

The role of clinical leadership in the implementation of large-scale Electronic Health Records in hospitals

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Abstract. Background: Many Information and Communication Technology (ICT) implementations fail to deliver described effects and organizational goals. Empirical evidence suggests that organizational and socio-technical challenges are frequently overlooked. Objective: The proposed PhD research project aims to develop theoretically informed guidelines and strategies for how clinical managers should be positioned and engaged in ICT implementation, change management and work practice adaptation. Methods: This qualitative study will employ an interpretive approach with data capturing at three different organizational levels: Top management, mid-level clinical management, clinicians. Empiracally we will use the implementation of a structured Electronic Health Record in Norwegian hospitals as case. Conclusion: A better understanding of how ICT portfolios can be governed, and how and too what degree clinical managers should be involved in an accusation and implementation process can improve outcomes and organizational effects of clinical ICT implementations. The proposed research project will study the implementation of large-scale clinical ICT, with the aim of identifying and describing strategies for what role and involvement clinical managers should have in both development, implementation and governance in order to facilitate the needed change management within own organization.

Introduction

Healthcare is a sector represented by great complexity, while it at the same time requires efficient coordination and communication for both patient and provider benefits (Moreno-Conde et al., 2015). Digitalization of work processes and the use of Information and Communication Technology (ICT) such as the Electronic Health Record (EHR) is expected to deal with some of these challenges (The Norwegian Directorate for e-health, 2018). In addition, the implementation of structured data formats and use of clinical standards for information modelling in clinical information systems (IS), is considered a key means towards organisational goals such as standardised patient pathways (Christensen & Ellingsen, 2013), clinical decision support (Silsand & Ellingsen, 2016), information interoperability and data exchange, standardisation of routines and practices, as well as safe treatment and care of patients (Fitzpatrick & Ellingsen, 2013). However, many large-scale ICT projects never live up to its ambitions, and the potential for increased quality and productivity remains largely unrealized, resulting in that many projects end up as outright failures (Øvretveit, Scott, Rundall, Shortell, & Brommels, 2007).

The many failures and problems suggest that organisational and socio-technical challenges are often overlooked (Boulus & Bjorn, 2010; Pollock & Williams, 2008). Frequently, new technology results in intended and unintended organisational consequences, which increases as both the number and complexity of the ICT portfolio is scaled up. The increasing scale of these projects also brings up another set of issues and concerns – that is, less focus on technical design issues and more focus on broader socio-technical complexity. Different user groups might have different and sometimes conflicting expectations for ICT, highlighting political tension about implementing new technology (Ulriksen, Pedersen, & Ellingsen, 2017).

Dealing with these challenges requires a thorough understanding of the organisation, a strategy for changing the organisation and not at least, a strategy for governing the ICT portfolio. These are crucial managerial tasks, also for clinical managers. They have to involve different types of users and have to provide necessary resources for the ICT projects. Still, without being able to govern the ICT portfolio effectively, it is very hard to achieve desired organisational effects. Traditionally many of the decisions related to ICT and implementation has been in the realm of ICT departments and the executive managerial level, while outside the comfort zone of most clinical managers (Øvretveit et al., 2007). Unfortunately, this has left managers in a largely passive role where they have been confined to approving the budget and endorsing major systems acquisitions. Only a handful take responsibility for driving ICT decisions within their organisation (Rosenmøller, 2013). This is also reflected in the ICT management research literature, which lacks conceptualisations of ICT; it is just referred to in very general

terms such as “the ICT” (Orlikowski & Iacono, 2001). At the same time, it makes no sense to expect clinical managers to adapt a “direct” management style on the ICT portfolio, both because managers have many other priorities and because large-scale portfolios are nearly impossible to fully control (Silsand & Ellingsen, 2014). Hence, the goal of good governance of an ICT portfolio for management must not be to direct it, but rather to shape and influence it (Tiwana, 2013; Williamson & De Meyer, 2012). However, it is not obvious what constitutes the optimal extent or the best means to shape and influence such systems. Furthermore, it is not clear how a robust engagement from the clinical managerial level can be achieved.

As a result, there is a need for a method for clinical managers to conceptualise the interconnections between both the ICT systems and the work practice and routines. Without a method or knowledge on how to address the associated socio-technical challenges related to developing and implementing a structured EHR, it will be difficult to realize the expected benefits described in this chapter.

In this research project, we will develop theoretically informed guidelines and strategies for how managers in hospital departments should govern ICT portfolios to achieve organisational goals, specifically how clinical managers are positioned and engaged in change management and work practice adaptation in the process of development and implementation of structured EHRs. Empirically, we will study the ICT portfolio consisting of three ambitious interrelated systems in the NORTHERN NORWAY REGIONAL HEALTH AUTHORITY (NNRHA). Our main objective is therefore to *identify a strategy for what role clinical management can play in the process of changing from an unstructured to a structured EHR.*

Theoretical framework

Given the focus on large-scale ICT portfolios, there is a need for a theoretical approach that can assist in conceptualise the findings. In this regard, the notion of Information Infrastructure (II) is promising. This framework has been used to study the design, implementation and use of large-scale information systems (Aanestad & Jensen, 2011; Hanseth & Lyytinen, 2010; Star & Ruhleder, 1996). These systems are not recognized as standalone components, but to be integrated with other information systems and communication technologies, as well as with non-technical elements. Analyses of IIs therefore need to take into account a broad range of socio-technical issues shaping the implementation process. A basic principle of an II is that it is never built from scratch; rather, it evolves from the installed base—the existing information system (IS) portfolio in specific contextual practices (Pedersen, Meum, & Ellingsen, 2012). As a part of this, the infrastructure shapes, and is shaped by, the work practice, in an ongoing co-construction process between technical and social elements (Bossen, 2011; Ellingsen, Monteiro, & Munkvold, 2007). During the progression of an II in any given context, the installed base may become very large, increasingly shaping its environment. Similarly, the size and

complexity of the installed base makes it difficult to replace or change. Therefore, newer versions are carefully introduced or adjusted, to replace previous versions, in order to maintain backward compatibility (Bowker & Star, 2000). This is a process of continuous negotiation and compromises for achieving stability or alignment between actors with different interests, competing agendas and related technologies.

In addition to II theory, Computer Supported Cooperative Work (CSCW) will serve as a valuable concept when investigating coordination and workflow design when implementing new technology in clinical setting. As CSCW seeks to look beyond the purely technological aspects of implementation, it is well suited for the investigation of how clinicians works in team within the hospital, and how the new ICT portfolio impacts these processes.

Empirical field

In 2011, the NNRHA initiated a large-scale clinical ICT project, intending to acquire and implement a shared ICT solution for all 11 hospitals in the health trust. The program, titled FIKS (*Felles Innføring i Kliniske Systemer; Implementation of common clinical ICT systems*), was initiated to facilitated the implementation of the EHR DIPS CLASSIC, as well as shared clinical ICT solutions for laboratory, radiology, pathology and electronic requisition for microbiological tests from General Practitioners. DIPS AS won the bid for delivering the EHR in the project, partly based on a detailed transition plan from DIPS CLASSIC to their new structured EHR DIPS ARENA within 2016 (Helse Nord RHF, Helse Sør-Øst RHF, & Helse Vest RHF, 2017). However, DIPS AS failed to deliver ARENA on time, resulting in major delays in FIKS. All the other goals in the project were reached within time and cost (Direktoratet for e-helse, 2017; Helse Nord RHF et al., 2017). The FIKS-program was officially terminated in 2017, and the consecutive program 'FRESK' (*Fremtidens Systemer i Klinikken; Tomorrows systems in the clinic*) was initiated to continue the processes from FIKS. In this research project, the FRESK-program and the implementation of large-scale clinical ICT systems will act as the study object.

FRESK is a highly prioritized program for the NNRHA, funded with 450 million Norwegian Kroner from 2017-2022. FRESK aims to use ICT strategically for achieving regional, clinical and organisational goals related to standardised patient pathways, clinical decision support, standardisation of practice, interoperability and quality improvement of medication management processes.

The core technology enabling these goals is DIPS ARENA. DIPS ARENA'S core data structure is based on a national initiative using the OPENEHR architecture (Thomas Beale & Heard, 2008). This approach is aimed at enabling standardising and structuring of the EHR content through OPENEHR archetypes, promoting interoperability between different systems, reuse of data for clinical decision

support and local tailoring of the EHR technology. The OPENEHR approach enables users (physicians and nurses) to design structured content suitable to their own needs. On the national level, the National Administration Office of Archetypes coordinates and organises the process related to recruiting and committing clinical users from each of the health regions.

Several related ICT projects meant to complement DIPS ARENA have also been initiated through FRESK. These are illustrated in Table I. One of the most central projects is the acquisition and integration of an Electronic Medication Management System (EMMS) delivered by international vendors IMDSOFT and EVRY. The EMMS shall replace the traditional paper-based medication charts that is currently in use. This is expected to decrease the risk of medication errors and increase the overall efficiency of the medication cycle. The EMMS shall also provide decision support regarding medication management in patient pathways.

DIPS ARENA, OPENEHR and the EMMS are interdependent; The EMMS needs to be tightly integrated with DIPS ARENA and vice versa. Similarly, DIPS ARENA depends on developed structured content from the OPENEHR project. Therefore, in 2015, the management in the EMMS project ordered several integrations between the EMMS METAVISION and the DIPS ARENA EHR from the vendors.

Table I. Large-scale ICT projects in the Northern Norway Regional Health Authority

Project	Start	Stop	Technology	Vendor	Key goal
DIPS ARENA	2011	Extended from 2016 to 2022	DIPS ARENA EHR	DIPS AS	Implementing DIPS ARENA across all hospitals in the region; clinical decision and process support
Structured EHR	2012	No stated end date	OPENEHR, ISO 13606	OCEAN INFORMATICS	Structuring EHR content, making it available for querying and secondary purposes i.e. registers
EMMS	2012	2022	METAVISION	IMDSOFT, EVRY	Documentation of patient vital parameters and medication, including drug interactions, dosages, adverse effects and administration

Unfortunately, so far the progress of these projects is far below expectations. DIPS ARENA is still not implemented and the end date is now delayed from 2016 to 2022. In addition, the EMMS project has been postponed and put on hold multiple times, and the planned implementation is now set to begin at the end of 2019. The OPENEHR approach suffers from a lack of involved and committed users as well as

a failure to fulfil the original ambition of user-controlled local tailoring (Ulriksen et al., 2017). The EMMS project is also delayed and faces major integration challenges with the current EHR. The preliminary tests of intertwined use of DIPS ARENA and the EMMS in clinical practice show several unexpected coordination problems for users (Bjørnstad, Christensen, & Ellingsen, 2017).

Overall, this raises several crucial questions related to ICT governance and architecture on how this has been established, how it has been carried out and what lessons one might learn from this about how to manage large-scale ICT portfolios and subsequently to obtain organisational goals.

In sum, these three technologies are perfect illustrations of architectural components in an ICT portfolio. Overall organisational success requires that each of the three projects succeed. Failure of one of them will mean that the high-end goals of support of patient's pathway (for instance surgery planning) and clinical decision support will not be realised. In addition, the implementation of such a large ICT portfolio require effective change management to be successful, as they inevitably will result in "(...) changes to the daily work routines for healthcare professionals in the hospitals" ('Rigger for én journal', 2019) (Styret Universitetssykehuset Nord-Norge HF, 2015). These challenges are increasingly recognised at the top Governmental level in Norway, as well as in the regional health authorities, but the strategies on how to deal with them are, however, not clear.

Method

This is a formative research project focused on the implementation of three interdependent ICT systems in the FRESK-program in the NNRHA as case. In order to address the objective stated, we will apply a mixed method approach where we endeavour to see things from different viewpoints to gain an increased understanding of the ICT portfolio as an emerging information infrastructure phenomenon, and get a complete picture of what is going on (Klein & Myers, 1999; Walsham, 1995).

In order to explore how new technologies and work practices co-develop, the study will aim to track the emerging ICT processes on three different healthcare levels that in various ways have been (and will be) involved in the three projects: I) On the top level, data collection will be targeted towards the regional health authority and the UNIVERSITY HOSPITAL OF NORTHERN NORWAY (UNN) at the director level through four open-ended semi structured interviews. The executive management level is included in order to investigate the strategic decisions and organizational motivation behind the ICT projects in the NNRHA, as well as strategies for development, change management and ICT governance; II) On the middle level, data collection will be targeted on departmental managers at the Department of Anaesthesia and Surgical Services, and the Department of Intensive

Care at UNN through 10 open-ended semi structured interviews. These departments have been selected for the initial implementation of the EMMS and DIPS ARENA and therefore it makes good sense to conduct our data collection here. Department managers are included in order to investigate how they are involved in strategic decisions and processes related to development and implementation of the ICT portfolio, and how they address the challenges of change management to motivate users in their own departments; III) On the ground level, data collection will target clinical users in these departments through five open-ended semi structured interviews in each department. Clinicians are involved in the study in order to investigate how they experience the implementation processes and changes in work practice. The analysis and topics revealed in the interviews will guide a subsequent round of observation among clinical system users in the departments. The aim of the observation is to investigate actual system use by clinicians.

In addition to the interviews and observations described above, extensive data collection will be conducted with participants and project members in FRESK. We plan to conduct five interviews with project participants from each of the projects in FRESK. Participatory observation will also be conducted within the Structured EHR project in order to investigate how the strategies and development process actually is operationalized, but also to identify and track emerging challenges throughout the implementation. In addition, extensive document analysis will be included. Interviews will be recorded in audio and transcribed verbatim. Analysis of qualitative data will be conducted according to the method of systematic text condensation as proposed by Malterud (Malterud, 2012).

The importance of social issues related to computer-based information systems has been increasingly recognized in IS, which has led researchers to adopt empirical approaches that focus particularly on human interpretation and meaning (Walsham, 1995). In practice, the movement of healthcare work activities is frequently much less linear than it is in other arenas, as it has flexibly defined roles. Interpretive research can help the IS researcher to understand human thought and action in a social and organizational context (Klein & Myers, 1999). Further, interpretive studies assume that people create and associate their own subjective and inter-subjective meanings as they interact with the world around them. The interpretive researcher thus attempts to understand through accessing the meanings participants assign to them (Orlikowski & Baroudi, 1991). Our study adheres to an interpretive research tradition of this nature. In general, qualitative research methods, such as interviews and observations, are optimally suited to understand a phenomenon from the participants' point of view, and in particular the social and institutional context. Qualitative research techniques can provide deep insight, identify problems and answer the "why" and the "how" questions that quantitative studies alone cannot answer (Ash, Berg, & Coiera, 2004).

Concluding discussion

Clinicians are dependent on effective, intuitive and adapted ICT systems for delivering quality care and treatment for patients. Not insignificant resources are used on designing and implementing ICT tools and systems that are essential to healthcare professionals in their day-to-day work. However, evidence shows that ICT implementations in healthcare often fail in delivering described organizational goals and effects. IT decisions and ICT governance is by and large in the realm of IT departments and top management. However, prior research indicates that involvement of mid-level management and clinical leaders are necessary for facilitating effective change management in ICT implementation.

The NNRHA has over the last decade put considerable efforts on developing and implementing shared and structured clinical ICT systems- a process that will require substantial changes in workflow and work organization for clinical staff. A lacking of change manage competency in managers is in FRESK project documentation recognized as a major risk factor for the success of the ICT implementation and level of goal realization.

A better understanding of how ICT portfolios can be governed, and how and to what degree clinical managers should be involved in an acquisition and implementation process can improve outcomes in this respect. The described research project addresses challenges central for realizing the potential in large-scale EHRs by investigating both the prerequisites and strategies at the executive level; the expectations and implementation feasibility at the department managerial level; and the motivation and perceived usability at the end-user level. By focusing on these three levels, we argue that the perspective gained from the different data points will be well suited to address the proposed objectives of identifying and describing strategies for what role and involvement clinical managers should have in these processes in order to facilitate the needed change management within own organization. Although findings will be context-sensitive, the proposed interpretive methodology and theoretical framework could prove valuable in providing transferable results. Change management in health ICT implementation and governing is a growing field of interest for decision makers and healthcare management. This implies a high degree of topicality, and the research project can be an important contribution in delivering sought-after insight and understanding into this topic.

Funding

This paper and subsequent study is funded by the NORWEGIAN CENTRE FOR E-HEALTH RESEARCH.

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