involves problems of a technical nature but also social and organisational ones (Bansler 1989), which influence the way healthcare is provided across the boundaries of the institution (Broens et al. 2007).

The management perspective

One of the main reasons for standardising healthcare services and hospitals ICT systems is the increased need to improve the effectiveness and efficiency of healthcare delivery, including improving quality, cost savings, and increased productivity (Greenhalgh et al. 2008). Healthcare managers believe that standardisation limits possibilities for errors to occur, significantly reducing patient risk by creating a workplace that is resilient to inevitable human error with the benefit of reduced expenditure (Clarke 2007). In this regard, large-scale inter-organisational change carries the ‘promise’ of significant design or redesign of the workflow (Ashkenas et al. 2002). The problem here is that the business literature traditionally flags top-down modelling to fulfil these needs; however, the actual user perspective tends to be overlooked (Ellingsen 2004). Most of the management initiatives follow a top-down approach aiming to standardise healthcare practice, professionals, and patients as well as to produce centralised data repositories (Rodon and Silva 2015). This fits well with a management and business perspective since such change is typically initiated from the leaders, often based on pre-defined models of the work in management and business studies (Ashkenas et al. 2002). The top-down approach is a hierarchic design with a centralisation of power at the top and defines a clear path of authority (Stream 2010). This reflects the traditional approach to infrastructure innovation and development, where the innovation process starts with a strong emphasis on stakeholders’ agreement on standards and their specifications. Often, a formal standardisation body organised in committees carries out the specification work. These

committees then agree on the infrastructure's functional requirements, architecture, and overall design; finally, the interfaces between the modules are specified in terms of technical standards. Only at this point do technology providers implement the standards within their products, and the infrastructure is built without repetitions of the defined specifications (Grisot and Vassilakopoulou 2013). In such processes, engineers design the functions and features of new systems based on pre-defined models of a work practice without much user involvement (see e.g. Ashkenas et al. 2002). Instead, they use computer-aided design tools and standardised forms to capture and formalise the results of a design process (Scacchi 2004). ICT designers in collaboration with healthcare managers define who should make the necessary decisions and what they are (Weill and Ross 2004). The goal is to have increased control of the design process, which is not always possible nor effective (Constantinides and Barrett 2014). Such strong controlling ICT governance has been ineffective and even impossible to apply within IT in healthcare (Constantinides and Barrett 2014). There are several actors, both on the clinical and technical side of healthcare, which need to be included in designing standards for healthcare ICT. One risk of using a top-down approach is that decision makers are likely to choose applications that benefit managers. They may have overlooked or underestimated the downsides for users, such as extra work required to maintain the application (Grudin 1989).

In recent years, there has been a shift within healthcare standardisation from a top-down to a more bottom-up socio-technical approach, focusing on the role of the organisation and the users in addition to the technology itself (Berg and Toussaint 2003; Berg 1999). Berg (1999) points out that making technologies work in concrete healthcare practices appears to rely on politically textured processes of organisational change. Aarts et al. (2007) focus on how implementing ICT affects the healthcare workers and the workflow in hospitals. They find that implementing health ICT systems may have serious unintended organisational consequences. A key lesson learned from these studies is the need for understanding clinical practices to recognise why and how health personnel act the way they do when new ICT is implemented (Ash and Berg 2003). It is important to standardise both the work practice as well as the ICT portfolios of healthcare to ensure the best possible interoperability between the different actors since healthcare is a sector with a wide range of different forms of communication between diverse, overlapping areas (Berg 1999).

The socio-technical perspective

There has been a shift towards bottom-up, experimental, and evolutionary socio-technical approaches (Hanseth, Monteiro, and Hatling 1996). Socio-technical studies focus on how technology and humans interact in the workplace (see e.g. Hanseth and Monteiro 1997; Bowker and Star 2000; Aanestad and Olaussen 2010; Meum, Monteiro, and Ellingsen 2011). The socio-technical approach recognises that technology is deeply embedded into organisations, and, vice versa, new technology therefore results in both intended and unintended organisational consequences. The socio-technical approach includes three

important aspects. First, it looks at healthcare practices as an effect of a heterogeneous network, where different actors participate and mutually influence each other. Second, this approach recognises healthcare workers as pragmatic and floating characters, in contrast to approaches that distance themselves from the messy and random nature of healthcare workers, and tries to structure healthcare by formal standardised rational structures in an ICT system. Third, the socio-technical approach makes use of empirical data based on qualitative research methods (Berg 1999).

The socio-technical approach of designing technology for healthcare conforms to user-centred development, where the users have a central role in controlling the process of developing and implementing healthcare standards (Berg 1999). Integrating users into the design process makes it possible to identify and deal with potential conflicts and misalignments between newly designed standards, existing technologies, and the social environment (Pipek and Wulf 2009). The socio-technical approach holds that if user needs are prioritised in system development, users are more likely to be satisfied with the new system; hence, this leads to higher productivity and satisfaction (Bansler 1989). This approach builds on the assumption that the starting point for implementing and designing an IT system for a work practice should be the experience and knowledge of the people working there (Berg 1999). Bowker and Star (2000) emphasise user participation as an important way to keep system development from getting too far from existing practice because the users are the ones that best know the existing work practices and routines. The goal of user-driven development is to ensure clinical reusable data, high-quality standards, and an easier transition from theoretical to practical use. Tamm (2010) has defined three reasons why it is necessary to have broad participation from many parties when establishing standards. First, this makes it easier to define a standard's content in a way that is acceptable to all involved parties, and power struggles may be avoided. Second, participation often involves commitment to adopt the standard, and, third, broad participation strengthens the legitimacy of the standard in the eyes of external parties.

It is crucial that those developing realisable implementation strategies understand the interplay between technology and practice. The socio-technical approach has a strong foothold in several research traditions; however, in this study, the computer-supported cooperative work (CSCW) was considered an important approach to address. Bannon (1989) defined CSCW as follows: 'CSCW should be conceived as an endeavour to understand the nature and characteristics of cooperative work with the objective of designing adequate computer-based technologies'. This definition focuses on understanding the nature of cooperative work as a foundation to designing information systems to support work processes (Schmidt and Bannon 1992). One of the main goals of CSCW research is to understand how the dynamic, contingent, and complex features of healthcare work, as well as the multiplicity of coordinative artefacts and technologies, are collaboratively connected. Combining the technology itself with the users of the technological solutions makes it possible to understand the social interactions and

the users' perspective in relation to the design development and evaluation of technical systems, underscoring how designing, implementing, and using technology involves complex challenges. This is necessary to design systems that can support collaborative practices in healthcare and to understand the dynamic, contingent, and complex features of this field (Hartswood, Procter, and Rouncefield 2003). CSCW focuses on how IT systems and digital artefacts shape cooperation as well as how actors in the process manage to work together (Bossen and Markussen 2010). CSCW studies tend to focus mainly on informal work processes, including how interactions between humans are influenced by new technology and how humans relate to technology in general (Aanestad and Olaussen 2010). CSCW also considers how people work within groups and organisations as well as how technology affects those processes (Hanseth and Lundberg 2001). A distinction between technology and organisation is recognised (Vikkelsø 2005); however, unlike the medical informatics tradition, CSCW research rejects the idea of the organisation as a uniform entity and argues that the ultimate benchmark of success is whether the ICT improves and supports practices at the floor level of the organisation (Vikkelsø 2005). CSCW research sees EPRs as tools for information sharing and collaboration in the organisation but argues that EPRs and the technology must be tailored to fit the needs of the users and the contingencies of medical work in order to have this impact (Vikkelsø 2005). The majority of the contributions have focused on smaller-scale interactions and prototype design (Schmidt and Bannon 1992), and in small-scale projects there are not many users to consider, thus power relations have not been addressed much in CSCW studies thus far.

To present an overview of the four perspectives for standardisation addressed and their relations to issues such as organisation, technology, power, users, scale, and practice, see Table 3.

Table 3. An overview of important issues related to the different standardisation perspectives

	Medical informatics	Organisation	Management	Socio-technical
Organisation/practice	Very little real practice focus	Varies between a broad and narrow organisational view	Organisation less important Practice has to adjust to the changes	Organisation is important in relation to technology
Technology	Engineering focus Technology-positive	Not so important	Technology will provide certain effects	Technology is important in relation to the organisation
Power	Not so important	Not much power focus; the main actor is the organisation	Power is associated with the management	Power relations not much addressed (due to many small-scale studies)
Users	Users typically evaluate small-scale pilot studies	Not much user focus	Management decides; users are not part of the decision-making	Users are important
Scale	Small-scale pilot projects		Large-scale projects	Bottom-up, small-scale projects

3.1.3 The process of standardisation

Generally, one tends to distinguish between formal and informal standardisation processes (Hanseth and Bygstad 2015). Traditionally standardisation in healthcare has been well-defined formal processes realised by formal standard development organisations, often sponsored by governments, and they run legally mandated processes of participatory consensus building, enabling the development and diffusion of compatibility standards that are democratically established and aligned with broader policy objectives (Blind 2002). Such processes, including a series of stages defined as definition, implementation, diffusion, and use, were the standards considered stable entities (Hanseth and Bygstad 2015), led in a top-down manner, defined by organisations, including all relevant stakeholders (Hanseth and Bygstad 2015). Examples of formal standardisation organisations are the European Standards Organisation (ESO), The European Committee for Standardisation, the Electro Technical Commission (IEC), and the ISO (Bild and Gauch 2008). The ISO is the largest formal standardisation organisation developing voluntary international standards. It has a technical committee for health informatics (ISO/TC 215) focusing on developing ICT standards for healthcare to provide interoperability between independent systems to enable the compatibility of health information data. ISO/TC 215 includes, for instance, healthcare delivery, disease prevention, and clinical research related to health services (Brunswicker, Rodriguez, and Warcham 2014). Hanseth and Bygstad (2015) describe how such standardisation organisations have detailed rules, specifying how to organise activities, who is allowed to participate, voting rules' criteria, and the specifications a standard must fulfil to be approved. Some of the major challenges in such standardisation work for healthcare in general, and the EPR system in particular, are to formalise the roles of the different actors and describe coherent and effective care delivery (Munkvold, Ellingsen, and Koksvik 2006). Based on anticipations of the future user needs, designers define formal standards, which hopefully the user requirements, and the standards are implemented within healthcare practice and adopted by users (Hanseth and Bygstad 2015). The standardisation of archetypes for openEHR-based EPR systems is an example of a formal standardisation process, where international and national organisations collaborate on standardising clinical concepts for healthcare practice (Leslie et al. 2009). However, formal standardisation processes may suffer major drawbacks, such as lengthy consensus forming processes and lack of market orientation (Brunswicker, Rodriguez, and Warcham 2014). Therefore, there has also been a need for developing standards through informal standardisation processes

Informal standards may be ad hoc solutions turning into permanent ones, including industry consortia (Blind and Gauch 2008; Simcoe 2012) and loosely coordinated temporary working groups and task forces as well as not-for-profit organisations that organise standardisation processes in more permanent ways (Brunswicker, Rodriguez, and Warcham 2014). In such standardisation there is an informal sharing of responsibility and task hand-overs, including informal dynamic and flexible standards and

the organisation of standardisation processes (Brunswicker, Rodriguez, and Warcham 2014). This relates to the growing number of standards and the need for connections and interdependencies between them (Brunsson, Rasch, and Seidl 2012; Hanseth and Bygstad 2015). Brunsson and Jacobsson (2000) summarise these trends as the beginning of a whole new ‘world of standards’. The dynamics of standards is a model used, for instance, for the development of internet standards (Hanseth, Monteiro, and Hatling 1996). The internet is developed layer by layer from the bottom up at the same time as standards for the internet as a whole are evolving. When the standards at one level stabilise, this layer serves as a platform for the experimental development of services and their standards at the next level. This approach is similar to the two-level modelling of openEHR archetypes, where the reference model has been formally standardised and serves as a stable entity, while the archetypes are flexible standards designed in a more informal way (Garde et al. 2007; Beale and Heard 2008; Chen et al. 2009). The standardisation process has moved from a defined organised standardisation organisation with regular meetings and defined members to an online standardisation process, including numerous users coming and going throughout the consensus process of establishing a national archetype. In addition, HL7 is an informal standardisation organisation developing standards for the exchange, integration, sharing, and retrieval of electronic health information to support clinical practice and health services. HL7 standards are developed by structured working groups (electronic health records, healthcare devices, clinical quality information, etc.), and this is an open organisation in which anyone can participate and become a member, including academics, professionals, governmental organisations, and IT vendors (Brunswicker, Rodriguez, and Warcham 2014). HL7 standards are global and freely available to the public through organisational members, and the standardisation process is consensus-driven. A protocol specification proposed and approved by a team, is ultimately approval by HL7 members (ibid.).

There are numerous ways of approaching standards and standardisation processes. Depending on the focus, there is a high correlation among disciplinary traditions and among themes of analysis, including the following: political science focusing on power and influence, economics focusing on optimal firm decisions (Simcoe 2012), engineering focusing on technological attributes, and sociology and anthropology focusing on institutional fields (Timmermans and Epstein 2010). One important question is whether there is a complementary or a substitutive relationship between formal and informal standardisations.

Challenges of standardisation in healthcare

Despite heavy investments and considerable efforts, standardisation in healthcare has proven to be a cumbersome and demanding process with numerous challenges (Timmermans and Berg 1997; Berg 1999). Unfortunately, many large ICT projects do not live up to the expectations, and some end up as failures (BBC-NEWS 2006; Riksrevisjonen 2008; Black et al. 2011; Lyse 2011). Explanations are typically related to bad design, user resistance, and non-intended use. For example, in the UK, the

National Health Service Commissioning Board (NHS) spent more than £12 billion on a ‘one-size-fits-all’ EPR system, which was eventually scrapped. This system was designed in a top-down management approach, where users were not much involved in the development process (NHS England 2015). Also, Addenbrooke’s Hospital in Cambridge was the first in the UK to use the £200 million Epic system; the system went live on 26 October 2014 and was one year later described as an ‘Epic fail’ (Shah 2015). An example from Norway is similarly illustrative: after major delays, the portal system project at the Oslo University Hospital proved a resounding failure and was terminated in May 2011, having cost approximately €23 million (Lyse 2011). In addition, the ePrescription project was designed as an electronic version of existing paper documentation for medical prescriptions, and most of the electronic messages defined did not satisfy the requirements of the users. Solutions conforming to the strategy were difficult to implement, and ePrescription was still not fully adopted into healthcare practice nine years after its implementation (Hanseth and Bygstad 2015). Meum, Monteiro, and Ellingsen (2011) have described how establishing terminology standards in nursing plans is constantly challenged by workarounds, trade-offs, and negotiations between different perspectives. These standards are designed more from an organisational perspective, where the technology is less important compared to the users and the way the work is organised (Hanseth et al. 2012). Similarly, the standardisation of health-based terminologies such as SNOMED CT, which covers diseases, findings, procedures, and anatomy, consists of more than 400,000 coded elements, making standardisation a complex process (KITH 2009). These are medical informatics processes focusing on how the standardised codes and terminologies affect the healthcare work processes.

3.2 Information Infrastructure and Infrastructuring

As a means to understand large-scale standardisation processes, it is necessary to take into account all involved actors and consider the existing work practices and users as well as the politics and power relations and balancing local and global requirements (Timmermans and Berg 1997; Hanseth, Monteiro, and Hatling 1996). To grasp the complexity of large-scale IS standardisation in healthcare, the information infrastructure theory is used as the main theoretical framework in all my five papers, focusing on the implementation and use of standards in healthcare information systems and the power relations between the actors in these processes.

Since the 1960s, a recurring goal of healthcare systems has been to establish integrated IIs (Bossen and Markussen 2010). In the 1980s, a growing research interest in a combined analysis of the ‘social shaping of technology’ and the ‘technological shaping of society’ resulted in a number of systematic treatments of infrastructures (Pipek and Wulf 2009). Further, in the 1990s, IIs were used in political settings to ensure interoperability for technical specifications and to create a transparent and consistent interconnection for stakeholders in a given market (Bygstad 2008). The notion of information

infrastructure (II), as a perspective on and a new category of IT artefacts, has gained much attention following the work of G.C. Bowker, C. Ciborra, O. Hanseth, E. Monteiro, S.L. Star, and others in the 1990s. II, as a theory, is used to frame a number of extensive case studies (see e.g. Star and Ruhleder 1996; Ciborra 2000). It is also used as a means to understand how artefacts and technologies are linked together (Hanseth and Monteiro 1998; Hanseth and Lundberg 2001; Star and Ruhleder 1996) and as a framework to describe the complexity and heterogeneity characterising large-scale information systems. II theory address the challenges of realising large-scale collaboration between ISs and communication technologies since these are heterogeneous socio-technical networks including technological components, human organisations, institutions, and so on (Hanseth and Lyytinen 2010; Monteiro and Hanseth 1995; Star and Ruhleder 1996; Edwards et al. 2007) in, for instance, an EPR system (Meum et al. 2013). This is relevant since both governments and healthcare providers work towards goals of national health II, where an interoperable EPR is a core actor. However, studies has showed that both implementing large-scale EPR systems and reaching interoperability has been challenging in the US (Ash and Bates 2005) as well as in Europe (Greenhalgh et al. 2008). An II typically forms when various systems merge, such as in a consolidation, and allows dissimilar systems to be linked into networks (Jackson et al. 2007).

An II is a socio-technical entity, and, for instance in healthcare, such structure may include several EPR systems, hundreds of medical units, and thousands of users. The different parts of an infrastructure are often independently developed by individual actors and have to fit together to make the overall infrastructure work (Aanestad and Jensen 2011). Hence, standards are the core elements of IIs to enable communication and interoperability between actors (Orlikowski et al. 1993; Star and Bowker 2006). Standards and infrastructures are considered flip sides of a coin (Hanseth and Lyytinen 2010). Hanseth and Monteiro (1998) state that ‘Standards are absolutely necessary for the II to exist; without standards, there is no such thing as an information infrastructure’.

In general, the II literature advocates iterative and adaptive development approaches along with ongoing alertness, monitoring, and interventions (Aanestad and Jensen 2011). These strategies address diverse challenges faced by IIs, for instance, bootstrapping (Hanseth and Aanestad 2003), adaptation (Hanseth and Lyytinen 2010), mobilisation (Aanestad and Jensen 2011), generativity (Grisot and Vassilakopoulou 2013), flexibility (Braa et al. 2007), and interoperability (Ure et al. 2009).

The design of large-scale health information infrastructures is a complex process, hence Hanseth and Lyytinen have defined five design principles to address the challenges in such II development (Hanseth and Lyytinen 2010). To address the ‘bootstrap problem’, they propose their first design principle, where the goal is to start with designing for direct usefulness. Before a large user base is involved, it is important to convince the initial users to adopt the design by targeting their needs and design functionality, providing immediate value for them, and to enable scalability, extension, and

completeness later. Secondly, Hanseth and Lyytinen (2010) emphasise that designers should ‘build upon existing installed base’, to reduce the development cost and the adoption barriers. The third principle recommends ‘expanding the installed base by persuasive tactics to gain momentum’; this includes creating positive effects from extending the user base. Hanseth and Lyytinen use the fourth and fifth principles, ‘making the IT capability as simple as possible’ and ‘modularise the information infrastructure’, to address the challenges of building flexible and adaptable IIs and to separate the layers of an II, to connect different layers, and to maintain loose couplings between the IIs (Hanseth and Lyytinen 2010).

There is an interrelation between actors, hence it is especially important to focus on how collaboration changes when new ISs are introduced, which happens frequently in healthcare since it is constantly adapting to changing circumstances (Garrod 1998). Infrastructural arrangements such as EPR systems are crucial for cooperation and coordination processes in hospitals, and they typically form when various systems (e.g. EPRs) merge and allow the linking of dissimilar systems into larger networks. This enables using the II framework to analyse processes such as large-scale standardisations at regional and national healthcare levels. Here, the framework from Star and Ruhleder (1996), later rephrased in Star and Bowker (2006), is used to present the characteristics of an II (Table 4).

Table 4. The framework of information infrastructures

	Characteristic	Explanation
1	Embeddedness	The infrastructures are sunk into other structures, social arrangements, and technologies.
2	Transparency	The infrastructure is not reinvented each time it is used or assembled for each task.
3	Reach or scope	IIs have reach beyond a single event, which can be either spatial or temporal.
4	Learned as part of membership	Users have to be included in it to understand it.
5	Link with conventions of practice	II shapes and is shaped by practice.
6	Embodiment of standards	The infrastructure takes on transparency by plugging into other infrastructures and tools in a standardised fashion.
7	Built on installed base	IIs are not established from scratch but are built on existing practice.
8	Become visible on breakdown	An II is the basis of, for example, a hospital faded into the background of other structures at the workplace. It is not visible to the users when everything is functioning well.
9	Fixed in modular increments	Because an II has layers and is complex, change takes time and requires extensive negotiation.

An II is shared by the involved actors, including vendors, users, and staff. The II will be constantly evolving since growth and innovation expands it, and an II is open to an unlimited number of users. Information infrastructures are heterogeneous entities, including technical components, organisational

concerns, vendors, and system users (Hanseth and Monteiro 1998; Hanseth and Lyytinen 2010; Tabish 2012), and they grow from existing practices and infrastructures (Hanseth and Bygstad 2015). Infrastructural development and maintenance require work, a stable technology, and good communication between the actors (Star and Bowker 2006). A good II is stable enough to allow information to be persistent over time yet remain modifiable at the same time (Star and Bowker 2006).

The installed base

Hanseth and Lyytinen (2010) define an installed base as the existing ‘set of ICT capabilities and their users, operations and design communities’, including existing institutional and organisational components. This is considered the starting point for ICT development (Hanseth and Lyytinen 2010), evolving and emerging slowly over time (Hanseth and Monteiro 1998; Bowker and Star 2000; Constantinides and Barrett 2014; Star and Ruhleder 1996). New information technologies are never isolated and absolute; they are always embedded in an intricate web of technologies, practices, and routines to which they relate in specific ways (Aanestad et al. 2017). This includes the organisational, institutional, regulatory, socio-technical arrangements that are already in place in addition to IT capabilities and their corresponding users, operations, and design communities (Hanseth and Lyytinen 2010; Aanestad et al. 2017; Hanseth and Monteiro 1997). Hence, an important part of an II is the role that existing work practices and routines have for the development of new functionality and new standards for an EPR system (Hanseth and Lyytinen 2010). Because the infrastructure is developed by extending and improving an installed base (Hanseth and Monteiro 1998), it shapes and is formed by the work practice in an ongoing co-construction process among the organisational, institutional, and socio-technical arrangements already in place (Pedersen et al. 2012; Hanseth and Lyytinen 2010; Aanestad et al. 2017). When developing new EPR systems, this means considering the old portfolios and practices so that there are not too many changes for the workers to adjust to (Bowker and Star 2000).

Several studies have pointed out how the installed base is an actor on its own, both hampering and facilitating change (Hanseth and Lundberg 2001; Aanestad et al. 2017). During the progression of an II in any given context, the installed base may become very large, especially when the II is regional or national, and will increasingly shape its environment, making it difficult to replace or change it. In the healthcare sector, for instance, an installed base may encompass patient record systems, medical departments, various groups of professionals as users (nurses, clinicians), dispensing practices, regulations, and so on. Therefore, newer versions to replace previous ones and secure backward compatibility are carefully introduced or adjusted (Bowker and Star 2000). Establishing and scaling IIs is defined as an infrastructuring process, which may be complex and challenging, especially for a heterogeneous healthcare practice.

Infrastructuring

The process of establishing an information infrastructure by expanding a small local IS into a large-scale integrated one, able to serve the needs of multiple actors (Clement et al. 2012), is defined as an infrastructuring process. This includes tools, methods, practices, and standards to emphasise the possibility of making visible, actively designing, and using a system. Karasti and Baker (2004) define infrastructuring as ‘an ongoing design process that highlights participation and co-construction, as well as the complex relationships between the long-term, data, participants, collaborations, information systems, and infrastructures’. Infrastructuring is a way for stakeholders to interact more actively in shaping the direction of an II, increasing the speed at which it progresses or adding new parts to the infrastructure. For example, the users of an EPR system practice infrastructuring activities (Pipek and Wulf 2009; Karasti, Baker, and Millerand 2010). From vendors’ perspectives, infrastructuring often includes how a system designed for one specific context can expand and move to others. In the II literature, several authors (see Edwards et al. 2009; Pipek and Wulf 2009; Karasti, Baker, and Millerand 2010) have used the notion of infrastructuring to emphasise the proactive engagement with large ICT portfolios. However, it is far from clear how numerous clinical practices influence and shape a collective infrastructuring process. Infrastructuring in healthcare is a process by which medical practices and artefacts become parts of social and technological networks with longer reaches and more channels through which coordination among distributed actors is enabled and formed (Bossen and Markussen 2010). Standardisation can be challenging in relation to infrastructuring processes since the existing ISs often have their own standards, and there must be established an integration between different standards or a common platform or information model the systems can use for communication.

Building infrastructures is typically a highly charged political effort as sometimes powerful and long-buried interests resurface when the hardened compromises threaten to become unstuck (Clement et al. 2012); there is therefore a need to address the power relations in infrastructuring processes and how they influence the outcomes of the processes. There are tensions detected both between global and local interests as well as between different actors in an II.

3.2.1 Power relations and tensions in large-scale IIs

From a medical informatics point of view, the power relations and politics between actors was traditionally not much addressed within the IS literature since it was very clear that the technology was the actor setting the premises for the organisation and the users to follow. However, the shift towards a more socio-technical approach within medical informatics, as, for instance, Berg (1999) and Aarts et al. (2007) emphasise, requires such issues to be addressed further in the future. Power and politics are issues addressed in several other knowledge fields, such as political science. Several authors, such as Aanestad and Jensen (2011) and Pipek and Wulf (2009), have emphasised the importance of politics and power relations in II without including these subjects to a large degree in their studies. Pollock and Williams (2010) are also concerned that there are too few studies focusing on the ‘policy’ level as well as

processes of large-scale technology selections and procurement in the IS field. CSCW studies have been very adept at describing the current situation in the healthcare setting from a work place perspective, but they have been far less concerned about analysing the (larger) change processes (Fitzpatrick and Ellingsen 2013). The larger the II becomes, the more important it is to address these subjects since the relations between the actors vastly influence the collaboration within an II. A core essence of larger-scale, policy-imbued projects is how new technology and associated new practices bring about disagreements, controversies, and negotiations (Latour 1987). Hence, it is important to address power relations and politics further in IS/II studies since the infrastructures are expanding to large-scale entities, introducing new power relations and tensions compared to small-scale ones.

Brunswicker, Rodriguez, and Warcham (2014) highlight the power relations between formal and informal standards in their paper comparing HL7 and ISO standards and the interrelation between them. They define five important areas of tension that are important to address. The first is singularity vs plurality, where the contradiction between different standardisation organisations working in the same field is addressed. There is a need to define how to solve the problems to avoid overlap and duplications. The second is the local vs global tension, where they address the contradiction for actors in local contexts to establish global standards and the challenge of organisations not being interested in members participating in international standardisation activities due to the lack of funding for such voluntary work. The third is market demand vs regulatory pull, where the tension between fulfilling regulatory frameworks, governmental expectations, and market needs are addressed. The fourth is the constant vs dynamic tension, where the contradiction between slow formal governmental standardisation processes and the aim for agility in the consensus making of, for instance, HL7 is the challenge. Formal standards in, for example, PDF formats are difficult to manage and update. Free vs paid for is the last tension Brunswicker, Rodriguez, and Warcham (2014) address. ISO standards cost money, and HL7 standards are available for free for members.

Another important area where power relations are important to address is related to the construction of standards since this is a process that demands extensive negotiation between the involved stakeholders (Berg 2001). Participants in standardisation processes are subjective and try to shape standards in a way that suits their own interests. When establishing standards for healthcare there is a complexity of users to consider (Brunsson, Rasch, and Seidl 2012); hence, it is necessary to balance the need for efficiency with the need for different users to participate in establishing high-quality standards (Brunsson, Rasch, and Seidl 2012). Therefore, standardisation organisations are likely to restrict participation when they have reached the necessary level of output legitimacy. Second, the standards will contribute to changing existing work processes and organisational structures, such as moving the responsibilities among healthcare workers, redefining patients, and shifting the relation between managers and workers in healthcare organisations (Timmermans and Berg 1997). Third, standards are a means to organise

modern societies. This perspective merges standardisation and organisation, thus standardisation is the organisation (Brunsson, Rasch, and Seidl 2012). Timmermans and Berg (2003) state that ‘Standards are inherently political because their structure and application transforms the practice in which they become embedded, changing the positions of actors, altering relations of accountability, emphasizing or deemphasizing pre-existing hierarchies and changing expectations of patients’. Hence, in large-scale IIs, standardisation of any kind will result in tension between different actors. Empirical studies demonstrate how political negotiations influence standardisation processes (Bowker and Star 2000; Hanseth and Monteiro 1997). Modern healthcare is embedded in a highly politicised and institutionalised arena where governmental and managerial rules, regulations, and policies are negotiated against local concerns and priorities. Patients, professionals, and healthcare ICTs co-constitute each other in complex ways, and changing such construction of social, organisational, and technical elements is a politically textured negotiation process with uncertain outcomes (Berg 1999; Vikkelsø 2010). In a study on information infrastructure integration, Sahay, Monteiro, and Aanestad (2009) found that the interplay of political interests and technical configuration aspects shaped the integration process as the stakeholders were associated with different powers of negotiation. Concerning terminologies in healthcare, it is interesting to examine closer how they are promoted and received among existing users as well as the consequences for existing terminologies and practices. Hanseth and Monteiro (1996) address the tension between standardisation and flexibility in information infrastructure contexts and processes of standardisation of II, paying particular attention to the technical and institutional mechanisms that enable and hamper the flexibility of standardisation (Hanseth, Monteiro, and Hatling 1996). The principle of interpretative flexibility (Bijker and Law 1992) stipulates that, in theory, everything can be disputed, negotiated, or reinterpreted; closure occurs when the actors involved in a design process reach consensus. Hanseth, Monteiro, and Hatling (1996) state that it is not enough to recognise that standardisation has a social and political relation; it is important to identify how the technology and the non-technical actors interact (Hanseth, Monteiro, and Hatling 1996). In a study of the evolution of the classification of diseases maintained by the WHO, they illustrate how coding and classification is anything but neutral (Bowker and Star 1994). Berg (1999) states that it is important to acknowledge that the EPR is a result of a political decision process, recognising technology for what it really is – namely, a means to change, form, and structure work practice in healthcare.

It is also important to address the relation between local and global interests in an information infrastructure, especially at a regional or national healthcare level, since global standards both shape and are shaped by local work practices (Ellingsen, Monteiro, and Munkvold 2007). Bowker and Star (2000) also underscore the tension between the desire to standardise on a global level to emphasise managerial agendas of control and accountability and the need for flexible local standards for work practice support. Many authors agree with this observation (see e.g. Star and Ruhleder 1996; Rolland and Monteiro 2002;

Hartswood, Procter, and Rouncefield 2003; Meum, Monteiro, and Ellingsen 2011). Star and Ruhleder (1996) also state that an infrastructure occurs when solving the tension between local and global requirements. CSCW research highlights the many ways in which standards are not objective ‘givens’ but need to be continuously negotiated and interpreted (Bossen 2011). Meum, Monteiro, and Ellingsen (2011) highlight the negotiation between global standardised classifications and local practice as a result of long-term use, characterising this process of standardisation as a pendulum movement entailing collective emerging accomplishments. Ellingsen and Monteiro (2006) discuss a case that cuts across several departments, and which represents a large-scale integration and standardisation between hospital laboratory systems and the EPR, detecting that managers’ need for large-scale integrations does not fit the laboratory needs for tailored systems. Similarly Hartswood, Procter, and Rouncefield (2003), in the introduction of an EPR, note ‘important divergences between the presumptions of the role of the EPR in achieving service integration, and the ways clinicians use and communicate through the medical processes’ (Fitzpatrick and Ellingsen 2012). Ure et al. (2009) found recurring socio-technical problems in the development of infrastructure for sharing and reusing data across sites for e-health research. A growing trend towards uniformity, globalisation, and standardisation as means to increase the efficiency of healthcare (Rolland and Monteiro 2002) makes the gap between local and global solutions even larger. In turn, the construction of large-scale IIs needs to balance with local variations and needs. Dynamics inherent in the adoption of standards result from the process through which those general rules become applied to specific organisations or ‘translated’ into localised rules and the question is whether a standard should be adapted to the local context or whether the local context should be changed to fit the global requirements.

For EPR systems in the US, for instance, there are extreme forces that pull standards in multiple directions. In the US, each state has its own conditions and legal requirements for handling healthcare data records, and within states, individual organisations have their own procedures and semantics, which can be fragmented further by technology vendors who, knowingly or unknowingly, embed some level of heterogeneity in their protocols, applications, or services. This makes standardisation as well as governing standards extremely difficult. Hence, to maintain such complex infrastructures and the balance between the actors and the healthcare levels, a good governance structure is required.

3.2.2 Governing large-scale information infrastructures

The governance of standards is inherently dynamic and implies a range of tensions that emerge throughout the negotiations by the actors involved in the standardisation process (Narayanan and Chen 2012). Given the scale of the information infrastructures and the complexity of standardisation processes and relations between users and technologies begs the question of how such large integrated infrastructures can be governed. A precondition for a large-scale II, such as an EPR system or a standardisation organisation, to be successful is a well-functioning governance organisation. ICT

governance can be defined as making and implementing decisions regarding goals, processes, people, and technology on a tactical and strategic level of an ICT organisation (Simonsson and Johnson 2006). Such governance addresses how to design and implement effective organisations by creating flexible ICT and IS structures as well as processes. ICT governance also specifies the decision rights and accountability framework to encourage desired behaviour in ICT usage (Weill and Ross 2005). According to Weill and Ross (2005), the overall goal of an ICT governance organisation is 'to assure the stakeholders that things will go as expected, and ensure the successful delivery of healthcare services'. Star and Ruhleder (1996) stated that the configuration mechanisms of governance are typically a mixture of various structures, processes, and relational aspects. In healthcare, there is an increasing need to establish ICT governance organisations at different levels to make decisions and monitor results and performances, especially because implementing ICT governance is expected to ensure the successful delivery of healthcare (Beratarbide and Kelsey 2009).

Traditionally, a top-down approach was used with a clear ICT governance structure defining decision makers and the necessary decisions to make (Weill and Ross 2004). Management studies promoted this design based on pre-defined models of work practices (see e.g. Ashkenas et al. 2002). However, such strong, controlling ICT governance has proven ineffective and even impossible to apply in IIs in healthcare (Weill and Ross 2004; Constantinides and Barrett 2014). Due to the constant growth in complexity and deviation from original intentions, an II is impossible to govern completely in a top-down fashion (Hanseth and Lyytinen 2010). Several actors from both the clinical and technical sides of healthcare need to be included in such governance. In addition, healthcare is constantly changing, with technological innovations, innovative treatments, new laws, and novel types of organisations arising almost daily. In addition to negotiating the day-to-day demands of a busy and complex organisation, healthcare leaders must be able to evaluate and understand the impact of alternative care delivery models (Tabish 2012). Hospitals and health systems struggle with issues of governance, particularly when it comes to care standardisation and quality improvement (ibid.). The concept of hospital governance is relatively new (Tabish 2012), and it includes all hospital activities as well as clinical performance. A pressing question is how and in what form an II in general and standards in particular can be governed at different levels of healthcare. Improved quality and more interoperable health information are necessary but very challenging to match with ICT governance principles and benefits in large-scale interorganisational IIs. Heterogeneous stakeholders have different goals and strategies for reaching them, resulting in frequent tension. This is particularly evident in a healthcare context with numerous actors. As a result, standardisation processes may be extremely challenging to accomplish due to the power relations between the different actors. Based on this, a new organisational governance structure needs to evolve that focuses on supporting the development of standardised clinical processes.

Brunswick, Rodriguez, and Warcham (2014) define four governance mechanisms responding to the tensions they recognised in relation to formal and informal standardisation: boundary spanning roles, meta processes, and boundaries as well as evolving resources. The interdependencies between formal and informal standardisation, in this case ISO and HL7, made it important to establish mediators and boundary spanners. They would lead the negotiation between vendors, academics, users, and representatives from national standardisation agencies on topics related to different contexts (technical, legal, and domain), in which standards are developed dealing with multi-domain topics such as property rights issues, the application of technology, and the coordination of people with diverse backgrounds (physicians, computer scientists, engineers, etc.). It was also important to have meta processes and routines, including multiple standardisation processes such as procedures and protocols to facilitate the exchange of ideas, use cases, and interdependent activities to identify needs and requirements for standardisation. In relation to evolving resources, several were identified to prevent tensions, such as bidirectional wikis, blogs, formal agreements, official dashboards, and overlapped pools of experts to follow what other groups were working on.

Agreeing on a governance structure for a large-scale II is not necessarily easy, and it has proven difficult for stakeholders to give up their local autonomy for an overall governance structure where they no longer make all the decisions but are dependent on other actors as well. One solution to this may be to organise a polycentric governance architecture. Such governance includes a number of governing units at different levels of healthcare instead of one monocentric one (McGinnis 1999). This provides for a distribution of decision-making across organisational layers and among different stakeholders. One key advantage of polycentric governance is the possibility of creating generally formed rules that can later be adapted to specific local needs (*ibid.*). However, this model requires that actors spend extensive time and energy on negotiating and compromising on acceptable collaborative solutions. Agreeing on governance structures acceptable to all parties is a major challenge because of the heterogeneity of interests and resources involved in healthcare IIs and the complexity of governing IIs (West 2007). The fragmented governance structure of an II, however, calls for an increased need to define the boundaries between the organisations to ensure collaboration between them (Gieryn 1983) and distinguish the responsibility areas of the different governance units (*ibid.*); this will also increase the number of tensions related to power between the actors involved.

4 Research Setting

The data collection for this project was conducted in several research settings, including the FIKS programme and both the regional and national archetype governance organisations.

4.1 The EPR Vendor and DIPS Arena

DIPS AS is the leading vendor of eHealth systems for Norwegian hospitals and has about 200 employees. Three of four health regions in Norway use the EPR system from DIPS AS, including about 80,000 healthcare workers and 4.3 million patients across the country (DIPS 2017). The overall goals are to improve the quality of patient treatment and increase patient safety and efficiency in healthcare (ibid.).

DIPS AS started to experiment with user-driven development in 2006 (Christensen and Ellingsen 2016), and in 2011, they decided to use openEHR architecture for their next-generation EPR. Hence, in 2012, the development of DIPS Arena started in close collaboration with the Northern Norway Regional Health Authority. The development included an extensive process of designing the necessary functionality for the system, developing the EPR module by module. The goals were to provide extensive quality improvements for patient treatment, and improved workdays for system users, by focusing on usability, functionality, and security (DIPS 2017). DIPS Arena ensures access to patient information across institutional and organisational borders, providing patients with the right treatment at the right time. The system builds on an open technology platform and international standards, enabling other vendors and hospitals to develop conforming functionalities and reuse the standards. DIPS AS has so far invested about €1310000 into this open platform system (DIPS 2017).

However, due to the complexity of the work on functionality for the new system, as well as the challenges of gaining momentum concerning the work with archetypes to standardise the clinical content, the development of DIPS Arena was delayed several times. According to the original plan, the first modules of DIPS Arena were supposed to be implemented in 2015. Updated plans from DIPS AS describe a delay of approximately three years, thus the implementation did not start until 2018.

4.1.1 The OpenEHR architecture

DIPS Arena builds on the openEHR architecture developed by the openEHR foundation, established in 1998. OpenEHR is an international online community aiming to promote and facilitate high-quality electronic healthcare records supporting the needs of patients and healthcare personnel. Today, the openEHR framework has a strong foothold in the medical informatics field (Chen et al. 2009; Lopez and Blobel 2009; Moreno-Conde et al. 2015). As of 2017, the openEHR foundation had about 1,500 members from 87 countries and a clinical knowledge manager (CKM) including 500 archetypes translated into 23 languages. Specifications, relevant programmes, and datasets are published under an open source license (Ingram 2002).

The openEHR architecture is a specification of an EPR system to manage, store, and retrieve structured health data (Christensen and Ellingsen 2016) through an open platform where the data are completely

shareable and independent of programming language, human language, and database technology. The openEHR architecture assumes that the clinicians can be in control of modelling the EPR themselves (Leslie et al. 2009) and builds on a two-level modelling architecture (see Figure 1), separating the reference model, used to represent the generic properties of health record information, from the CIMs. The CIMs are archetype standards used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality, or service (Garde et al. 2007; Beale and Heard 2008; Chen et al. 2009).

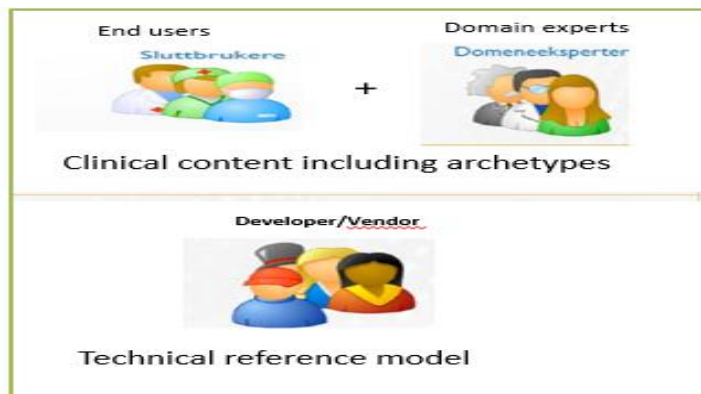


Figure 1. The two-level model of openEHR architecture

The first level, the technical reference model, is used to increase semantic interoperability and secure the reuse of data (Garde et al. 2007; Beale and Heard 2008; Chen et al. 2009) since it is a stable object model generic enough to store any type of clinical information and build software and data on. At this level, the design of functionality for an EPR system is included; these are system-specific designs, not built on generic archetype standards. The second level contains the CIM in forms of archetypes and templates, as standards for the clinical content. These standards define a set of classes that forms the generic building blocks of the EPR (Kalra 2006). The two-level model of the openEHR makes it very flexible, enabling users to make changes only to the clinical content of the archetypes without having to alter the underlying openEHR information model.

4.2 The National Archetype Governance and the Archetype Standards

4.2.1 Developing archetypes on the national level in Norway

Based on the vendors' experiences and the work with Action 27, a decision to work with archetypes at the national level and to establish a Norwegian archetype repository (CKM) was made by NICT² in

² National ICT (NICT) is the specialist health services main arena for interaction related to ICT. NICT is set to underscore the goals of specialist healthcare within ICT, such as better and more complete documentation, quicker access to patient information and easier access to data used for managing healthcare information (NICT 2017).

2013. Three of the four health regions had chosen DIPS Arena as their future EPR system, and using the same standards was an opportunity to improve the interoperability between the health regions and to establish a national collaboration on standardising clinical information. This also conformed to the overall goals for Norwegian healthcare defined in Whitepaper 9, including easier access to patient data and information, following the patient through the complete patient trajectory. The National Editorial Group for Archetype Development in Norway (NRUA) was established in 2014 to coordinate the national archetype work. NRUA is responsible for maintaining and updating archetypes, and they are in charge of the national consensus process for reviewing and approving the clinical standards, including more than 350 reviewers (NRUA 2017). Moreover, NRUA supports local initiatives of archetype design and use in Norway and coordinates the work of the regional archetype governances. They also collaborate closely with the international CKM run by the openEHR foundation through weekly meetings and parallel consensus processes. NRUA has five part-time engaged employees in addition to two or three representatives from each of the four regional health authorities in Norway.

In the North Norwegian Health Authority, a regional archetype governance organisation was established in 2017 as a part of the overall clinical governance organisation. This was a result of the increased regional focus on DIPS Arena as well as the recommendation from NRUA in 2015 that the health regions organise archetype governance groups to anchor this standardisation regionally and increase the archetype competence in the health regions. The regional archetype organisation has three employees in part-time positions, and the goal is to establish a close collaboration between the national and the regional archetype work as well as between the regional and the local archetype work. This includes more systematically assisting in the national work (reviews, translation of archetypes, and modelling) and collaborating with FResk and other health regions in the archetype work.

4.2.2 Using archetypes to structure clinical data

The archetypes are information models set to standardise clinical concepts and include a maximum dataset of clinical data. They are structured information models and the core elements of the openEHR-based EPR systems. This includes facilitating semantic interoperability, evidence-based practice, and the easy reuse of information (Moreno-Conde et al. 2015; Kalra 2006; Chen et al. 2009). Archetypes include contextual elements to provide the necessary clinical information, and they are used to define how clinical data are seamlessly stored and transferred between EPR systems (Moreno-Conde et al. 2015). To ensure interoperability, archetypes have the same meaning in all EPR systems and everywhere inside an EPR. Figure 2 illustrates the structure of an archetype.

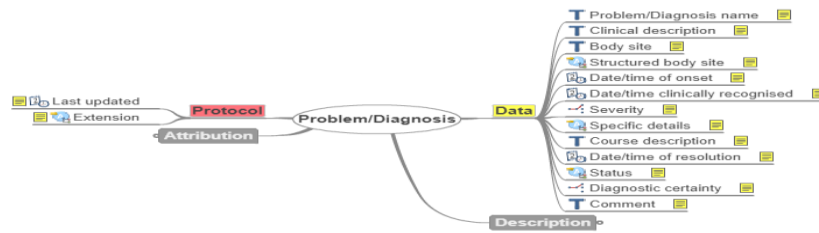


Figure 2. A model of the archetype problem/diagnosis, including all related nodes of information

The archetype methodology is a version of the CEN/ISA standard ISO 13606, improved through the openEHR architecture (NICT 2012). Archetypes are standardised building blocks defined for clinical domains or organisations (Kalra 2006) used to record the elements of a clinical process as well as to describe and support the complete patient trajectory of care (Chen et al. 2009). This is an iterative clinical process, including the clinician’s personal knowledge base and access to evidence-based knowledge to support decisions. Archetypes are divided into four main categories, as shown in Figure 3. Observations are archetypes that present clinical opinions or evidence, including symptoms described by the patient, findings during examinations, measurements such as blood pressure, and lab results. Evaluation archetypes include the registrations and documentations of observations and findings. They are used for describing risk assessment, problem/diagnosis, goals of treatment, adverse reactions, and so on. Instruction archetypes describe what needs to be done ahead of time, such as initiating care, defining workflows, ordering medications, and requesting laboratory tests. Action archetypes are documentations of measures actually performed, such as clinical activities, the administration of medication, and following instructions for ordering medications.

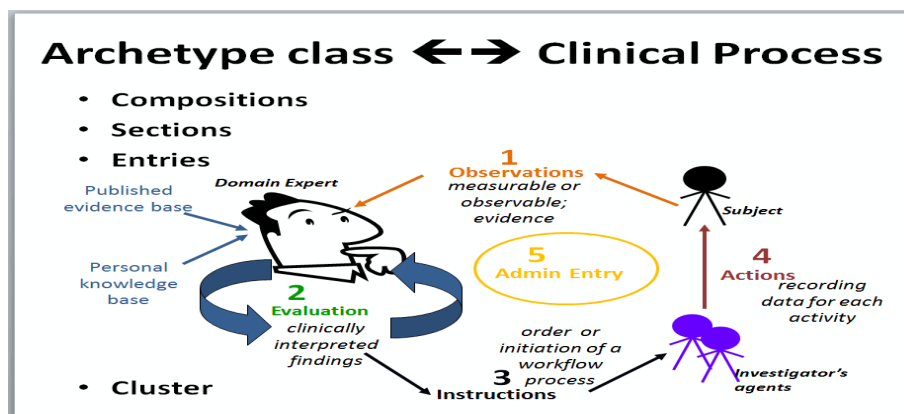


Figure 3. The clinical process and the use of archetypes

Archetypes are combined as building blocks for templates, and the same archetypes can be used for several different templates (Kalra 2006). Templates are used to create documents, messages, and specific forms/reports, including GP referrals, radiology reports, and discharge forms. Garde et al. state, ‘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 using designed structures to express the required clinical data' (2007). The consistent use of archetypes ensures a high degree of interoperability between different openEHR-based EPRs as well as the efficient reuse of data across different contexts (Kalra 2006). Another important feature of the archetypes is the possibility to connect them to terminologies such as SNOMED CT and Logical Observation Identifiers Names and Codes (LOINC) (NICT 2012).

5 Method

This chapter address my methodological approach, including the data collection, data analysis, and reflection on the method used.

5.1 Research Design

Within all research, the method has to adjust to the purpose; therefore, it is important to choose the method that is the best fit to examine and answer the research questions (Malterud 2003). In this study, a qualitative method was used because the goal was to cover more than quantitative measurable facts (Robson 2002). Qualitative research techniques are useful to provide deep insight, both to identify problems and to answer 'why' and 'how' current situations emerge (Klein and Myers 1999). The aim was to capture the viewpoints of diverse actors in the different regional and national standardisation processes by following them closely over time. Using a qualitative research approach implies taking into account different people's interests and actions set in a broader context (Walsham 1995; Klein and Myers 1999). This approach allows both researchers and informants to interpret what is investigated, based on the researchers' subjective participative role (Robson 2002). In agreement with Mack et al. (2005), the strength of a qualitative approach is the ability to provide complex textual descriptions of how people experience a given issue. It provides thick descriptions addressing the 'human' side of a process. This is useful for identifying the interaction between the different actors in large complex standardisation processes.

The literature defines several directions of qualitative research: ethnography, narratives, phenomenology, grounded theory, and case studies. Klein and Myers (1999) state that they found no explicit distinction between ethnography and case studies except in how long the study lasted and how closely the researcher engaged in the life of the social group under study. My study lasted from 2014 to 2017, and data were collected at different phases of the study. Thus, the time spent in the research field was not long enough or continuous enough to qualify as an ethnographic study in the traditional sense, even though it could be defined as multisided ethnography (Marcus 1995).

However, following the standardisation and system development processes for several years involved frequent visits to the field site over an extended period, which made it possible to define it as an in-depth

case study. Case studies can be defined as positivistic or interpretivist, with an up-close or in-depth view as well as detailed examinations of subjects of study. Interpretive studies provide insight into the way people understand and relate to certain phenomena (Orlikowski and Baroudi 1991). The interpretive approach, including epistemology, addresses how to obtain knowledge about the world; ontology relates to how one sees the nature of reality; and methodology defines the best means for gaining knowledge of the world (Denzin 2003). Qualitative interpretive research therefore includes evaluation criteria for both case studies and ethnographies as long as the underlying philosophy is interpretive (Walsham 1995; Klein and Myers 1999; Robson 2002). Qualitative research has been criticised for a lack of framework to make it plausible and generalisable. Thus, it has been important to create frameworks for conducting such studies; one example is the set of principles for case studies within interpretive field research presented by Klein and Myers (1999), which has its origins in the philosophical perspective of anthropology, phenomenology, and hermeneutics. This set of principles was used as the analytical tool for the study.

Walsham (2006) states that phenomenology and hermeneutics are philosophical positions underpinning interpretive research. Interpretive research can help the IS researcher understand human thought and action in a social and organisational context (Klein and Myers 1999). In their second principle of contextualisation, Klein and Myers (1999) state that the subject matter must be set in its social and historical context so that it is possible to grasp how a situation under investigation emerges. Analysing longitudinal case studies is a continuous and iterative process with an ever-changing intensity, focusing on developing and increasing the understanding of a phenomenon by exploring diverse viewpoints within a specific context (Walsham 1995; Klein and Myers 1999). This is also a way to understand how the context influences the process (*ibid.*). Walsham (2002) states that the IS is both influenced by and influences the context in which it takes place. Further, interpretive studies assume that people create and associate their own subjective and intersubjective meanings as they interact with the world around them. The interpretive researcher thus attempts to understand subjects through accessing the meanings participants assign to them (Orlikowski and Baroudi 1991).

Due to the evolving socio-technical complexity of the project and the way I followed the standardisation processes, this study is considered an action research project. Action research became highly relevant in the 1990s, with the need for closer collaboration between researchers and the actors they studied. This approach aims to solve current practical problems at the same time as scientific knowledge expands by studying organisational changes as well as actually contributing to the changes happening (Baskerville and Myers 2004). This approach requires close collaboration between the researcher and the actors in an iterative research process within a given context (Baskerville and Myers 2004). Action research represents a highly involved type of research study, providing operational advice to the project

managers, vendors, and key users involved in the actual change process (see e.g. Granlien and Hertzum 2009).

This is a direct response to the frequent call for IS researchers to make their work more relevant to practice (Walsham 2006). Baskerville and Myers (2004) present action research as a potential way to improve the practical relevance of IS research. Action research is described as the primary methodology for studying the practice of organisational development. Going in as an action researcher means bringing your former knowledge and background, which may influence the way you interact with the field. In Klein and Myers's (1999) fifth principle, they state that researchers should be aware of their preconceptions and prejudices when starting a research project and that their view may be challenged during the research process. Walsham (2006) also says that our backgrounds, knowledge, and prejudices make us biased, and we see things in certain ways and not others. The researcher should not let his background and preconceptions determine what is important in a study and what is not.

Forsythe (1999) emphasises the importance for the researcher to be an outsider: 'Competence as an insider does not make one an accurate observer. In fact, ethnography usually works best when conducted by an outsider with considerable insider experience'. As an outsider, you are able to detect things that insiders take for granted, and therefore cannot see. To have some inside experience means that you understand the different aspects of a workplace better and are able to use the data collected during the research in a more useful way. Forsythe (1999) also states, 'There is a risk that a closely involved field researcher becomes socialised to the views of the people in the field, and loses the benefit of a fresh outlook on the situation'. In his paper from 1995, Walsham argues that it is important for the researcher to be an insider in order to get all the necessary information. He also lists a number of advantages to being an insider, such as in-depth access to actors and data that enables observation and participation in action; the actors may also view the researcher as trying to make a valid contribution by being an insider.

I think it is necessary to go even further than being an action researcher; hence, the participatory action researcher (PAR) role seemed like a useful and interesting approach for the best possible outcome of my research. In PAR, the focus is on creating dialogue and generating knowledge through interaction between researchers and participants, and both parties are contributors to the understanding of the research and its results (Brydon-Miller et al. 2011). Participation is important not only in the sense of collaboration; it also claims that all participants need to be involved in the whole of the project undertaking. In such project, a key goal is for researchers to provide feedback and information to the empirical field, enabling them to adjust and improve the process as it moves along. The participants from the empirical field can also provide feedback to the researcher on the interview guide, participant selection, and problem identification. In a PAR project, it is important that participants are able to verify, discuss, and shape the findings as they emerge.

5.2 Data Collection

Ethnographic methods, studying the detailed social organisation of actual working practices through participant observation methods and in-depth interviews, can be highly useful here. Such methods can illuminate interdependencies between work tasks, and demonstrate, for example, how tasks that seem to be executed in a highly variable way are actually fine-tuned to match a highly variable context.

The data collection was conducted over four years, from 2014 to 2017, to identify interesting issues at different stages of the standardisation processes and the EPR development. The fieldwork is based on my role working in FIKS for two years before starting my PhD and afterwards continuing to follow activities in the project by participating in workshops and meetings connected to the development of the new EPR system and the standardisation work in HOS from 2014 to 2015. I was also an observer and participant in both the regional and national work with archetypes in Norway between 2015 and 2017, engaging in meetings, workshops, and discussions. From 2017, I worked part-time in the regional archetype governance, collaborating closely with NRUA. The goal of collecting data was to identify interesting issues at different stages of the process as well as to see the process as a whole, inspired by the hermeneutic circle defined by Klein and Myers (1999).

Interpretations in case studies typically relate to subjective opinions, concepts, descriptions, and definitions (Anderson 2006), and the data collection is conducted over shorter and longer periods as iterative processes with a focus on development over time. The data collection for this research was an iterative process conducted over several years and involving multiple data sources aimed at describing the same phenomenon by observation, conducting semi-structured interviews, and engaging in discussions (Koch and Gross 2006). In qualitative data collection, the researcher is the key instrument collecting data through ethnographic techniques such as document studies, observations, and interviews. This ethnographic eye is helpful in interpreting infrastructural challenges (Star and Bowker 2006). Ethnography may also be efficient in identifying, analysing, and evaluating changes in work practices, which emerge from using an IT system as part of the design and implementation of a system (Simonsen 2009). In addition to the qualitative data collection, in one of the papers, a simple quantitative statistical analysis was done to get an overview of the national archetype reviewers. The purpose was to identify how many of the about 350 registered archetype reviewers in Norway actually participated in the consensus work. It was also important to capture reviewer details, such as how many review iterations they had participated in, their occupation, what health region they represented, and so on, to gain an overview of this work.

5.2.1 Interviews

As noted by Walsham (1995), the main sources of data collection in interpretive qualitative studies are interviews, and I chose to interview workers from different user groups, with various roles in the process, to enlighten the standardisation and infrastructural issues from different actors' perspectives. The data collection included 36 open-ended and semi-structured interviews with different actors involved in the standardisation processes and development of the new EPR system as well as interviews with clinicians and technologists working with archetypes and regional and national archetype governance (see Table 5).

Table 5. Details of the data collection process

Description of data collection	No. of interviews	Duration	Period
Interviews			
Persons from FIKS working in the regional standardisation	4	60–90 min	
Representatives from local clinical governance	3	60–120 min	
Representatives from regional technical governance	3	60–90 min	
Representative from regional health authority	1	90 min	
Archetype reviewers	12	30–90 min	2014–2016
NRUA members	5	60–90 min	2014–2015
Persons involved in the EPR development	7	60–120 min	2013–2015
Developer of the new EPR system	1	60 min	2016
Observations			
FIKS/HOS regional standardisation		100 hours	2012–2016
NRUA/regional archetype governance		200 hours	2014–2017
Development of EPR system		80 hours	2012–2016
Archetype review and CKM use		5 hours	2014–2015
Discussions		150 hours	2012–2017
Document studies			
		400 hours	2015–2016
PAR			
NRUA/regional archetype governance		300 hours	2016–2017

This included personnel from FIKS, regional and local ICT governance, NRUA, regional health authorities, the vendor, and persons from different health trusts. In addition, several interviews and observations on the use of the CKM for reviewing archetypes as well as conversations with archetype reviewers and archetype governance were included in the study. The goal of interviewing actors with dissimilar roles in these processes was to detect the variety of viewpoints and experiences the actors had and to identify different perspectives and aspects of the regional processes. The processes examined included multiple data sources aimed at describing the same phenomenon through interviews and discussions about the given subjects (Koch and Gross 2006).

Focusing on the roles of different actors in the process of developing the EPR system and the clinical standards, as well as the organisational requirements surrounding these processes, made the qualitative interpretive method a useful approach for the study. Because this study involved several contexts (e.g. FIKS, regional archetype governance organisation, and NRUA), garnering reflections of their different viewpoints was necessary, and interviewing actors participating in different parts of the process seemed like the best way of gleaning this extensive knowledge. This was useful to understand the whole process and the interaction between the actors in the process better. In Klein and Myers's (1999) sixth principle of multiple interpretations, they address the need for confronting conflicting interpretations of the participants in the field by seeking out and documenting multiple viewpoints along with the reasons for them. This enables the researcher to examine the influences that the social context has on the actions under study. For example, in this research, when I asked about governing the clinical requirements of the existing EPR system, a representative from the regional technical governance stated that they performed most of these governance tasks. When I interviewed an actor from the clinical governance organisation at UNN, she stated that they were responsible for the clinical governance.

The interviews were a mix of open-ended and semi-structured ones, and the distinction among these interview forms is not very clear and might seem a bit artificial (DiCicco-Bloom and Crabtree 2006). The first interviews in relation to the standardisation of the existing EPR system and governance were semi-structured, in which I had some pre-defined questions in an interview guide to make sure the subjects I considered important were covered in the interviews. The questions were not too rigid, and often the interviewees included the topics just by telling their story before I had asked direct questions. Later on in the process when interviewing people working in the archetype development and archetype governance, I mainly used open-ended interviews, in which participants told their stories without my perceptions of the process getting in the way; this was useful to discover what was out there. Using open-ended interviews resulted in new and interesting issues emerging from several interviews. The overall aim of interviewing different actors was to obtain a historical and contextual understanding of the regional infrastructuring processes of large-scale standardisation and ICT system development.

Data collection occurred throughout the research period to explore how the relation between new technologies and practices developed and changed during the project as well as how the standards for the new EPR were customised and exploited in practice. In agreement with Klein and Myers (1999), that using a fixed design may risk ending up with interviews and research data coloured by researchers' opinions and pre-set assumptions, the interviews conducted in this research were as open as possible. Some of the actors were interviewed more than once based on their important roles and being identified as key informants. The interviews were all recorded and transcribed completely, and interesting citations related to the relevant topics were translated into English. The transcribed interviews were the main sources of data collection in this research. It is important to remember that the data collected may not

be the results of the research but the information the researcher analysed and worked with to find what is useful for the outcome of the research (Forsythe 1999).

Because the regional standards, the new EPR system, and the archetypes had not yet been implemented in the health trusts, interviewing physicians and other end-users was not required at this point. Their perspectives will be more important to highlight after completing the implementation of standards and the new EPR system in 2018. The data protection commission for research in the health region and the Norwegian Centre for Research Data (NSD) approved the data collection for this study. All informants provided written consent for the interviews by e-mail.

5.2.2 Observation and document study

Longitudinal participatory observations in NRUA meetings, regional workshops, and national workshops as well as meetings in the regional archetype governance organisation and the regional EPR governance organisation were important parts of the data collection. These ethnographic observations were essential to understanding the ongoing processes and registering not only what the actors said they did but also the things they did without thinking about it or things they did not consider important to mention in interviews. An ethnographer typically registers inconsistencies between what people say they do and what they actually do in daily work. People act according to formal rules, standards, or aspects of activities that become invisible even to themselves. Further, participant observation and documentary sources are used in combination with interviews, enabling the fieldworker to investigate the relationships between the work with standards and the EPR system as well as the organisational challenges surrounding them (Forsythe 1999).

Documents from the CKM and official reports from organisations such as the NICT, the health trust, the NDE, HOD, and other websites, such as the official site of the openEHR organisation, were also included as part of the data collection. This was done to gain the best possible knowledge of the challenges and focus areas contributing to a contextual overview of the ongoing events.

5.3 Data Analysis

The interpretation of text is a necessary part of the research process in qualitative studies (Lindseth and Norberg 2004). Multiple forms of data were gathered, reviewed, and analysed by organising the data inductively into more abstract units of information. In an iterative analysing process, the data are categorised by working back and forth between themes and the database, collaborating with participants to categorise them (Creswell 2013). Then, deductive thinking is used for building themes that are constantly checked against the data and the theory used (*ibid.*).

The data analysis in the project was mainly done by applying the seven principles for conducting and evaluating interpretive field research in ISs defined by Klein and Myers (1999). The hermeneutic circle is the first and the main principle; it relates to text interpretation and analysis in which a complex whole is understood from preconceptions, including the meaning of each part and the interrelation between them within a given context (ibid.). Alternatively, the parts can give a preliminary understanding of the interpretive researchers and the participants in the study, whereas the whole consists of the shared meanings that emerge from the interactions amongst the different parts (Klein and Myers 1999). The knowledge of reality is gained through social factors such as language, consciousness, shared meanings and documents (ibid.). The seven principles were defined as an attempt to frame the qualitative work when evaluating ISs, and it is important to include all the principles when using this hermeneutic interpretive method in research to gain the best possible framework for the data analysis (Klein and Myers 1999). When using phenomenological hermeneutics, the goal is not to state facts but to define the experiences of different actors (Lindseth and Norberg 2004). Both the researcher and the interviewee are included in defining the important themes and the essential characteristics of the different actors' expressed meaning (ibid.). The hermeneutic principles are used with critical reflection on the social and historical background of the study, including the researcher's own role in it. The study demonstrates interpretations from multiple participants and illustrates how data findings sometimes contradict earlier theories and how to relate the findings to theories showing sensitivity to biases and distortions (Walsham 2006). The challenges of organising a regional governance organisation and dealing with power relations between different actors were some of the main issues detected.

In practice, the data analysis started when the interviews were transcribed, and the text was defined according to interesting themes. The interviews were colour-coded to highlight topics that were interesting to address and data related to these themes. Walsham (2006) states that the researcher's best tool for analysis is his or her own mind, supplemented by the minds of others. Therefore, the process of analysing findings and data was an ongoing discussion between my co-authors and me. My co-authors have extensive experience with studies of EPR development and ISs in healthcare as well as theoretical expertise within the CSCW and II fields. Our discussions throughout the project period resulted in a deeper understanding and contextualisation of the empirical material. Important topics to include in the interviews were addressed in addition to discussing the findings in relation to the theory of standardisation, II, infrastructuring, and CSCW; these discussions have been very important for the work to evolve. The fourth principle by Klein and Myers (1999) of abstraction and generalisation states the importance of connecting the empirical findings to theory to distinguish the findings from just being stories of people's experiences of phenomena. Connecting the data to theory enables the generalisation of the findings. Walsham (1995) describes four types of generalisations from interpretive case studies: the development of concepts, the generation of theory, the drawing of specific implications, and the

contribution of rich insight. This study mainly focused on providing rich insights and drawing specific implications. To supplement the data, analysis project documents from FIKS; reports such as Whitepaper 9, NICT, national eHealth strategies and logs from the Norwegian CKM; and openEHR were read several times, both separately and combined with the interview data as a whole, to extract the most important overall topics.

The Norwegian CKM repository consists of nationally approved archetypes, including the documents from each review iteration in which clinicians discuss and approve the content of each part of an archetype in what they refer to as consensus processes. The data collected through the participatory observations in NRUA meetings, vendor workshops, working in the regional archetype governance, and the standardisation project in FIKS over several years were also included in the process. In addition, the data collected from the PAR as one of the employees in the regional archetype governance and member of NRUA was important to include. I also did an observation of one of the reviewers while he used the CKM to review an archetype to increase my understanding of how clinicians use this web-based tool. There was a highlighting of events and milestones from the observations, and some of them even became the starting point for questions in the interview guide. This part of the analysis was also an iterative process in which analysed and transcribed data led to new questions in the next interview.

One example of using the CKM as an analytic tool is described in paper 3, 'Infrastructuring in Healthcare through the openEHR Architecture', in which the consensus process of the evaluation archetype problem/diagnosis was used as the basis for the paper. The logs of the five iterations in the consensus process were read several times, both separately and together as a whole, to extract the most important topics to analyse. The logs are the comments from the reviewers of the archetype as well as the replies from NRUA. From reading these documents, it was possible to detect disagreements during the large-scale collaboration that occurred between clinicians, between clinicians and technical archetype reviewers, and between NRUA and reviewers. I followed up on the observations and descriptions of ongoing work through interviews with participants in the consensus process. The open-ended interviews were transcribed and analysed in relation to the II framework and CSCW, as part of a whole, to complement different perspectives of the process. The empirical setting was selected due to the authors' in-depth knowledge of the chosen context and the work with archetypes in Norway.

5.4 Reflection on Method

5.4.1 From observation to action: The shifting researcher role

The researcher role can be challenging to define when using a qualitative interpretive method. The researcher will always have an active role in forming the data by interpreting how different actors understand an ongoing process, such as standardisation or system development.

Due to the evolving socio-technical complexity of the project, an approach was required that would take into account different factors as well as the users' perspectives to find out what was really going on in the processes of developing and standardising an EPR system and clinical practice. An action research approach seemed like the best way to capture a nuanced picture of such a large-scale standardisation. As noted by Walsham (2006), there is a distinction between an 'outside researcher' and an 'involved researcher'. The former, for example, refers to a researcher carrying out a study mainly through formal interviews, with no direct involvement in the field; the latter refers to a participant observer or action researcher. For the outcome of this research, it was highly valuable to be an action researcher contributing to the ongoing processes. The inside information conducted as an action researcher provided a good understanding of the regional processes and easy access to the research field as well as actors to interview. Walsham (1995) argues that it is important for the researcher to be an insider to obtain all the necessary information. The researcher needs to be included as a member of the workplace. If not, there is the risk of missing important information deemed too sensitive and confidential for outsiders. There must be a balance between getting involved in the process and keeping a critical distance in order to understand all the necessary aspects.

Klein and Myers's (1999) fifth principle states that researchers should be aware of their preconceptions and prejudice when starting a study and that their view may be challenged during the research process. In an effort to avoid letting my background and preconceptions decide what was important or not in the research process, I chose a loose structure for the interviews. The first interviews were semi-structured to ensure that all interesting topics were covered. After a while, my interviewing skills improved and my knowledge of the field and the ongoing processes increased, leading to a shift from using semi-structured interviews to using open-ended interviews. First, I did not want my prior knowledge to influence the interview, and, second, using this open form allowed the participants to tell their stories and bring in new and interesting topics. I started with interviewing participants in the regional standardisation work in FIKS, and even though I had worked in the project until 2014, I tried to establish a researcher role as an outsider with extended inside information. Forsythe (1999) emphasised that ethnography usually works best when the researcher is an outsider with substantial insider experience to get a more distanced perspective and include more aspects of a process. At the same time, having inside knowledge provides a better understanding of the processes. Establishing an outsider role worked quite well for the work related to the standardisation in FIKS and the regional governance in Northern Norway. Because I no longer worked in FIKS, I felt increasingly distant from the project, which enabled me to see the standardisation with 'new' researcher eyes. In relation to developing the new EPR system, I was an outsider all along, simply participating in some workshops and meetings in the process. At first, it was easier to ask critical questions related to the development process than the regional standardisation process. This probably related to the loyalty I felt towards HOS from working there for

two years. However, it is also possible that from working in HOS I had a better knowledge of the standardisation process, and from that extensive knowledge, it seemed like there were fewer critical questions to ask at an empirical level.

In the work with archetypes in Norway, I started as an observer in the regional archetype group and NRUA in 2015, and the role gradually shifted to an action researcher role, in which I was more active in the ongoing processes and participated in the consensus work. Increased knowledge of the field also made it possible to be an active participant in workshops and meetings. In 2017, the regional archetype governance was established, and as one of three employees, I contributed to building and defining the organisation and defining its content. Thus, my role shifted gradually from being a traditional action researcher to a PAR, with constant interactions with the empirical field on both a national and a regional level.

From the extensive understanding of this part of the process, it has been possible to gain knowledge from the different arenas of the research fields. For example, from working in the archetype governance, I noted the lack of anchoring and understanding of the archetype work in the regional health authority. Because the regional health authority was responsible for the mandate of this governance, the authority acknowledged the need to extend its understanding of archetypes and the archetype work in Norway. Thus, we held a presentation introducing the subject and the need for clinicians to contribute to this work. In addition, working with translating, quality improvement, and reviewing archetypes in close collaboration with NRUA provided me with extensive information and understanding of the ongoing national processes and requirements, such as the challenges and importance of recruiting clinicians as archetype reviewers and the complexity of modelling archetypes. This was information that I could bring back to the regional clinical governance where the regional archetype governance was organised to underscore the importance of having such governance in the region.

As a part-time employee, I was involved in all the ongoing processes of establishing regional archetype governance and participated extensively in the national archetype work as a member of NRUA. Consequently, while doing my job as an EPR advisor in the archetype governance, I simultaneously collected data for my project. There is a risk that combining the researcher role and that of an employee can be a bit unclear both to the researcher and to the other collaborators. If everything discussed in meetings and workshops becomes potential research data, then there is a risk that the discussions become more constrained than normal. It was sometimes unclear whether others in meetings and workshops knew that I was participating as both an employee and a researcher. I did feel the ethical dilemma of these competing roles, and sometimes I chose not to use potential data due to the risk of harming the process more than helping it. Another issue was whether my role as a PAR may have brought me too close to the archetype work and thus unfit to see the work in a broader perspective. In some discussions with my supervisors, I felt like I was too loyal to my employee role, defending potential challenges and

problems too strongly. Eventually, it became challenging to be very critical concerning ongoing processes. With action research, there is always a risk for the researchers to lose critical distance regarding the value of their own contribution (Walsham 2006). It is necessary to be aware of the role you have as a researcher and how this role can influence the results of the research. There must be a balance between getting involved in the process by, for example, participating in meetings and workshops and keeping a critical distance to understand all necessary aspects and get an overview of the ongoing processes. Klein and Myers's (1999) third principle of interaction between researchers and the field raises highly relevant concerns about how the researcher roles influence the interpretation. It is also important as an action researcher to consider the seventh principle of Klein and Myers (1999): that of suspicion. The researcher must be aware of the chance of favouring certain opinions and meanings. It is necessary to let the experiences encountered in the research period determine the outcome of the research and not to try to make them fit your preconceptions. It became very important for me to be extra careful with the data that I collected and balance the research between highlighting relevant themes and not being too critical. To maintain a high level of data quality as well as to ensure high credibility, I checked all findings thoroughly by discussing them with supervisors and fellow researchers. I also asked extra follow-up questions in relation to observations to be sure that my findings and comprehensions were correct. There was a need to present the actors in the process in a balanced way by not being overly positive or negative concerning any of them.

Lastly, being this closely involved in the archetype work may have led to my missing out on other interesting aspects of the process, such as following the regional implementation of standards in HOS further or being more closely connected to the development of the EPR system in general.

5.5 The Regional FIKS Project

The North Norwegian Health Authority, including six health trusts and 11 hospitals, was in 2002 set to provide necessary specialist health services for the population of North Norway and Svalbard (HelseNord 2017). In 2011, it initiated a large bid for tender process and included all major ICT systems in the region. This was to see whether any vendors were capable of delivering a total package, including all the ICT systems. Another goal was to increase the competition within the Norwegian market and try to capture the interest of bigger international vendors delivering suite solutions to be able to compare suite systems and 'best of breed' systems. The North Norwegian Health Authority also wanted to standardise the regional ICT portfolio to ensure regional collaboration and communication between the systems within the health region as a step towards the national goals defined in the whitepaper 'One Citizen, One Journal' (HOD 2012).

Consequently, FIKS ('Standardisation of the Regional ICT Portfolio Project') was established to run from 2011 to 2016 with about 25 employees and five sub-projects. With a cost likely to exceed €100

million, this project was one of the largest and most ambitious ICT projects in Norwegian healthcare. The main goal of FIKS was to establish a regional ICT portfolio as a foundation for regionally standardised patient pathways, decision support, and integrations between clinical ICT systems. Standardising EPR work practices was a necessary requirement to reach such a goal, improving the health authority's possibilities to administrate and compare information from all the hospitals in the region. The FIKS project ran in close collaboration with system users from hospitals and the EPR vendor in addition to regional and local governance organisations.

The two EPR-related projects in FIKS – the Standardisation of Practice Project and the Development of the DIPS Arena project – were important parts of my research setting. I worked in the Standardisation of Practice Project between 2012 and 2014 and participated in some workshops and meetings the following years. The goal of this project was to 'increase quality and safety in patient treatment through standardizing clinical practice related to EPR usage across the region' (Nilsen 2013). More than 500 system users from all 11 hospitals in the region collaborated on defining regional standards for the EPR. The project aimed at identifying existing work practices (the installed base) at all hospitals and used 'best practice' principles to standardise work routines and procedures. In the development of the DIPS Arena project, I participated in workshops and meetings between 2014 and 2016. User involvement was very important for designing and governing the functionality for the system. Hence, more than 100 system users from all hospitals in the Northern Norway Regional Health Authority contributed to developing functionality for DIPS Arena. FIKS ended in 2016, and to continue the work of FIKS, a new programme, named FResk ('The Future Systems of the Clinic'), was established, focusing on a structured EPR and patient trajectories as well as implementing DIPS Arena and a new medication system in the health region.

5.5.1 Scope of the data collection

The research project started with a rather clearly defined scope of detecting the effect of the new EPR system on the patient pathway processes at UNN. However, with the delays in developing and implementing the EPR system, the scope had to change. When the development processes scaled in relation to, for example, establishing standards and governance structures, the project scaled as well. With no control over the processes, which were dependent on following the work of the vendors and other actors in the process, I just had to follow the ongoing processes and gather data when something was actually happening.

Because I had worked in FIKS and the HOS project for two years before starting my PhD, the work with regional standardisation and regionalising the North Norwegian Health Authority seemed like the right place to start the research. From interviewing participants in this work, it became clear that one of the most important elements for such standardisation to be successful was missing – the organisation to

govern the standards when the project ended. With healthcare constantly changing, the standards have to change to include new legal, clinical, and technical requirements to remain useful for the healthcare practice. In addition, the extensive power struggle between the health trusts and the existing governance organisation called for an organisation to mediate between them to find positive solutions that benefit the individual actors while keeping a regional focus.

In addition to the work in HOS, I also participated in some workshops related to developing DIPS Arena. One of the issues I took an interest in was the fact that the new EPR was built on an openEHR architecture, in which archetypes are the key elements for standardising the clinical data. However, no such standard existed in Norway in 2014, and I was curious how they planned to address this important task in time for the system to be implemented. In addition, I was interested to see how the work, including the extensive need for users to lead the development process, would be organised. One of my supervisors worked on a postdoctoral project related to semantic interoperability and the archetype work in Norway, and he was very active in the ongoing national archetype initiatives in NICT and NRUA. He recruited me to the regional archetype group and gave me access as an observer to NRUA meetings. This provided me with extensive knowledge on the archetype work regionally and nationally and resulted in my part-time employment in the regional archetype governance established in 2017. Hence, another important issue to address was the balance between regional and national requirements for such an organisation. Although the extensive focus on the important work with archetypes was interesting to investigate, it made it difficult to follow other parts of the process as closely as I had hoped to, such as the implementation of the regional standardisation and the work with developing the EPR.

6 Findings

The five papers in the thesis addressed different standardisation issues at a regional or national level of healthcare in Norway. In addition, the interrelation between the different actors in the standardisation processes and the socio-technical relations also served as a thread throughout the papers. This section also includes a summary of the papers in relation to theory and implications.

6.1 Paper 1: The Politics of Establishing ICT Governance for Large-Scale Healthcare Information Infrastructures

This was my first published paper, and it was presented at the Hawaii International Conference on System Sciences (HICCS) in 2016. Later an extended version was published in the *International Journal of Social and Organizational Dynamics in IT* (IJSODIT). The paper addresses the regional standardisation processes and how to establish clinical EPR governance on a regional level.

The paper discusses the complexity of healthcare governance related to the different goals and policies of the heterogeneous actors involved and the importance of establishing well-functioning ICT governance organisations to handle large infrastructures. In addition, the challenges of regionalising an EPR system and the interrelation between technical and clinical governance is addressed. The paper focused on the following research questions: How do organisational politics shape the process of establishing an ICT governance organisation in a heterogeneous healthcare environment, and what does it take to establish such an ICT governance organisation?

The contribution of this paper is its emphasis on the importance of the longitudinal and political process of establishing an interorganisational ICT governance in a heterogeneous healthcare context. Governing an evolving II should be less concerned with creating uniform organisational structures and focused more on a process for handling diverging political interests and managing tensions and complex interdependencies. This case has illustrated that establishing a uniform interorganisational governance regime is a formidable, if not impossible, task.

DIPS Arena requires a governance regime grounded in local practice with high competence in regard to how the new technology affects the clinician's daily work. In contrast, FIKS's standardisation of practice calls for a more authoritative governance regime. The regional standards and routines must be implemented in clinical practice, and the users must adhere to the standards for the standards to continue to evolve alongside the clinical practice. Such governance needs to include the local, regional, and technical aspects of governing the regional ICT portfolio. Regionalising an ICT portfolio is challenging, and even if different actors, including clinicians, participate in the process, there is a risk that the standards will not fit local needs and clinical practice. Therefore, a strategy for handling regional disagreements and evaluating requirements for the standards is important to work out. In addition, it is necessary to define the structure of such an ICT governance organisation.

The standardisation of technology and work processes is necessary for EPR systems to evolve from today's information storage systems to interoperable user-centred work tools. A key factor for success is establishing an ICT governance organisation where standards evolve alongside the EPR system. Operating two EPR solutions simultaneously also creates challenges, and the interplay between the old and new portfolios requires extensive technical and clinical knowledge because technical and clinical decisions affect each other. The three governance perspectives introduced in this paper – *local*, *regional*, and *technical* – are interconnected.

A strategy for solving the local and regional challenges has been to fragment the governance into smaller domains similar to a polycentric governance model, which offers opportunities for organising several governing units at diverging scales instead of one monocentric governance unit. A key challenge with the fragmented governance structure suggested is defining the boundaries and the areas of responsibility between the different units. There is a call for close regional collaboration to maintain and model the

clinical content, including archetypes and templates; this point towards trying out the suggested polycentric governance model. Such an approach demands close collaboration and clearly defined borders between the different actors.

6.2 Paper 2: Structuring the EPRs: The National Development of Archetypes for Core Functionality

This is the first paper to focus on the new EPR systems and the work with archetypes. The paper is published in the *International Academy, Research, and Industry Association (IARIA)* journal and provides thorough insight into the empirical work with archetypes in Norway, focusing on the following research questions: What are the challenges in the national archetype process so far, and how can these challenges be met through developing a set of core archetypes?

The emphasis in this paper is the need for speeding up the work with archetypes in Norway and the requirements for archetypes in the new EPR system. There is a dilemma regarding whether the regions should wait for archetypes to be nationally approved before implementing them or if they should start working on their own archetypes to speed up the development process. The Northern Norway Regional Health Authority decided to use only nationally approved archetypes, resulting in the work with the surgical module being delayed several times. The Southern and Eastern health regions started developing their own archetypes, for instance, in a small venereal clinic. This resulted in a great deal of work to improve the archetypes when the module was implemented. However, trying out both national and local archetypes in this project was important to gain knowledge on how archetypes fit into clinical practice, the quality of the archetypes, and their interrelation with the EPR system.

The paper addresses the importance of introducing a set of core archetypes to succeed with the national consensus work on archetypes in Norway. This is illustrated by emphasising four challenges identified through the national archetype work:

- The process of establishing a well-functioning national archetype organisation, including a network of clinical and technical archetype reviewers
- The interdependence between developing archetypes and the new EPR
- The development of local archetypes, including testing them for clinical practice
- The need to define the total number of archetypes for an EPR to plan future archetype work

NRUA has defined a set of core archetypes to fulfil the generic needs of an EPR system. The original estimate was 30; however, the number was first extended to 50 and then to 200. Establishing core archetypes will increase clinicians' understanding of structured EPR systems, enable the creation of a

prototype EPR system to test out the archetypes, and define the quality of the clinical standards and the new EPR system.

Determining the number of archetypes for an EPR system is important to define how many resources the work requires and to estimate the timeframe for the work. Another important issue is how to distribute the governance of the archetypes between NRUA and system vendors to ensure that the archetypes are as high quality as possible.

6.3 Paper 3: Infrastructuring in Healthcare through the openEHR Architecture

As the main paper of the thesis, this level II paper was published in a special issue of the *Computer Supported Cooperative Work (CSCW)* journal. The extensive paper highlights the interrelations between standardisation, openEHR, and infrastructuring. The topics are addressed through the following research question: What are the challenges of infrastructuring in a large-scale, user-driven standardisation process in healthcare? The main objective of the paper is separated into three sub-questions: How are the openEHR-based archetypes standardised in practice? What is the role of daily clinical practice and existing systems in the process of developing archetypes? How may related but supposedly independent infrastructuring projects shape each other's progress?

The focus is on a gap in the existing CSCW literature regarding power relations in infrastructuring processes (i.e. politics and socio-technical negotiations) and stakeholders with different interests. The interdependencies between archetypes and clinical practice; between clinical and technical relations; and among vendors, system users, and NRUA were discussed in the paper. In addition, the paper examines the role of NRUA and how to balance the need for speeding up the consensus work with the requirements for user-driven processes according to the two-level model. The challenge of recruiting clinicians and keeping them as active archetype reviewers constituted another main issue here. The next subject to address was the power of the installed base in infrastructuring. In the national archetype work, the clinicians brought parts of the installed base from their hospitals (II) to the national consensus work, and it was necessary to establish agreement and collaboration between them.

There was a concern that national archetypes would not fit local requirements and clinical practice, and the importance of testing archetypes for clinical practice to bring them from a theoretical to a practical level was underscored. The collaboration with the openEHR foundation on making the Norwegian and the international archetypes as similar as possible was also discussed, including the risk of compromising Norwegian requirements to fit the focus of the openEHR foundation. Another important issue addressed was the different, but still interdependent, temporal scales of the national archetype work. The temporal challenges of developing the new EPR within project time and developing the

archetype standards over a long-term infrastructuring time were discussed. There was a dilemma detected between the Norwegian CKM of archetypes being a technology-independent II and the need for adjusting archetypes to fit DIPS Arena's requirements because this was the only large-scale EPR system in Norway conforming to the openEHR architecture.

The findings of the paper were as follows: First, it is necessary to establish an extensive socio-technical negotiation between the different actors and define the power balance among them. There is a need for more infrastructuring studies addressing the power relations and politics amongst different actors and how this tension influenced the result of large-scale processes. Second, standardising openEHR archetypes is a large-scale infrastructuring process that depends on a national network of system users. Third, the actor controlling the large-scale infrastructuring process, in this case NRUA, must balance the informal and formal sides of the process. Fourth, there is a closer interrelation between the archetypes and the EPR system than expected. Fifth, it is highly important for the vendor, NRUA, and the system users to test and try out archetypes for clinical practice to improve them and create the best possible clinical standards for Norwegian healthcare.

6.4 Paper 4: How to Involve the Users in the Large-Scale Work with openEHR Archetypes in Norway?

This is the only paper for which I am the solitary author. The previous two papers outlined the importance of user involvement, and this paper goes into more detail on the role of users involved in the work with openEHR archetypes in Norway. The paper systematically examines the documentation of all archetypes in the CKM and conducts a mini quantitative analysis using very simple statistical measurements to get an overview of user involvement in this work.

When scaling up the work with openEHR archetypes from small-scale projects to the national level, the way the work is organised and how users are involved need to be rearranged. This includes a shift in the users' roles from personal to generic, where clinicians become reference users representing an entire medical field. The focus is on the following research questions: Why are so few users involved in the consensus work? What is the role of reference users in this process? How can users align in the consensus work?

There are three main issues discussed in the paper. The first is how users commit to such large-scale consensus processes. Contributing to the national work on their free time and communicating only through the CKM feels less obligating than regular project work. Second, shifting the user role from individual to reference user is demanding for the users. There is seldom more than one representative from each medical field; hence, that person might represent, for instance, all orthopaedics in Norway, which is a huge responsibility. The third issue relates to challenges of aligning the numerous users

interacting across organisational borders to reach consensus on an archetype. The notion of process alignment is introduced to increase the success of a generification process.

Going through all the archetypes in the CKM revealed the following challenges: There are not enough clinicians involved in the national archetype work in Norway: there are fewer clinicians (39) than medical specialties (45). There is an extensive need for both recruiting and keeping clinicians as reviewers to prevent the development of archetypes from being delayed or stopped during the consensus process. The challenges of recruiting participants for the consensus work raise some important questions. Is there a risk of decreased reviewer quality due to challenges in recruiting clinicians? Is it possible that knowing which reviewers are available influences NRUA's choice of participants? Is the workload of the clinical specialists too high because there is only one from each specialty field? There is a need to work continuously with recruiting clinicians for the consensus process. It is important to make them feel committed to the national review process as the reference users representing their fields in this complex national II.

6.5 Balancing Local-Global Tension in Large-Scale Healthcare Standardisation – the openEHR Case

This paper was submitted to the *New Technology Work and Employment* journal in July 2018, and it is at the time of writing in the process of being accepted.

The standardisation of archetypes today is mainly conducted at the national level in Norway in collaboration with the health regions and the openEHR foundation. Since the standardisation was conducted as a collaborative process, including regional, national, and international levels of healthcare, balancing the requirements of the different actors was important to address in addition to how the power relations among the actors influenced the standardisation processes. Hence, the research questions are *How to balance global and local interests in the process of standardising national archetypes, and how do formal and informal standardisation shape this process?*

The regional archetype governance organisation was designed based on two requirements. One was the national request from NRUA to anchor the archetype work within the health regions as well as assisting the national work, and the other was the need for the health regions to increase their competence in regard to developing archetypes and ensure that the archetypes fit local needs. It was, however, necessary to prioritise the national archetype work to complete the standards for the EPR system since without the standards there would be no system to implement in the health regions. Another tension was how to prioritise between national and global requirements since working closely with the openEHR foundation generated a need to balance between the overall need for system-independent archetypes and the national need for archetypes that fit the new EPR system and Norwegian conditions. There is a risk

that prioritising regional requirements generates standards that are too closely related to the EPR system, compromising the role of openEHR archetypes as system-independent standards.

In the work with archetypes, the need to balance between the formal and informal processes of archetype development increases regional, national, international tensions. Since it is necessary to combine formal and informal standardisation processes at all healthcare levels in this large-scale standardisation creates continuous tension in the process. The Norwegian archetype work was the most formalised one world wide including the modelling of archetypes, the steps of the consensus process and the archetype governance organisation. However, two important areas remained informal – namely, the recruitment of reviewers and the actual consensus work in the CKM. The paper underscores the importance of formalising the recruitment process to anchor the archetype work within the healthcare organisations and commit the health regions to free up clinicians for this important standardisation work. However, it is important to keep the actual consensus work flexible and informal for two reasons. First, this allows for communication amongst the actors and between reviewers and NRUA alongside the consensus work, and, second, this enables clinicians to participate in the archetype work through the informal CKM whenever they have time. It was more important to get all available clinicians to participate than to formalise the consensus work.

Due to the complexity of the archetype standardisation, it is important to educate expert users, with both clinical and technical competence, to balance the different requirements of the archetypes and serve as translators between the different types of reviewers focusing on clinical or technical relations and different healthcare levels. Having expert users, as an intermediary link between the closely connected clinical and technical issues of the new EPR system will increase the chance of the infrastructuring process of establishing a regional EPR system becoming a success.

6.6 Summary of the Papers in Relation to Theory and Implications

This section presents an overall summary of the five papers, emphasising the main contribution from the study. It then goes into detail on the four research questions and the associated contribution from each of the papers. In addition, the chapter discussing the implications of the thesis (which follows this one) is closely related to this chapter. The main objective of this thesis is to ‘provide empirical insight into the socio-technical challenges of the large-scale standardisation of an openEHR-based EPR system, focusing particularly on collaboration across professional and institutional boundaries’. I have used information infrastructure as an overall theoretical framework, where the standardisation processes of establishing infrastructures such as the national archetypes, the DIPS Arena EPR system, and the standardised regional EPR system were emphasised. In addition, I analysed the role of the installed base and the diversity of the actors involved. Moreover, I included the socio-technical CSCW as a supplement

to II to zoom in on the ‘nitty-gritty’ details of the interrelation between technology and practice. Standardisation theory was also important to include since standards are considered the ‘backbones’ for interoperability in large-scale IIs, and openEHR represents a standardisation effort per se. The importance of user involvement conforms well to modern standardisation work and is an important part of the openEHR framework (Garde et al. 2007; Beale and Heard 2008; Chen et al. 2009). According to the openEHR architecture, the users can develop archetypes (standards) completely disconnected from EPR systems and local practice. This is touted as one of the main benefits of openEHR and similar systems that adhere to the two-level modelling approach. However, in my PhD study, I challenge this fundamental assertion and in contrast argue for close interrelation and interdependency between the archetypes, the EPR, and local practices.

The interrelation between the archetypes and DIPS Arena was a major concern addressed in several of the papers. Paper 2 suggests using a set of generic core archetypes to design a prototype of an EPR system for clinicians and other system users to test out the archetypes. This is important to understand the potential of such standards and to generate knowledge on how the theoretically designed archetypes might fit clinical requirements. Along similar lines, paper 3 underscores the close interrelation between the development of standards and the system in which they are implemented. The paper elaborates on the importance of providing clinicians with possibilities to test out the archetypes for clinical practice since they struggle to understand the concept and potential of the archetypes. This paper also addresses the temporal scale of designing archetypes and the relation between *project time* – the timeframe of developing the EPR system – and the *infrastructuring time* – the development of system-independent archetype standards. The study underscores that the close interrelation between the EPR system and the archetype standards makes it necessary to design archetypes within the project timeframe of developing the EPR system since this is the only large-scale system in Norway using archetype standards. Hence, there is a need to shift from defining archetype standards as a visionary process within the infrastructuring time to a more efficient standardisation process conforming to today’s requirements as well. It is not beneficial for the health regions to spend time on developing high-quality archetypes for future use if this delays the implementation of the new EPR system. The interrelation between an ICT system, local practice, and users has been addressed in several socio-technical contributions in the IS and CSCW community (see for instance Bowker and Star 2000; Aanestad and Olaussen 2010; Meum, Monteiro, and Ellingsen 2011). Still, the interdependencies between the actors in relation to the emerging international openEHR framework have never before been addressed on a global or national scale. Consequently, it is important to recognise the complex interplay between the EPR, the archetype standards, and local practice in future work with archetypes and the EPR system. The vendor, NRUA, and the users need to gain extensive knowledge of the archetypes, and the archetypes have to evolve

from theoretical to practically useful standards, and this generates a need for the frequent testing of archetypes in, for instance, a test model/prototype.

I have defined four research questions to provide a detailed response to the main objective of the thesis, and I will now go through the research questions, emphasise how the different papers relate to each question, and highlight the associated contributions of each paper.

RQ1: ‘What are the challenges of balancing formal and informal standardisation processes: the case of Norwegian archetype standardisation?’

This research question was addressed in papers 2–5, mainly related to the recruitment of clinicians for the consensus work and how the CKM is used as the collaborative tool for working with archetypes. Paper 2 presents a thorough empirical overview of the archetype work in Norway to the present, highlighting some of the challenges related to the process of large-scale standardisation. Moreover, even if this paper lacks a theoretical chapter, the theory was used implicitly to discuss the findings. Some parts of the archetype work are structured as a formalised standardisation process. This includes the steps of the consensus process, the modelling patterns, and how to define participants for the consensus work as well as the archetype governance organisation coordinating this national infrastructuring process. However, other parts of the process remain informal, such as the recruitment of clinicians as archetype reviewers and the actual consensus work. One of the most important challenges outlined in this paper was the need to plan future work with archetypes due to the interdependency with the EPR system. This included defining the total number of archetypes necessary to complete the EPR system and estimating the resources required to develop a complete set of archetypes. Planning this work was very difficult due to the informal involvement in this work, where clinicians participated if and whenever and they had time, making the process highly unpredictable.

Paper 3 expands on some of the issues from paper 2, including the importance of a formalised archetype governance and archetype processes to gain momentum of the national archetype work. The paper asks if it is possible to formalise all parts of the national archetype standardisation or if there are some elements that should remain informal and flexible. The study shows that user involvement has to be at least partially informal. Involving hundreds of system users in a large-scale standardisation process makes it impossible to use a traditional approach. In the archetype work, the online CKM was used as the informal collaboration tool. The actual consensus work is not formally structured, and even if this can be defined as ‘standardisation *in* an organisation’ (Brunsson, Rasch, and Seidl 2012) in relation to the established governance organisation coordinating the work, this is not a typical standardisation process. Standardisation is usually done *by* an organisation with a defined number of users participating in meetings and project activities (ibid.). Establishing a large-scale network of clinicians to collaborate on national standardisation using only online communication is a new form of collaboration between

clinicians and system users in healthcare standardisation. This collaboration format enables numerous clinicians to participate in the consensus work, and it is a cost-saving, asynchronously flexible solution since there are no travel expenses, and system users can participate whenever they have time. Involving such a large group of clinicians from all over the country in the process of standardising clinical data for an EPR system has never before been done, which made this a very interesting process to follow. In the informal consensus work, reviewers write their comments directly in the CKM for anyone to see, which makes it possible for the reviewers and NRUA to have discussions alongside the process. However, never meeting face-to-face makes it easy to drop out of the work.

Another informal process related to the national archetype work is the recruitment of clinicians. So far, members of NRUA have mainly used networks, colleagues, and private connections to recruit archetype reviewers since there is no formalised anchoring of the archetype work or recruitment of reviewers nationally or regionally. One of the main challenges for clinicians is the lack of compensation for the time they participate in the archetype work. Clinicians have to review archetypes for free in their spare time, which makes it complicated to combine with a busy schedule. There is an ongoing dialogue in the health regions addressing how to include clinicians in the national archetype work to contribute to finishing the standards for DIPS Arena. It is essential for users to be the lead developers in the archetype standardisation to create standards where the content and language conform to clinical practice and the EPR system. In the paper, I underscore the importance of keeping most of the archetype work formalised, and from the findings in my project, I recommend formalising the process of recruiting archetype reviewers for the national work. The health regions need to decide on how to dovetail the archetype work into the workday of clinicians. At the same time, it is important to keep the consensus work informal to enable a large number of system users to participate and for the reviewers to be able to participate in some of the archetype standardisation without engaging in all of it.

In paper 4, I looked closer into the consequences of the informal process of recruiting and keeping clinicians as archetype reviewers. A very simple quantitative analysis was conducted to get an overview of the status of the archetype work, including the number of archetype reviewers in relation to, for example, occupations, health regions, and number of review iterations. The conclusion was that too few clinicians participate in the consensus process (2016); not all of the 45 medical specialties in Norway have even the minimum of one active archetype reviewer, which makes the archetype development process highly vulnerable. Ideally, there should be several clinicians representing each specialty to ensure that the right clinicians are available for the consensus work at all times. There has already been quite a few examples of archetypes for which the consensus work was delayed or even stopped due to a lack of available clinical specialists. The difficulties in recruiting participants for the consensus work generate a risk of compromising the quality of the archetypes to speed up the consensus process. It is important to work continuously on recruiting clinicians and to formalise how to keep the clinicians as

reviewers, including the need for education material and face-to-face interaction between clinicians and NRUA to create a sense of commitment to the consensus work.

In paper 5, I conform to the notion of Hanseth and Bygstad (2015) in addressing the importance of balancing between the formal and informal parts of a standardisation process. The Norwegian archetype work is the most formalised worldwide, with NRUA as the governance organisation coordinating the formalised processes. Two important areas of the archetype work have remained flexible and informal – namely, the recruitment of reviewers and the actual consensus work in the CKM. The paper underscores the importance of formalising the recruitment process and committing the health regions to free up clinicians for this important standardisation work. The paper stresses the relevance of keeping the actual consensus work flexible and informal for two reasons. First, this allows for communication amongst the actors in the consensus work, and, second, flexibility allows for enabling more clinicians to participate in the archetype work whenever they have time, even if this generates an unpredictable process and problems with estimating how long the archetype work will take.

RQ2: ‘What are the roles of users in the emergence of Norwegian archetype standards?’

This issue is the main objectives in papers 3 and 4 and is addressed in papers 2 and 5 as well. User involvement is one of the most important factors for the national archetype work to succeed. In paper 2, the clinicians’ role as the main developers of the archetype standards according to the two-level modelling approach as well as the challenges of recruiting participants for the consensus work were recognised. It was important for clinicians to have an essential role in defining and designing the archetype standards according to the socio-technical approach (see section 3.1.2) as well as the two-level model (see section 4.2.1). The clinicians were intended to play important roles in the archetype work, yet how to fulfil these roles was not defined, and it was unreasonable to expect clinicians to standardise the content of the EPR system in their free time since this was an extensive process to enable interoperability and collaboration within Norwegian healthcare.

Paper 3 elaborates on the need for clinicians to be the main developers of the archetypes. Several researchers have underscored the need to achieve more flexibility in the standardisation process (see section 3.1.3) to make it adaptable across diverse practices. In the archetype work, an unconstrained number of voluntary users were expected to collaborate on leading the designing standards for the EPR content. Still, this is not problem-free: transferring the standardisation process to a large group of users increases the risks for extensive negotiation processes (Latour 1987) with unpredictable outcomes. Scaling the archetype work to the national healthcare level made the consensus work complex and time-consuming, and even if this was an opportunity for an unlimited number of users to design ICT capabilities for themselves, it became difficult for the end-users to participate. The archetypes were complex standards demanding technical as well as clinical knowledge, and only expert users were likely to fully comprehend the standards as well as have time to participate in such voluntary process. Hence,

the notion by Schloeffel (2003) that openEHR archetypes enable putting the clinicians back in the driver seat of development only partially applies for the end-users.

However, after working with archetypes for a while, the need to balance between the extent of user involvement and the efficiency of the archetype standardisation process became apparent. In this project I recognised that involving as many clinicians as possible in the standardisation of archetypes might not be the best solution since this led to a very complex and tedious process. Paper 4 addresses this dilemma further and introduces the notion of reference users as a means to solve this issue. One solution to make the standardisation process more efficient was to establish new roles as reference users, where each reviewer represents a number of others (see section 7.1.2). Brunsson, Rasch, and Seidl (2012) underscore the need to balance between efficiency and a high degree of user participation, and their solution is to limit the number of users in the standardisation processes to only a few participants or a single expert. Pollock and Hyysalo (2014) also state that it is enough to include a few users in standardisation work. However, in the archetype work I found it necessary to include at least one clinician from each medical specialty as reference users. The diversity of the medical specialties is impossible to cover by only one or a few reference users in total. I also recognised that including the clinicians as reference users sometimes made it even more difficult to recruit them since some clinicians viewed being responsible for an entire medical specialty as an immense responsibility. There was also a risk for the standards to become vastly influenced by the persons participating as reference users since it is challenging for users to move from an individual to a reference user position and avoid focusing on local requirements. However, introducing reference users was a means to limit the number of participants in the archetype standardisation and speed up the production of national archetypes in Norway.

Paper 5 addresses the need for expert users in the standardisation of archetypes. The archetypes are new forms of clinical standards, hence both technical and clinical relations must be included in the review process. It is therefore necessary to educate expert users with a combined technical and clinical competence, making them capable of understanding all the aspects of the archetypes and allowing them to be an intermediary link between the clinicians and the technologist participating in the archetype work. In 2009, Leslie et al. recognised that only a few persons have the capability and expertise required to understand both the technical and clinical domains of archetypes, which are by definition technical specifications. The expert users will also have extensive insight into the archetype work at different healthcare levels and be able to negotiate in relation to local–global tensions.

As an overall finding, the informal user role in the archetype work has shifted several times over the years. First, the vendor stated that the system users were able to design their own archetypes whenever they needed one for their clinical work; this was a very flexible model with end-users as the central developers. However, the notion of standardisation and interoperability resulted in organising most of

the archetype work at the national healthcare level. Here clinicians still had a role as main developers, but they had to collaborate with reviewers from all over the country to agree on overall standards, and expert users were introduced into the work. Then the health regions recognised a need to develop modules for DIPS Arena, including the necessary archetypes. These archetypes were designed as a collaboration between a few clinicians from the health regions and the system vendor. Due to the lack of archetype competence both within the health regions as well as with the system vendor, these archetypes demanded extensive work after they were tested for clinical practice. Recently the vendor has taken on increasingly more archetype work; however, it has found that designing high-quality archetypes is complex and demanding, and now it collaborates closely with NRUA on this work. Moreover, the users are now mainly represented as reference users in combination with expert users. The clinicians (end-users) seldom have the chance to participate in such voluntarily work; hence, their roles have been reduced from the intended leaders of the development process to being mere participants in parts of the standardisation. It is difficult to balance between efficient standardisation processes and the need for high-quality standards in a complex heterogeneous healthcare setting including diverging medical specialties without departing from the principle of users controlling the development process.

RQ3: ‘How do power relations influence the development of openEHR and archetype standards: the case of DIPS Arena?’

This is the most important question in papers 3 and 5 and is addressed in paper 2 as well. Paper 2 emphasises some of the power relations in the national archetype work without going into detail on them. The close interrelation between the EPR system and the archetype standardisation generates tension among the infrastructural requirements, such as the balance between waiting for archetypes to be nationally approved before implementing them in DIPS Arena modules and the need to design local archetypes to be able to complete a module to test for clinical practice. Introducing core archetypes to establish a prototype of an openEHR-based EPR system would empower the clinicians since testing out archetypes would increase their knowledge and their possibilities to understand the important requirements to include. The power relation between the health regions is also addressed in this paper since it is important to distribute the workload of the archetype development equally amongst the health regions that will use the archetypes to result in archetypes that fit all local requirements.

In paper 3, the main focus was on the power relations in infrastructuring processes, including the politics and socio-technical negotiations amongst the different interests of the stakeholders. In the national archetype work, this included the interdependences between all the actors in the archetype standardisation. Power relations are important to address since the larger the II gets, the more important the role power relations play in the outcome of infrastructuring since the interrelations amongst the actors vastly influence the collaboration between them. Since this project addresses two different large-scale standardisation processes, it became even more important to analyse how actors, interests, and

negotiation power came into play than in less complex infrastructuring processes. It was also important to discuss the tension generated by the need for close collaboration between technical and clinical resources when designing and approving national archetypes since there was no tradition for close collaboration between these occupations in healthcare standardisation. Another important actor to consider in this standardisation process was the installed base. The study detected a number of tensions between the existing EPR system and the new one as the two systems had to coexist for years. One important issue to consider was the possibility of the new EPR system being limited by the need to collaborate with the existing one. There were also power tensions registered between different installed bases since the archetype standardisation did not build on one installed base but instead upon fragments of all the installed bases from the actors involved. The way the power struggles played out vastly influenced and even decided the outcome of the standardisation processes in relation to how the work was organised and the end-result of the archetypes as well as the final structure of the clinical governance organisation. All these potential power struggles called for establishing a high-quality governance organisation to coordinate the standardisation and negotiate between different requirements. Coordinating users from different healthcare levels through the online tool CKM was both a challenging and unpredictable process but necessary for the flexibility of this work. Another question related to the balance between the system and the standards is how closely the vendor should be involved in the standardisation of system-independent archetypes. To prevent power struggles, it is necessary to include extensive collaboration and boundary work to define the roles of the different actors. Which archetypes require approval through a national consensus process, and when is it sufficient for the vendor to create system-specific standards? What should the balance between the clinicians, vendors, and NRUA be in the consensus process? Moreover, how should the tension between these actors be addressed?

It was also important to address the tension between the local and global requirements of the archetype work, and, in paper 5, balancing between regional, national, and international requirements was one of the main objectives. The paper outlines the national archetype organisation's responsibility for balancing the needs stemming from both the regional archetype governance and the international work with archetypes in the openEHR foundation. This relates to one of the key challenges in II: how to balance local use and heterogeneity against uniform solutions (Bowker and Star 2000), including the tension between global standardisation and the need for designing flexible local standards. One important dilemma is the need to design archetypes that fit the regional and national requirements of the new EPR system and the regional archetype organisation's need to contribute extensively in the national archetype work since it is not possible to complete the new EPR system without finishing the necessary archetypes for the system. Another issue was the close collaboration between NRUA and the openEHR foundation. On one side, this contributed to raising the quality of the Norwegian archetypes since identical archetypes went through parallel national and international consensus processes. NRUA also

had a vast influence on the international archetype work since this was the most formalised archetype work in the world to date and the only CKM collaborating actively with the openEHR CKM. However, on the other side, the requirements from openEHR demanded interoperable generic archetypes set to fit any EPR system, which did not conform to the need to include national requirements and ensure that the archetypes matched the demands of the system.

RQ4: ‘Why choose a fragmented governance structure for a regional EPR system in Norway, and what are the challenges associated with such solution?’

The paper discusses the complexity of establishing clinical healthcare governance for a regional EPR system. The challenges were closely related to the power relations amongst the heterogeneous actors involved in the II and the diverging requirements for the organisation set to govern a large-scale information infrastructure. Regionalising an ICT portfolio is challenging and strategies for handling regional disagreements and revising the existing as well as adding new standards are important to work out. After years of discussing the shape and content of such organisation, a fragmented governance solution was suggested. This model resembled the polycentric governance model described by Constantinides and Barrett (2014) (see section 3.2.2). The regional clinical governance model conformed to opportunities for organising several governing units at diverging scales instead of one monocentric one. Introducing a fragmented governance model was a compromise between the health trusts’ desire to govern their own EPR and the health authorities’ request for an overall governance unit. The fragmented governance model was not explicitly defined as a polycentric governance model even though I recognised a number of similarities with such model. In a polycentric governance model, any group of individuals facing a collective problem is able to address that problem in whatever way it sees fit. In the North Norwegian health region, the health authorities defined the governance model as well as the number of governance organisations, including their focus areas. The notion of self-governing, independent units was important in the polycentric governance; however, in the regional governance model, even if the different governance units had some autonomy, their mandate was defined by the health region.

Notably, there were several concerns related to implementing a fragmented governance solution. Such solution demanded close collaboration and clearly defined borders between the different governance organisations involved. Another risk detected was how to make all health trusts consider, for example, an EPR governance situated in UNN to be a regional organisation and how to prevent the governance from focusing too much on local concerns. Another worry was the fact that the fragmented governance solution resulted in nine governance organisations at three healthcare levels governing parts of the new EPR system, generating a risk for slow and tedious governance processes related to DIPS Arena. In addition, there was no overall organisation with total oversight of the EPR system, and no one had the final say if disagreements could not be solved. A fragmented governance solution demanded constant

negotiation between organisations that were not used to having to collaborate, for instance, between the four health trusts and between clinical and technical governance organisations in this large-scale II.

7 Implications

7.1 Practical Implications

7.1.1 Interdependencies between system design and archetype standardisation

The main objective of the thesis relates to the interdependency between system design and archetype standardisation. From a medical informatics perspective (such as openEHR or similar) (see e.g. Coiera 2009; Arts et al. 2007), the construction of new technology is the dominant focus (see e.g. Lopez and Blobel 2009), whereupon the users and organisations have to adjust to the technological requirements. This stands in contrast to fields that mainly emphasise organisational issues and user perspectives (see e.g. Brunsson, Rasch, and Seidl 2012; Orlikowski and Iacono 2001; Aanestad and Olaussen 2010). DIPS Arena is an example of a system in which the technological solution will provide changes affecting both the system users and the surrounding organisation since new functionality, such as decision support, influences the organisation of patient trajectories and how clinicians work. For instance, to facilitate decision support it is necessary to establish interoperability amongst the systems included in patient treatment, such as EPR, medication systems, and electronic charts, to allow the decision support system to extract the necessary information about the patient from all involved systems. In recent years, healthcare standardisation in the medical informatics field has shifted from a top-down to a more bottom-up socio-technical approach, focusing increasingly more on the organisation and the users in addition to the technology itself (Berg and Toussaint 2003; Berg 1999). This correlates well with the findings of this study related to the importance of close connections between the new EPR system and the standardisation of clinical practice.

In the openEHR system, the two-level model with the ability to separate the technical and clinical parts of the EPR system is a fundamental architecture. This approach enables clinicians to work with the archetype standards independent of the reference models and the functionalities of the EPR system (Kalra 2006; Garde et al. 2007; Chen et al. 2009). My study shows that this conforms well to the shift towards socio-technical thinking since the model places clinicians in charge of the archetype standardisation. However, it is not that simple. The archetypes are complex technical standards, and since the work with archetypes in Norway is new, it is essential to combine technical and clinical competence to develop high-quality information models. One interesting question relates to whether it is even possible to separate the development of the system and the standardisation of the archetypes, as

the two-level model presents, due to the identified interrelations between the technical and clinical requirements. As an example of this interdependency, in 2016 the vendor started to design archetypes of its own related to the development of modules for the new EPR system. This was conducted in projects where one or a few clinicians were involved. The reason why the vendor started developing archetypes was a result of the cumbersome and complex national consensus process. However, after trying out these archetypes for clinical practices, the vendor recognised that it was more challenging to design high-quality archetypes than expected. The vendor did not have extensive knowledge on archetype modelling and had included only a few clinicians, generating the need for comprehensive work to change the archetypes after they had been developed and implemented. This resulted in the extensive use of time and money in finishing the archetypes, and DIPS AS recognised that it was crucial to collaborate with NRUA to ensure high-quality archetypes. Recently the vendor has begun defining the requirements for an archetype and then sends it to NRUA for quality improvement through the consensus process.

The need for close collaboration between the archetype work and the system development was first recognised in paper 2, when reviewers stated the need for testing the archetypes in clinical practice by designing a prototype of an openEHR-based EPR system to grasp the concept of archetypes and how to use these standards in the EPR system. There were some infrastructuring challenges related to developing both the new EPR system and the archetypes at the same time, and an interdependency between the processes was detected in this project. It was impossible to finish the EPR system without the archetypes, and it was demanding to design high-quality archetypes without a system to test them out in clinical practice. Paper 3 addressed this issue further when I connected this interrelation to the temporal infrastructuring challenges of balancing ‘infrastructuring time’ and ‘project time’, introduced by Karasti, Baker, and Millerand (2010). I recognised how the ‘project time’ of developing the EPR system strongly influenced the ‘infrastructuring time’ of establishing archetype standards. Karasti, Baker, and Millerand (2010) argue that development processes must be aware of multiple temporalities, including the importance of producing both short-term products as well as demonstrating long-term viability. In the work with archetypes and the EPR system, this was illustrated as such: in the long term, the users had the possibility to be in charge of structuring and standardising the content of the archetype standards for the EPR themselves. However, from the short-term perspective, the EPR system was dependent on these standards being produced as fast as possible to finish the new EPR system. This required the inclusion of qualified expert users in the standardisation processes, compromising the role of the end-users.

This thesis illustrates that it is important to establish a closer interrelation between the archetypes and the EPR system in which they are to be used than the two-level model describes. This interrelation may have been extra important in this study since both the archetypes and the EPR system were developed

simultaneously. However, closer interdependencies generate a risk of ending up with archetypes that are too system-specific. This challenges the notions of openEHR archetypes being system-independent and suitable for all openEHR-based EPR systems.

7.1.2 The importance of balancing between legitimacy (many users) and progress (few users)

Standardisation organisations face the challenge of endowing the rules they develop with legitimacy, especially since they do not possess any legal authority (Brunsson, Rasch, and Seidl 2012). Without legitimacy, adopters are unlikely to follow a standard. One way to achieve legitimacy is to include different stakeholders in developing a standard and encourage consensus amongst them (ibid.). For instance, in the work with national archetypes numerous clinicians are included to ensure the development of high-quality standards useful for clinical practice, including a maximum dataset of clinical knowledge. However, after evaluating the archetype work thus far, I started to question whether including as many clinicians as possible was the best solution. Tamm Hallström (2008) address the risk of reducing the efficiency of the standard-setting process by including too many users since reaching consensus becomes very difficult. In the Norwegian archetype standardisation, some archetypes took months or even years to be nationally approved due to disagreements amongst the reviewers on the content and structure of the standards. Brunsson, Rasch, and Seidl (2012) likewise argue for limiting the number of users, stating that involving too many users slows down the standardisation process. They suggest including only the users essential to ensure the quality of the standards. The need to balance between including as many users as possible and the efficiency of the process was addressed in papers 2–5. Ideally, there would be several reviewers from each medical specialty involved in the national archetype standardisation to ensure that all medical field were covered and that relevant reviewers were available at all times. As of the time of writing (2016), not all of the 45 medical specialties in Norway have even the minimum of one active archetype reviewer. These missing reviewers for certain medical specialties may have serious consequences since a part of the consensus process is to define which occupations need to be represented to approve an archetype. Problems occur if for instance an archetype requires a paediatrician to reach consensus, and there are no paediatricians available as reviewers; then the process stops until either a paediatrician is recruited, or the archetype is approved without that particular competence involved, risking compromising the archetype's quality. In the thesis, I found that one of the most extensive challenges in the national archetype work was recruiting as many clinicians as reviewers. Another important issue was how to speed up the archetype consensus work to provide the necessary standards for DIPS Arena. Both challenges related to the difficulties of recruiting and keeping clinicians as archetype reviewers and the time limit related to the new EPR system. NRUA shifted its strategy from involving as many clinicians as possible to focusing on recruiting reference

users representing the different medical fields and other user groups. Brunsson, Rasch, and Seidl (2012) state that since there is a need to balance between efficiency and a high degree of user participation, organisations need to limit the user involvement in the standardisation processes to a few representatives with similar interests and ideas, sometimes even to a single expert (ibid.). However, I recognised that introducing the role as reference users may increase the challenges of recruiting clinicians since it can feel like an immense responsibility to be responsible for all the content related to a given medical field. Introducing reference users generates a risk that the standardisation may become vastly influenced by only a few reviewers since it is difficult for clinicians to take on the perspective of the whole medical field instead of focusing on local needs and personal interests. Thus, such a change in the makeup of participants (in terms of number and diversity) can result in changes in the content of the respective standards. However, introducing reference users was a means to limit the number of participants in the archetype standardisation and design a more efficient archetype consensus process. There is a need to focus on how to gain archetype standards of the highest quality by balancing between the number of reviewers involved and the need to speed up the development process. Still there is a need for keeping up the extensive recruitment process to ensure that there are enough clinicians available at all times.

7.1.3 The emergence of new user roles

Formal standardisation processes are often complex and time-consuming (Brunswick, Rodriguez, and Warcham 2014); this has required a shift towards more informal standardisation processes since they are more efficient due to more frequent meetings and communication between participants. These organisations are flexible and open to new members; in addition, it is possible for anybody to participate as guests or become members, and the standards developed are often available to members for free (ibid.). This informal standardisation format seems to be an ideal way of working with archetype standards and involving numerous users in the work. However, such an informal process generates challenges related to recruiting and keeping system users as archetype reviewers; this was addressed in papers 2–5. Recruiting clinicians is one of the main objectives since this is a challenging process essential for the success of the archetype work. One of the main reasons is a lack of formalising the way health regions recruit clinicians for archetype standardisation. The importance of clinicians participating in designing these standards for clinical practice is recognised through the two-level model of openEHR as well as the socio-technical standardisation approach. However, the importance of such user involvement, including a number of clinicians, is not fully recognised yet in the health regions as they have no strategy for ensuring ample clinicians for this work. As a result, clinicians participate in the archetype work on a voluntarily basis, without any compensation for the time they spend. This makes the recruitment process challenging, since most clinicians have a very busy schedule and do not want or have time to work for free. A number of clinicians expressed interest in participating in the national archetype work if they were to be allotted some time to do the job. As their involvement is highly

recommended for the standardisation to succeed, it is necessary to draw attention to factors fostering motivation for participation. One important reason why clinicians have to participate in the archetype work for free is the lack of anchoring the archetype work both at national and regional healthcare levels in Norway. Nationally, the NDE has not defined what standards to use for interoperability and system communication in Norwegian healthcare. Hence, different systems conform to diverging standards, requiring complex integrations for interoperability. Without a national anchoring, it is difficult to impose the archetype work on the health regions since they do not know if these standards will be used over the long term in the future. However, since three of four health regions have purchased an EPR system conforming to the archetype standards, this should be motivation enough for the health regions to organise clinicians to contribute to the work.

NRUA has strongly recommended each health region to establish regional archetype governance; still, in 2018, the only region with such governance up and running was the North Norwegian Health Authority. However, even in Northern Norway, with such organisation formalised, anchoring the archetype work at a regional healthcare level was very challenging since the health region prioritised assignments that were more urgent. There is an ongoing dialogue in the health region on how to involve clinicians in the best possible way to finish DIPS Arena, including the archetypes, since a socio-technical process with users as lead developers was required to ensure resulting archetypes that include content and language relevant for clinical practice. So far, the recruitment process has been quite random, mainly based on networks and personal connections. In the thesis, I question whether such an informal recruitment process is the right approach for the national standardisation of clinical information for an EPR system. In addition, it is important to establish a strategy for recruiting archetype reviewers and for retaining clinicians as reviewers. This included the provision of education materials on the complex archetype standards as well as face-to-face interaction between clinicians, NRUA, and other reviewers for an improved understanding of the standards and a stronger commitment to the standardisation process. Today reviewers never meet face-to-face; they communicate with NRUA and other reviewers only through the online CKM. This makes the commitment to the archetype standardisation weaker than when taking part in projects with the rest of the project participants face-to-face and engaging in a certain percentage of their time. In the archetype work, the reviewers can conduct their reviews when they please. This informal participation enables numerous clinicians to participate as reviewers; however, it generates a very unpredictable consensus process since it is impossible to know the number and occupations of the available reviewers from archetype to archetype. Consequentially, it becomes demanding to estimate the time it will take to approve one archetype and impossible to estimate the timeframe for designing all archetypes necessary for the EPR system.

The outline of the archetypes and the CKM have quite a technical design. Hence, it is very challenging for clinicians to fully comprehend the archetype concept. Leslie et al. (2009) state in regard to the

clinicians: ‘We cannot realistically expect them to invest time, money and effort to become technically competent in order that they can engage with technicians, information architects, vendors and standards organisations’. Even when NRUA tried to facilitate the consensus to make it possible for clinicians to focus strictly on clinical relations, they still found the archetypes highly complex to work with. They also reported that it was necessary to understand some of the technical relation to grasp the complexity of the archetype standards. It was necessary to establish close collaboration between clinicians and technologists to garner a complete understanding of the archetypes.

In addition to including end-users, educating a group of expert users with a combined technical and clinical competence to have an intermediary role between end-users and technologists was important. In 2009, Leslie et al. recognised that only a few persons have the capability and expertise required to understand both the technical and clinical domains of the archetypes, which are by definition technical specifications. To address this problem, the North Norwegian Health Authority started educating employees from the archetype governance with a clinical background to become information architects with the necessary competence described by Leslie et al. (2009). The archetype governance organisation was established in 2017, and the focus areas of this governance were to collaborate closely with NRUA on recruiting clinicians for the archetype work and assisting the regional project FRESK³ as well as to establish close collaboration between the national and the regional archetype work. This includes assisting the national work (recruiting participants, performing reviews, translating, and modelling) as well as establishing close collaboration with the local and regional EPR projects to bring regional needs to the national archetype work and to collaborate with process and information architects in the regional technical governance. The success of the collaborative work here strongly influences the archetype work and the implementation of the new EPR system in the region.

It is very important to focus on the new evolving user roles; first is the need to formalise and anchor the archetype development process better regionally and nationally to free up clinical resources for participation in the standardisation. Second, users need to be the main developers of clinical standards as either individual or reference users. In the national archetype work it seems necessary to introduce reference users to speed up the consensus work; however, it is important to have enough representatives from each medical field to ensure that there is someone available at all times and to reduce the workload of each reference user. Third, it is important to define expert user roles to work as intermediary translators and negotiators between the technology/technologists and the clinicians.

³ FREmtidens System i Klinikken (FRESK; future systems of the clinic project) 2017–2022 is aimed to provide more optimal treatment for patients in the North Norwegian Health Authority by improving the interaction between DIPS Arena and MetaVision. FRESK has four focus areas: patient pathways, structured patient journals, DIPS Arena implementation, and MetaVision implementation.

In such intermediary organisation, several power relations were detected, these are addressed in the next section.

7.1.4 The influence of power relations on large-scale standardisation processes

Power relations were traditionally not addressed much in IS standardisation (Pollock and Williams 2010; Aanestad and Jensen 2011; Pipek and Wulf 2009). Within medical informatics, the main focus is on how the technological solution can improve healthcare practice rather unproblematic (Leonardi 2009; Blobel, Goossen, and Brochhausen 2014). Organisations and users are expected to make the necessary adjustments for the new technology to succeed. In contrast, from an organisational perspective, the organisation is at centre stage, and the technology and users have to adjust accordingly to cohere with the organisational requirements. Orlikowski and Iacono (2001) outline how the IS field has taken information technology for granted, focusing on the context in which the technology is used, without defining the actual technological solution or how the technology will influence the organisation after the implementation. From a management perspective, the power is centralised at the top, and this top-down approach is designed as a hierarchy with a clearly defined path of authority (Stream 2010). Here the stakeholders agree on standard specifications in formal organisations (Brunsson, Rasch, and Seidl 2012). Such standards can be defined as terminology standards designed to ensure the safe and secure exchange of information across organisational and professional borders (Timmermanns and Berg 2003), and they are connected to the surrounding architecture and the overall design. Also in the socio-technical approach and CSCW, authors such as Aanestad and Jensen (2011), Pipek, and Wulf (2009) emphasised the importance of politics and power relations in II without including such subjects much in their own studies. The focus has been on small-scale workplace studies including a limited number of users (Schmidt and Bannon 1992).

Power relations was not one of the original focus areas for this PhD; however, analysing the relations between the different actors in the standardisation processes caused power to become one of the main issues address in this thesis in order to comprehend the outcome of such complex standardisation processes. In the regional standardisation of the existing EPR system addressed in paper 1, the relation between the autonomy of the different health trusts and the overall regional requirement vastly influenced the standardisation process and the process of developing a regional clinical governance organisation. Vast requirements for negotiation between the local needs for flexibility and individuality and the global needs for efficiency and comparability were detected.

Paper 3 emphasises power relations as one of the main focus areas. An element of larger-scale, policy-imbued projects is how new technology and associated new practices bring about disagreements, controversies, and negotiations (Latour 1987). Hence, it is important for IS and CSCW researchers to

address how power relations and policy issues may shape large-scale workplace studies. Since this project address two large-scale standardisation processes including numerous users, it was important to analyse how interests and negotiation powers came into play in the infrastructuring processes. This included the power each stakeholder possessed and how the power was exercised in the negotiation processes and influenced the outcome of the negotiation processes. This was particularly important when it was necessary to address both the technical and clinical relations of the archetypes simultaneously, and reviewers from different occupations had to collaborate closely. In addition, the tension between national and regional requirements affected the construction of, and the work within, the regional archetype governance. Focusing too much on regional requirements and requests from the health region compromised the contribution to the national processes. Even if the organisation was a part of the regional governance structure, prioritising national requirements was crucial since the national archetypes were the clinical standards for the new EPR system. Slowing down the national archetype work consequentially delayed the implementation of DIPS Arena.

Another power relation was between the existing EPR (the installed base) and the new one. Since these IIs had to coexist for years, it was necessary to address how to do this in a seamless way for the system users. This resulted in the old EPR hampering the new one since it was impossible to exploit the potential of DIPS Arena as long as the installed base had to be included. Implementing a compromised version of the EPR system without features such as decision and process support resulted in users being dissatisfied with the solution and even more reluctant to participate in the archetype standardisation. When standardising in healthcare, it is important to pay close attention to the installed base (Hanseth and Lyytinen 2010; Hanseth and Monteiro 1998; Bowker and Star 2000). The existing system is the basis for the new one since the work practice is deeply embedded in the system. Unlike the EPR system, the archetype work did not build directly on an existing installed base. As stated by Karasti (2014), in today's connected world, we can hardly avoid linking into some existing IIs. In this large-scale standardisation, all the reviewers brought in parts of their work processes (installed bases) to the consensus process, making extensive negotiation between the different installed bases an important tension to address.

The way the power struggles in the standardisation processes played out vastly influenced and even decided the outcome of the standardisations and the governance structures. Such work required close collaboration and boundary work between numerous actors; hence, the national archetype work was a slowly evolving infrastructuring process. The larger the II gets, and the more actors that are involved, the more important power relations and politics are to address. The participants in standardisation processes are subjective actors that try to shape the standards to suit their interests (Brunsson, Rasch, and Seidl 2012). Thus, constant negotiation is important to establish a balance between the different actors involved, such as in relation to the interdependences of the EPR system and the archetype

standardisation; amongst the different user groups in the review process; and between NRUA, the vendor, and the reviewers in the consensus process.

Coiera (2009) pointed at the constant mismatch between the local and national goals. This relates to one of the key challenges in II: how to balance local use and heterogeneity against uniform solutions and, at the same time, take into account how these extremes transform and influence each other (Bowker and Star 2000). Hence, the tension between requirements from different healthcare levels and how NRUA had to balance global and regional requirements in the national archetype work was addressed in paper 5. It is important to address relations between local and global interests in an information infrastructure especially at a regional or national healthcare level since global standards both shape and are shaped by local work practices (Ellingsen, Monteiro, and Munkvold 2007). The question is whether a standard should be adapted to the local context or if the local context should change to fit the global requirements. It is important to identify the power relations amongst the different actors in large-scale information infrastructure to understand the outcome of such processes. The most important tensions detected in this study were amongst the different actors in the archetype consensus, between regional and local requirements in the regional standardisation, between the installed base and the new EPR, and amongst different healthcare levels in the archetype work.

Large-scale standardisation processes demand an extensive governance organisation to run the negotiation processes amongst the numerous actors in the process. Challenges related to establishing such governance as part of a regionalisation process are addressed in the following section.

7.1.5 Fragmented governance for large-scale solutions

The complexity of establishing a governance organisation for a health region is addressed in paper 1, stressing the challenges of designing a fragmented governance structure for a regional EPR system. However, establishing a well-functioning governance structure in the North Norwegian health region was crucial to enable continuing the standardisation of this large-scale information infrastructure after the project period was over. Governance theory traditionally emphasises a top-down ICT governance (Weill and Ross 2004); however, such structure has not proven to be efficient for heterogeneous healthcare practices (Constantinides and Barrett 2014; McGinnis 1999). Therefore, a shift towards a more bottom-up, socio-technical governance structure including a focus on the dynamic interactions between technical and social elements was required (Constantinides and Barrett 2014). There has been an increased focus on addressing the complexity of ICT governance and the challenges of governing regional information infrastructures through an interorganisational governance lens focusing on interoperability and standardisation challenges, including information sharing amongst healthcare organisations with diverging goals and organisational politics involving stakeholders with different interests (Dahlberg and Helin 2014).

These issues have made power relations an important topic to address as well as the balance between regional requirements and local autonomy. Hence, Constantinides and Barrett (2014), suggest a polycentric governance approach where different stakeholders are engaged in the governance processes. The polycentric governance approach is a bottom-up approach where it is possible to organise multiple independent governing entities at different healthcare levels instead of one monocentric governance unit (McGinnis 1999). Polycentric governance enables distributed decision-making across organisational layers and different stakeholders – each layer deals with similar matters at different scales and detail levels (ibid.). This complex approach demands considerable time and effort spent on negotiating acceptable solutions for all the actors involved (Latour 1995). It seems almost impossible to agree on adequate governance structures for complex IIs in healthcare due to the heterogeneity of interests and actors involved (Constantinides and Barret 2014). To grasp the challenges of governing such IIs, it is crucial to understand the various interests and associated mechanisms involved and how these play out over time. The fragmented governance structure in which each health trust was responsible for the regional governance of a part of the ICT solution in the North Norwegian Health Authority was a direct consequence of power relations and politics within the health region and the importance for the health trusts to keep some local autonomy in the regional collaboration. Important issues to address relate to the amount of influence of the different health trusts in a regional solution, and how to prevent the health trust responsible for governing, for example, the EPR from influencing the work too much. However, the most important problem to solve was how to get all health trusts to accept a regional solution situated within one of the health trusts. One solution was to include employees from all health trusts in the regional governance.

Introducing a fragmented governance structure generated a lack of total oversight of the EPR system and an extensive need for collaboration and constant negotiation between health trusts that traditionally do not collaborate much. Some of the consequences of fragmenting the governance structure relate to making governance processes related to DIPS Arena slow and tedious, and when conflicts arise between the governances, there is no overall authority to make final decisions. Moreover, even if the region has established a governance advisory board to have oversight over all the governance organisations, the authority of this board is not well defined, and it is difficult for such a board meeting once a month to gain a meaningful overview of all relevant activities in all the governance organisations involved. In future projects, it is important to have an extensive focus on establishing governance organisations at an early stage of the standardisation work, defining the decision model and structure of such governance and how to collaborate amongst the different governance organisations.

7.2 Theoretical Implications

7.2.1 The dynamics between the formal and informal in standardisation processes

Hanseth and Bygstad (2015) highlight the importance of a balance between the formal and the informal standardisation processes and the need to have one constant part as well as to enable flexible standardisation in other parts of an infrastructure. For instance, the work with archetypes started similarly to the standardisation of the internet, as described by Hanseth, Monteiro, and Hatling (1996), where the internet is developed layer by layer from the bottom up while at the same time the standards for the internet as a whole are evolving. When standards at one level stabilise, this layer serves as a platform for the experimental development of services and standards at the next level (*ibid.*). In the two-level model, the reference model was a stable entity developed by system designers, while the second level, including archetype development, was run by clinicians (see e.g. Chen et al. 2009). In the archetype work the consensus process was defined as an informal flexible process; where some of the standards had to be designed nationally as an overall core for the EPR system, others could be designed by clinicians ‘on the fly’ whenever they needed archetype standards. However, lately, the archetype work has shifted from a flexible informal archetype process enabling clinicians to design archetypes for their own work practice towards more formalised processes to ensure that the resulting archetypes conform to national requirements for interoperability. Even though the clinicians were promised to be in the ‘driver’s seat’ of the archetype development, this role was compromised when the complexity of archetype design became apparent. In addition, the need for an organisation like NRUA to take on a formalised role in controlling and governing the process (Garde et al. 2007) compromised the role of the end-users.

Traditionally standardisation in healthcare has followed well-defined, formalised processes run by formal standardisation organisations (Blind 2002). ISO defines a standard as ‘A document, established by consensus, approved by a recognised body, that provides for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context’ (ISO 2001). As an example, the standardisation of archetypes for openEHR-based EPR systems is defined as a formal standardisation process (Leslie et al. 2009; Chen and Klein 2007; Garde et al. 2007). A formal standardisation process includes a series of stages, such as definition, implementation, diffusion, and use, led in a top-down manner, involving all relevant stakeholders (Hanseth and Bygstad 2015). In the archetype work, most of the processes are formally defined, such as how to model the archetypes, the steps of the consensus and approval process, how to define the need for clinicians for each archetype, and what technical tools to use to design the standards.

However, formal standardisation processes are viewed as time-consuming and complex (Brunswicker, Rodriguez, and Warcham 2014), hence, an increased need for informal standardisation has evolved. Informal standards are established in work places through ad hoc solutions and non-profit organisations (ibid.), including informal dynamics between the actors, organisations of standardisation processes, and flexible solutions (Brunswicker, Rodriguez, and Warcham 2014). This relates to the growing number of standards and the need for connections and interdependencies between them (Brunsson, Rasch, and Seidl 2012; Hanseth and Bygstad 2015). This also conforms to the consensus work of approving openEHR archetypes, where reviewers from different occupations and backgrounds use an online collaboration tool (CKM) to discuss the content and modelling of the archetype standards amongst themselves as well as with NRUA. This work is not formally structured, and even though it is possible to define the process as standardisation within an organisation (Brunsson, Rasch, and Seidl 2012) since there is an established governance organisation coordinating the work, this is not a typical standardisation process. In addition, the way the reviewers work differs from traditional standardisation organisations since it is possible to work in the online CKM whenever the participants have time. The CKM is both a collaboration tool and a repository for storing all information about the national archetypes useful for research related to archetypes as well as an easy source for healthcare providers to extract relevant data to evaluate the archetype work. Using the CKM for collaboration makes it possible for clinicians to participate in the archetype work whenever they have time. Since they contribute to the consensus process on a voluntary basis, in addition to their daily work, their situations vary in regards to if and when they have time to participate, how often they contribute as reviewers, and how much time they prioritise to spend as reviewers. This is possible since the archetype work is defined as a flexible infrastructure open to numerous users (Bowker and Star 2000). This flexibility, however, compromises the predictability of a more formalised review process where the timeframe and resource use can be defined beforehand.

Recruiting clinicians for the archetype work is also defined as an informal standardisation process. In papers 3 and 4, I argue for extensive user involvement in the archetype standardisation and show how the recruitment of clinicians is an informal process where members of NRUA have mainly used personal contacts and networks since there is no formal collaboration between NRUA and the health regions on how to free up clinicians to participate in this work. In the North Norwegian Health Authority, there was an attempt to formalise the recruitment process in 2014, where the regional archetype group sent out requests through the department managers at the university hospital in North Norway requesting clinical resources. About 30% were positive about participating, however very few actually contributed when review requests were sent out. An important question to address is how to balance between formal and informal standardisation in large-scale archetype work. In the thesis, I argue that recruiting clinicians for the archetype work is a process that needs to be formalised, making the health regions take

responsibility for freeing up resources for this national effort. However, the actual consensus process needs to be informal since it is important to have flexible collaboration and communication, where clinicians can discuss the archetypes with other reviewers as well as NRUA. In addition, it is better to have an informal process where clinicians can participate whenever they have time since some participation is better than none at all.

Formal standardisation processes may suffer major drawbacks, such as lengthy consensus processes and a lack of market orientation (Brunswicker, Rodriguez, and Warcham 2014). An illustration of this is the shift of the vendor from enabling clinicians to design the national archetypes to taking on more of the archetype design to speed up the process. The EPR vendor designing increasingly more of the archetypes creates a risk that the archetypes may become too vendor-specific, when the main point of openEHR is to have system-independent standards. Another risk is that the archetypes designed by the system vendor may not fit clinical requirements as well as the archetypes designed by the clinicians themselves. To end up with standards that conform to the clinical requirements is one of the major arguments for increased user involvement in establishing healthcare standards (Berg 1999; Bowker and Star 2000). Even if there are some informal elements in the archetype standardisation, the national work with standards in Norway is the most formalised archetype standardisation in the world, including more than 500 system users. Despite the limited number of clinicians participating, there is no other country where so many clinicians and system users are involved in the archetype consensus work as in Norway. In fact, in Germany, they are working on establishing a CKM based on the Norwegian model.

It is important to find the best possible balance between informal and formal standardisation; this is necessary to design archetype standards for a large-scale information infrastructure with hundreds of participants. It is not possible to include 500 system users in a traditional standardisation organisation contributing regularly to the work. This makes the online CKM a good option for collaboration between large numbers of system users and an informal method of user involvement necessary.

7.2.2 Expanding the scope in workplace studies

The main theoretical framework of the thesis is the information infrastructure. In addition, I have used an extensive amount of CSCW literature since this field focuses on zooming in on work processes. It was very useful to get into the details of some of the processes to understand the interdependencies amongst the different actors in the standardisation processes as well as the power relations between them. CSCW emphasises workplace studies to provide rich and detailed insights on collaborative healthcare work (Schmidt and Bannon 1992) focusing on social interactions and the users' perspective. The framework is therefore suitable to provide a detailed view of why things develop the way they do and what makes large-scale standardisation processes challenging.

However, at the same time, the scale and duration of my project has made such an approach challenging to include. Many CSCW studies look at a limited number of users in one or a few contexts; only a few have addressed care and information flows across institutional boundaries, and even fewer have looked at the same phenomena in multiple settings (Greenhalgh et al. 2009). Until recently, the openEHR-based EPR systems had only been implemented in small-scale projects at a local or regional healthcare level. One example described by Chen et al. (2009) was the integration of the EPR system and the guideline system for lymphoma treatment using archetypes (ibid.). Buck et al. (2009) describe the modelling of a prototype neonatology EPR using openEHR archetypes for two different departments (Buck et al. 2009). However, large-scale EPR systems such as DIPS Arena and national work such as the archetype standardisation in Norway including numerous practices and professions (Berg 1999; Winthereik and Vikkelsø 2005) suggest a need for a focus different from that traditionally found in workplace studies. Such large-scale standardisation processes influence and shape work-practice, including different roles for different actors in various contexts. The outcome of such complex technology is highly demanding to predict (Ellingsen and Monteiro 2006); hence, there is a need for the large-scale evaluation of healthcare systems, challenging the traditional workplace studies of CSCW. Some studies address change processes, such as Hardstone et al. (2004) and Morrison et al. (2011); however, these studies address changes only over short periods. Some studies have tried shifting the focus in workplace studies to include different stakeholders, such as project managers, vendors, and key users (see e.g. Granlien and Hertzum 2009).

Accordingly, CSCW researchers should take the opportunity to focus on larger issues of policymaking and technology selection, addressing, for instance, the interconnection between local and global requirements. As an example, in Norwegian healthcare, the focus on interoperability and communication between the EPR systems and the overall goal of Whitepaper 9 (i.e. to have one journal for each citizen) demands a large-scale II; therefore, it is important for CSCW to shift focus to also include regional and national contexts. In the national archetype process there is a co-construction detected between the need for bottom-up processes where clinicians are responsible for designing the archetypes, including an informal recruitment and consensus process, and the need for more top-down formal processes of establishing governance organisations and modelling patterns for archetypes. The archetype work builds on several existing practices, from the clinicians participating in the consensus work but also from the openEHR foundation and the international CKM.

Because the main objective in this relates to the interaction between different actors in the standardisation processes, it is important to underscore the new forms of collaboration needed in relation to the new EPR system. This, however, requires more longitudinal approaches to cover the development cycle (Pollock and Williams 2010). Hence, it is necessary to use a socio-technical approach with detailed insight into collaboration and organisational issues such as CSCW as a supplement to the overall

framework as information infrastructure, since zooming in on the interactions between technology, organisations, and users may generate a better overall understanding, which may vastly influence the standardisation processes. I found it very useful to include the CSCW framework in this complex study even with the limitations addressed, and I recommend the use of such combination of theoretical approaches in future studies since they complement each other in a very useful way.

7.3 Reflections on the Chosen Theoretical Perspectives and Limitations of the Perspectives in Relation to the Empirical Findings

The initial plan for this PhD project was to look at the effects from implementing DIPS Arena in the North Norwegian Health Authority. However, the development process was extended to last beyond my project period, forcing me to adjust my scope accordingly, resulting in establishing more or less a new project. Since it was impossible to look at the effects of DIPS Arena, exploring some of the ongoing regional and national processes to prepare for the new regional EPR system caught my interest. I started by focusing on the enduring process in the North Norwegian Health Authority to standardise the use and setup of the existing EPR as part of a regionalisation process. Then I continued with addressing the national process of standardising and approving the clinical content for the new EPR in the form of archetypes.

Information infrastructure was chosen as the main theoretical perspective for this study since this is a well-known framework within IS research, used to address large-scale integrated and interconnected workplace information technologies (IIs) (Fitzpatrick and Ellingsen 2012; Monteiro et al. 2012). It is useful when a number of different health ISs are entangled in complex networks of healthcare professionals, activities, stakeholders, and socio-technical entities, which comprise complex healthcare IIs (Berg 1999). The regional and national standardisation processes are examples of such complex networks, including numerous actors from different occupations, collaborating for several years. The possibilities for information infrastructures to span localities and temporal scales enabling the distributed connection of structures beyond proprietary silo systems made this a suitable framework to analyse large-scale standardisation processes and the development of a regional EPR system. It is a framework in which it is possible to comprise numerous actors, including technical systems, organisations, and users (Hanseth and Monteiro 1998; Hanseth and Lyytinen 2010; Tabish 2012). I considered this highly important since the main objective of my study was to provide empirical insight into the socio-technical challenges of the large-scale standardisation of an openEHR-based EPR system, focusing particularly on collaboration across professional and institutional boundaries. The interrelation between different heterogeneous actors was important to analyse to understand why standardisation

processes evolved the way they do (Hanseth and Monteiro 1998). These interactions change constantly in standardisation processes, hence the II is continuously evolving in scope and functionality (Aanestad et al. 2017; Hanseth and Lyytinen 2004). This framework fit well with the informal parts of the national archetype standardisation, where the number of reviewers varies from iteration to iteration, and the duration of a consensus process can last from three weeks to a number of years. Information infrastructures always grow from an installed base, and it is important to consider how existing practice, such as the EPR system already in use, influences the standardisation processes since the users' experiences with existing systems influence how they contribute in the standardisation of a new EPR. Information infrastructure has many interesting elements for analysing large-scale processes, and the installed base is one of the most important. I chose to focus on the role of the installed base since I realised that both the regional standardisation and the archetype work were heavily influenced by existing practice. This aligns well with the literature on II that underscores the importance of considering the installed base when establishing an II since an II never evolves from scratch (Aanestad et al. 2017; Hanseth and Monteiro 1997). In the regional standardisation project, the new standards were established as a direct result of gathering existing practice within the health region and defining a best practice principle as a collaboration between system users, vendors, and ICT governance. The new openEHR-based system with its new and innovative technological capabilities has to 'blend in' with the already existing II of work routines, current systems, and standards. A challenge is how the new and old can fit together as the complexity and intertwined nature of IIs often makes them difficult to change (Aanestad et al. 2017; Hanseth and Lundberg 2001). This was important to underscore since the new EPR was developed in modules, making the new and the old system coexist for years. The installed base may be an asset as well as a limitation for developing a new EPR (Hanseth and Lundberg 2001; Aanestad, et al. 2017). It is important to use the installed base as the starting point; however, staying too close to existing practice may inhibit necessary innovations in, for instance, an EPR system such as DIPS Arena. For example, it was difficult for clinicians to grasp the concept of the new EPR system, and how to use the archetypes, without relating it to clinical practice; hence, it was challenging to contribute in the archetype work. Implementing DIPS Arena and archetypes led to a shift in technology as well as work routines and organisational arrangements. In the large-scale standardisation processes, spanning regional and even national settings, elements of different installed bases were combined to form a new information infrastructure. This called for vast negotiations between the actors in such processes to ensure the consideration of all interests. In several of my papers, I discuss subjects in II theory concerning both the actual II framework by Stars and Ruhleder (1996) as well as the design principles of establishing an information infrastructure defined by Hanseth and Lyytinen (2010) without defining them as such. I will address this further in the next section.

Standardisation is very closely interrelated with information infrastructures since standards are used for interoperability and communication within the EPR system. Bowker and Star (2000) emphasise that IIs are an embodiment of standards. Hanseth and Monteiro (1998) state that ‘Standards are absolutely necessary for the II to exist; without standards, there is no such thing as an information infrastructure’. I used standardisation theory in addition to II as a way of illustrating the need for more socio-technical, bottom-up processes in healthcare as opposed to the traditional top-down standardisations. I also used the standardisation principles by Timmermanns and Berg (2003), focusing on terminology standards as supplements to my theoretical analysis. However, it may have been useful to expand on the standardisation theory in the analysis to include the relations of formal and informal standardisation processes introduced by, for instance, Brunswicker, Rodriguez, and Warcham (2014) as well as to analyse the standardisation processes in relation to different types of standards, and perspectives, to extend the understanding of the challenges and outcomes. I have addressed the need for users to be in charge of the standardisation processes since it has been very difficult to standardise healthcare in a traditional top-down manner (Fitzpatrick and Ellingsen 2013; Timmermanns and Berg 1997; Black et al. 2011). User participation relates to the socio-technical thinking as well as the two-level model of the openEHR architecture.

II is a theoretical framework focusing on the overall relations between different actors in a large-scale infrastructure. Accordingly, there is a tendency that many II studies do not zoom in on micro practices and detailed work processes. To study such processes in more detail, I lent on the CSCW literature. Research within the field of CSCW has contributed extensively in providing an understanding of how ISs or artefacts can support distributed collaborative work among user groups (Bossen and Markussen 2010). CSCW research has been important throughout the thesis because of its way of exploring, describing, and conceptualising the collaborative nature of healthcare processes in relation to healthcare technologies.

Concerning the archetype work, I recognised the emergence of several collaboration processes; for instance, the use of an online CKM was a new form of collaboration between numerous users in an II enabling working together asynchronously and over distance. The work with national archetypes also required collaboration between NRUA and the health regions to balance between national and regional/local requirements. I also found it necessary to go into detail on the interrelations amongst the actors to really understand how they influenced the regional and national standardisation processes and how the power balance between them are in flux. Accordingly, in the national archetype work, I found it important to look closer into some of the processes to detect why it took so long before the first archetype was designed and why the archetype consensus work was so cumbersome. Zooming in on some important episodes also expanded my understanding related to the overall processes and the bigger picture. A limitation in relation to CSCW is that concepts such as coordination and collaboration have

been used as a supplement to analyse empirical findings in the study without being defined specifically and elaborated on as theoretical principles.

7.3.1 Limitations in the theoretical perspectives in relation to the empirical findings

To grasp the concepts and strategies of large-scale infrastructures and the regional and national standardisation processes, it was necessary for me to start this study from a medical informatics perspective, using the development of DIPS Arena and the requirements for archetype standards as my starting point. The first papers I wrote addressed the ongoing standardisation processes in the North Norwegian health region related to exploiting the possibilities in DIPS Arena. I gained an understanding of how the existing EPR was standardised, the complexity of this process, and how this installed base influenced the development of the new EPR system. These papers were merged into paper 1, presented in the thesis, where the challenges of the standardisation processes as well as the development of a regional clinical governance were addressed using information infrastructure and standardisation theory focusing on the role of the installed base. In this paper, I shifted from a medical informatics- to a more socio-technical perspective focusing on the interaction between the technology and the users. This paper is missing a definition of power, and using power relations to explain challenges in the standardisation processes, such as how the health regions were concerned with giving up their local autonomy for a regional solution, improved the paper extensively. Power relations and politics were also reflected in the resulting governance solution since a fragmented governance was a compromise used to get the health trusts to accept the regionalisation. CSCW concepts such as coordination and collaboration were used as a supplement to analyse the empirical findings without being explicitly defined as theoretical principles. Such concepts were important to include to understand the regional standardisation process in which hundreds of system users, vendors, and governance personnel worked together to define best practice for how to use the existing EPR system. In addition, the work on establishing regional clinical governance addressed in the same paper demanded extensive collaboration between the different health trusts and the existing governance organisations to find a good regional solution. In the fragmented governance solution, nine different governance organisations were included in governing parts of DIPS Arena. A limitation is that the governance part of the thesis addresses only the regional clinical governance organisation. Including the national and regional archetype governance and challenges in relation to designing and structuring them as well would have enriched the knowledge on governance in the study.

In paper 2, I presented a detailed description addressing the status of the archetype work in Norway from a medical informatics perspective, focusing on how the technology influenced the organisation and the users involved. The paper did not include a theory section; hence, there were no extensive

analyses in the paper. Still, there was a discussion section including some infrastructuring and standardisation elements implicitly without defining them specifically as such. The infrastructuring process of establishing the archetype governance, NRUA, was described in detail without elaborating on infrastructuring as a concept. In addition, ‘the bootstrapping problem’, one of the design principles for II defined by Hanseth and Lyytinen (2010), should have been introduced as a concept since this fits well with the main objective of the paper: defining a set of core archetypes and designing a prototype of an EPR to test archetype standards for clinical practice. This is a possibility for designing ‘for direct usefulness’ to fit the requirements of a small group before scaling the process. In addition, the interrelation between the EPR system, the archetypes, and the installed base was recognised for the first time in this paper. To address this, it was useful to introduce the II principle of ‘embeddedness’. The paper should also have been connected to standardisation theory; both the principle of the standardising of an organisation and of the standardising by an organisation by Brunsson, Rasch, and Seidl (2012) would have been useful to include in the discussions related to organising the archetype governance and the actual consensus process.

Writing up such an extensive empirical description provided me with a very good overview as well as a new and extensive understanding of the national archetype work. It was a maturity process for me to understand the extensive empirical field well enough to relate it to theoretical concepts. However, this was necessary to enable shifting from an empirical to a conceptual theoretical level in my PhD project, not just using the theory to frame my empirical findings. There was also an ongoing maturity process in the national archetype work. When I started working on my PhD in 2014, NRUA had been recently established, and there were no national archetypes developed. In 2016, however, there were about 60 national archetypes approved, with about 100 more in the process, and the archetype work and the governance organisation had been formalised.

The theory was introduced properly as an analytical tool in the third paper. This resulted in one of the main objectives from this thesis: proving the need for a close relation between standardising the archetypes and the development of the EPR system, merging two complex infrastructuring processes. The close interrelation between the two extensive IIs, including the existing EPR as the installed base, resulted in a very complex project to comprehend. Addressing this interrelation, the principle of ‘embeddedness’, stating that infrastructures are sunk into other structures, social arrangements, and technologies, would have been useful to include. The extent of this interrelation was not revealed until the archetypes were tested for clinical practice. In paper 3, I also go into detail on the infrastructuring process of the national archetype work, and the II principle ‘The reach of the infrastructure’ would have been useful to include related to analysing such process. In the archetype standardisation the challenges recognised by Karasti, Baker, and Millerand (2010), balancing between project time (today’s needs) and infrastructuring time (future needs) became clear. There was a conflict between establishing archetypes

fast enough for implementing the new DIPS Arena and the need for using enough time to design high-quality, system-independent standards (2010). The design principle of ‘the adaptability problem’ also addresses this issue since the goal is to design not only for today’s challenges but also for future needs. Hence, including this principle would have been beneficial to elaborate on this tension.

The archetypes as clinical standards were quite complex technical entities to understand for me, coming from a non-technological background. This influenced both how I approached the standardisation work as well as my ability to grasp the complexity of the modelling and consensus work. However, I think it was useful for both the project and for me as a researcher to approach the processes from a non-technological perspective to address the interrelations between actors from an II perspective. This enabled me to conceptualise issues such as the balance between formal and informal standardisation and the power relations, not focusing only on the technological challenges addressed by, for instance, Beale and Heard (2008) and Chen et al. (2009). Sometimes challenges with developing and implementing technological solutions such as an EPR system relate to challenges surrounding the technology and not the technological solution per se. The complexity of the archetypes required close collaboration amongst reviewers from different occupations in the consensus process. It was not a tradition for clinicians and technologists to collaborate closely on standardising clinical information in Norwegian healthcare. CSCW was used to address this collaboration; however, the concepts of collaboration and cooperation should have been elaborated on to extend the knowledge of the complex infrastructuring processes.

Analysing the data in this paper revealed a need to discuss power relations and a need to point out that power has not been extensively addressed in large-scale standardisation work within IS and CSCW previously. The II principle ‘Fixed in modular increments’ relates to the complexity of the II and how it is possible to design, combine, and use IIs in several places simultaneously. This creates tension between various aspects of standardisation processes, such as today’s vs future use and requirements as well as flexible archetype design and interoperability. This is an important principle that would have been useful to include in analysing the power relations addressed in the study.

In relation to standardisation theory, the relation between formal and informal standardisation processes was addressed briefly in paper 3 in relation to the role of NRUA in the archetype standardisation. This topic should have been discussed in more detail at an overall level to grasp the complex interrelation of the consensus work. How to approach the regional and national standardisation processes and the need for shifting from a top-down to a more bottom-up approach was addressed in paper 1 and further in paper 3. OpenEHR is suggested as a useful bottom-up, socio-technical standardisation approach for developing EPR systems since the users are defined as the leaders of developing the clinical standards for such system.

The role of users in the archetype work is also addressed in this paper, and the need for a large number of users to fulfil the goals of archetypes as maximum datasets designed to fit both regional and local requirements is highlighted. This need could have been balanced better by including standardisation theory. Tamm Hallström (2008) state that it becomes difficult to reach consensus when you have a high participation rate, which creates a risk of reducing the efficiency of establishing standards. Brunsson, Rasch, and Seidl (2012) also recommend limiting the number of users since involving too many users slow down and complicates the standardisation process. Their solution is to include only the necessary number of users to ensure the quality of the standards at all times.

Exploring the balance between the numbers of users in relation to the efficiency of the standardisation work was exploited to some degree in paper 4 by introducing the concept of reference users, as defined by Pollock and Williams (2010). However, the notion of reference users could have been elaborated on by attaching it to standardisation theory. For instance, Brunsson, Rasch, and Seidl (2012) addressed the need for broad user involvement for standards to be accepted. This relates to the socio-technical principles of the users of the standards being the ones that know the necessary requirements for a standard (Berg 1999). Including users is important to keep standards such as archetypes from getting too far away from the existing practice (Bowker and Star 2000). Brunsson, Rasch, and Seidl (2012) address the different roles a user has when representing themselves as an expert and representing an interest group. This could have been an interesting element to bring to the discussion of reference users. Is it enough to include reference users in such a large-scale standardisation process? Moreover, how many users are necessary to include as reference users? In this paper, the shift from designing openEHR-based systems as a small-scale project to establishing an overall national II in Norway is addressed. The tension between local needs and national requirements is recognised in the paper without relating it much to the concepts of power. Power relations associated with the tension between local and global interests are addressed by, for instance, Bowker and Star (2000) as well as Rolland and Monteiro (2002). User involvement in the archetype work is described in detail in this paper, and the challenge of recruiting reviewers is underscored. To include standardisation theory addressing formal and informal standardisation, such as in Brunswicker, Rodriguez, and Warcham (2014) as well as Hanseth and Bygstad (2015), would have made it possible to discuss these findings at a conceptual level.

Paper 5 addresses the power relation between local/regional and national requirements in the archetype work. User-oriented approaches where users have control of the standardisation process have been called for to enable the recognition of local needs (Coiera 2009; Bowker and Star 2000, Constantinides and Barrett 2014). It would have been useful to introduce the II concept of 'Fixed in modular increments' in this relation as well. In addition, the paper questions the use of top-down approaches for establishing terminology standards such as archetypes. The need for a socio-technical approach is recognised since

the openEHR technology is deeply embedded in the organisations and vice versa. Introducing new technology will therefore result in organisational consequences (Fitzpatrick and Ellingsen 2013).

There are many reasons for the insufficiencies of the theoretical frameworks for this thesis. Perhaps the estimated time of a PhD project of three years was too short to enable comprehending and conceptualising such large-scale standardisation processes going on for years and with numerous actors involved. It is possible that I spent too much time disentangling the empirical complexity of the standardisation processes to be able to conceptualise the study well enough. As an alternative strategy, I could probably have delimited my project better in ways that enabled me to go deeper into parts of the process; however, using such a broad scope made it possible to get an extensive overview of the complexity of the different information infrastructures and infrastructuring processes. This made it possible to detect the exact parts that were interesting to zoom in on at a more detailed level. If I did not have the overview of all the interrelated processes, I might have missed important issues, and I may have ended up focusing on relations not as important to the bigger picture. For instance, the need to address power relations was a result of addressing the empirical findings in detail, and if I had not spent an extensive amount of time on comprehending the empirical findings, I would probably not have been able to grasp the importance of addressing power relations. Power was originally not one of my focus areas; however, it emerged as an important factor to include in understanding the outcome of large-scale infrastructuring processes and relations amongst the actors. From addressing the standardisation processes in relation to II theory, the importance of power relations and politics between the actors emerged; however, it took some time before it was revealed as one of the main subjects to discuss, and hence power is introduced rather late in the study and is not addressed specifically in all the papers. Still, this is an important red thread in my study and an important factor to understand the interrelations between the actors in the standardisation processes. First, in paper 3 the notion of power relations between the actors was recognised to explain the tension in infrastructuring processes and IIs. When starting to really analyse the data and conceptualise the power relations, I realised that power was also one of the most important issues in paper 1, influencing the standardisation of the existing EPR as well as establishing the regional clinical governance organisation.

Diverging interests between, for instance, reviewers from different health regions or diverse occupations, between NRUA and reviewers, between the system vendors and NRUA, or between NRUA and the health regions resulted in tensions and power struggles even though all actors wanted the same thing – namely, high-quality standards that fit the clinical requirements as well as possible. To analyse the interrelations between the actors in such a large-scale information infrastructure, actor network theory (ANT) would have been useful to introduce. ANT includes a detailed understanding of the relationships between information technology and its use (Hanseth and Monteiro 2002). This is a perspective useful to describe and explore the interests of actors, both human and non-human, in

constantly shifting networks, such as the II established for the national standardisation of archetypes. However bringing the notion of the actor network into such a complex project (and amongst existing theoretical perspectives) would have extended the complexity of the study even further, and I therefore chose to address power only through the II framework. I found that reviewers from different occupations had to negotiate frequently on how to design an archetype since different requirements for the archetypes are prioritised. All the reviewers brought parts of their installed bases to the national archetype work, and there was a constant negotiation on how to include all necessary requests and how to make the national standards fit local requirements. In addition, the larger the II gets, the more important it is to address power relations since the relations between the actors vastly influence the collaboration within an II. Hence, power relations related to the construction of standards are important to address since this process demands extensive negotiation between the involved stakeholders (Berg 2001). Participants in standardisation processes are subjective and try to shape standards in a way that suits their interests.

I also realised that it was important to address the relation between local and global interests in an information infrastructure, especially at a regional or national healthcare level, since global standards both shape and are shaped by local work practices (Ellingsen, Monteiro, and Munkvold 2007). Bowker and Star (2000) also underscore the tension between the desire to standardise on a global level to emphasise managerial agendas of control and accountability and the need for flexible local standards for work practice support. Another important relation exists between the national and international archetype work and the risk for diverging interests and priorities to occur. In addition, power relations are necessary to address in relation to the interdependences of the EPR system and the archetypes; between the different user groups in the review process; and between NRUA, the vendor, and the reviewers in the consensus process.

8 Conclusion

This thesis addresses the socio-technical challenges of large-scale standardisation related to an openEHR-based EPR system, based on three different case studies. All the papers build on a qualitative interpretive approach and gathered data via interviews, observations, and document studies using an action research approach. The study emphasises a need for extensive interaction between different actors involved in standardisation processes at both the regional and national levels of Norwegian healthcare. Important focus areas include balancing the requirements between technological, organisational, and user requests in socio-technical, large-scale IIs and the changing roles in regard to how to include system users in infrastructuring processes. Theoretically, information infrastructure has been the main framework, focusing on the role of the installed base and the infrastructuring process of establishing new, large healthcare IIs. However, the II is mainly an overall framework, hence the socio-technical

CSCW approach was used to zoom in on the interrelation between technology and organisations and the power relations between the actors in the standardisation processes.

The main contribution of this thesis is the need for closer interrelation between the archetype standards and the EPR system than that which the two-level model presents. One of the main benefits of such model is the possibility to separate the work with the technical and clinical parts of the EPR system, leaving the clinicians in charge of designing the archetype standards. This project outlines two important reasons as to why such separation is challenging if not impossible. First, the archetype standards include both clinical and technical elements and require addressing both to result in high-quality standards. Second, this project has revealed the need for a close interrelation between the archetype development and the openEHR-based EPR. There is a need to balance the temporal aspects of large-scale standardisation between establishing high quality, system-independent archetypes (infrastructuring time) and producing enough archetypes to enable the new openEHR-based EPR to be implemented as soon as possible (project time). However designing archetypes to fit the EPR system generates a risk of compromising the notion of system-independent standards.

To design high-quality archetypes to structure and standardise the clinical practice, it is important to have extensive user involvement from clinicians and other healthcare personnel. The archetypes are designed based on the principle of including a maximum dataset of clinical knowledge. According to the socio-technical principle, user involvement is important to prevent system development from getting too far away from the installed base since the users are the ones that best know the requirements and needs for the new standards. However, there were some challenges detected in relation to user involvement. It is crucial to shift from an informal to a formalised recruitment process to get all the required clinicians involved in the standardisation and to get the archetype work anchored within the healthcare organisations. There is also a need for an extensive recruitment process to ensure that there are enough clinicians available at all times since a lack of necessary specialists leads to the consensus process being delayed or stopping all together. It is also essential to address the need to balance between the number of users included and the efficiency of the consensus process. Defining reference users representing the medical specialities is one way of reducing the number of reviewers to make the consensus work more efficient. Since the archetypes are technical information models set to structure the clinical content of the EPR system, it is important to establish a group of expert users with both technical and clinical competence to work as intermediary translators and negotiators between the technical and clinical requirements. An overall concern related to user involvement is the shift from the notion of users as the main developers of archetypes, able to design their own archetypes, towards a standardisation process where the vendor undertakes increasingly more of the archetype development. The goal to include as many reviewers as possible is replaced by including a group of reference and

expert users due to the complexity of the standards, the challenges of including clinicians, and the need for more efficient standardisation processes.

Addressing the interrelations between the numerous actors in a large-scale information infrastructure made it important to take into account the power that each stakeholder possesses since establishing standards in a healthcare setting demands extensive negotiation between the heterogeneous actors involved, and the standards are likely to change existing work processes and organisational structures. It was important to address the power relations between local and global requirements in large-scale standardisations including vast negotiations between the local needs of flexibility and individuality as well as the global requirements for efficiency and comparability. It was also essential to balance the needs between technical and clinical requirements and for reviewers from different occupations to collaborate closely in the consensus process. In addition, power relations were an issue between NRUA and the EPR vendor, influencing the design and modelling processes related to the archetypes.

To handle the power relations and other complexities of a large-scale infrastructure, it was important to establish a well-functioning governance organisation. In Northern Norway, parties negotiated for years to define the structure and content of such organisation in the health region, and because of power relations amongst the health trusts, they ended up with a fragmented solution similar to a polycentric governance organisation, where all health regions were responsible for parts of the regional governance. However, this resulted in nine governance organisations managing parts of the same EPR system, generating a need for collaboration and constant negotiation between health trusts and governance organisations that are not used to having to collaborate. The inclusion of this many organisations makes governance processes related to DIPS Arena slow and tedious, and when conflicts arise, there is no overall authority to make final decisions. Such governance model also lacks a total overview of the EPR system, and it is difficult for collaborating parties to know which organisation to direct their requirements to.

In the archetype standardisation, it is necessary to balance between formal and informal standardisation processes since it is important to establish a formal organisation such as NRUA to govern and coordinate such large-scale standardisation including hundreds of system users, and it is necessary to define the steps of the consensus process and the modelling patterns of the archetypes. One of the findings in the study relates to the need to formalise the recruitment of clinicians to the archetype work and to anchor this at a regional and national healthcare level. However, it is necessary for the actual consensus process to be flexible and informal, using the online CKM for the consensus work, where reviewers can discuss the content of an archetype with other reviewers as well as NRUA. Clinicians can also participate in the archetype work whenever they have time and do not have to attend meetings and commit themselves to projects. This way more clinicians will be able to participate; however, the process becomes more

unpredictable since it is impossible to predict how long the standardisation process will take due to the uncertainty as to whether clinicians are attending.

I suggest that for future work it is important to elaborate on power relations in the field of II and to use CSCW and work practice studies to supplement II/IS studies since the II framework is rather generic. It is also necessary to include large-scale studies in the CSCW, focusing on larger issues of policymaking and technology selection, addressing for instance the interconnection between local and global requirements.

The promising ambitions of standardisation – to reach interoperability and improve communication across healthcare organisations – and standards being the core components of any large-scale II have resulted in a great deal of standardisation efforts at different healthcare levels in Norway. Standardising clinical information to establish a more structured EPR system with easily accessible and reusable information is a goal in line with Whitepaper 9, ‘One Citizen, One Journal’, focusing on improving the role of the EPR systems and the communication between them. The national archetype work was a slowly evolving infrastructuring process that included extensive negotiation between the existing IIs, the many actors involved, and the healthcare organisations. However, prioritising time and money to complete the standardisation is crucial because without the archetype standards, there will be no new EPR system for the health regions to implement.

The most important finding from this study is the need for close collaboration between technology organisations and system users in large-scale healthcare standardisation. Overall, standards always have to relate to some degree to the local requirements of the system in which they will be used. Hence, the main contribution of this thesis is the need for closer interrelation between the archetype standards and the EPR system than that which the two-level model presents. It is also important to find a balance between user involvement and the efficiency of the standardisation processes and to address power relations between the different actors in the standardisation processes and include enough end-users for such processes to be successful.

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Artikkel 1

Artikkel 2

Artikkel 3

Artikkel 4

Artikkel 5