KTH ROYAL INSTITUTE
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Doctoral Thesis in Technology and Quality in Healthcare Systems

Unpacking the Sociotechnical Complexity of a Surgical Setting

Capturing the Context of Use to Inform Design and Evaluation

HEDVIG AMINOFF

Stockholm, Sweden 2022

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Abstract

This thesis focuses on how the implementation context for a surgical telementoring service can be understood as a complex, adaptive sociotechnical system. Teleguidance was a service for remote surgical consultation in Endoscopic Retrograde Cholangiopancreatography (ERCP), a highly specialized clinical procedure.The solution had been developed in a participatory design setting and had also been successfully trialed in a pilot study. It was to be deployed at four additional hospitals, but differences between the implementation contexts would make it challenging to understand clinical outcomes, and could also affect matters such as adoption.

This thesis includes four papers which converge on user needs and the sociotechnical implementation context for teleguidance. The aim was to demonstrate how a sociotechnical systems oriented approach could be used to identify factors that could interact with the implementation. The first paper describes an investigation of attitudes and expectations among end-users and other stakeholders. The second paper shows how modelling the sociotechnical work system made it possible to investigate and proactively identify issues that might influence implementation and adoption. The third paper explicates methodological aspects of modeling the domain. The fourth paper describes a study designed to capture early reactions to working with the system. Seen together, the research represents a design science approach, that proposes that the implementation context can be viewed as a complex, adaptive system, and provides examples that show how focusing on user and stakeholder needs and wider context of use is a viable approach for supporting the implementation and evaluation of telemedicine systems in complex settings.

Keywords
Telemedicine, Implementation, Complexity, Sociotechnical systems, Design Science

Sammanfattning

Denna avhandling växte fram ur ett större telemedicinprojekt vid Karolinska Universitetssjukhuset, Innovationshubben för vård på distans. Där hade man utvecklat en tjänst kallad teleguidance. Teleguidance utformades för att möjliggöra kirurgisk konsultation på distans i ERCP, en högspecialiserad endoskopisk procedur. Lösningen hade utvecklats i en deltagande designmiljö och hade också framgångsrikt testats i en pilotstudie. Den skulle sättas in på ytterligare fyra sjukhus, och en klinisk studie planerades för att utvärdera resultaten. Det var dock uppenbart att det fanns skillnader i hur ERCP genomfördes på de olika sjukhusen, vilket med stor sannolikhet skulle påverka införandet.

De fyra artiklarna som ingår i avhandlingen är konvergerande studier om det organisatoriska och sociala sammanhang i vilket teleguidance skulle introduceras. Syftet var att ta fram en flernivåanalys av de faktorer som påverkar arbetet med ERCP, och som kan förväntas samverka med implementeringen av teleguidance. Det första steget var att undersöka attityder och förväntningar hos slutanvändare och andra intressenter. Det andra steget var att modellera det sociotekniska arbetssystemet för att undersöka och proaktivt identifiera faktorer som kan påverka implementering och införandet av telemedicintjänsten. Det tredje steget var att fånga tidiga reaktioner på att arbeta med systemet. Sammantaget representerar forskningen ett proaktivt tillvägagångssätt för att identifiera organisatoriska konsekvenser av att introducera nya digitala tjänster i en komplex vårdmiljö. Studierna visar exempel på tillvägagångssätt för att aktivt få en djupare kunskap av användarnas och intressenternas behov samt implementeringskontexten vid teknikinförande, vilket är avgörande för att stödja de anpassningar som krävs för framgångsrik implementering i komplexa miljöer. Resultaten är avsedda att bidra till området digital hälsa genom att ge praktiska exempel på hur sociotekniska metoder kan bidra vid design, implementering och utvärdering av nya teknologier som är avsedda att driva förändringar i sjukvården.

Nyckelord
Telemedicin, Implementation, Sociotekniska system, Komplexitet, Design

Preface

This thesis sprung from the opportunity to participate in a telemedicine project at Karolinska University Hospital, where a service for remote surgical guidance in endoscopic retrograde cholangiopancreatography (ERCP) had been developed. This service went under the name teleguidance, and the project was a collaboration between the Gastro Unit and the Center for Innovation (Innovationsplatsen) at Karolinska University Hospital, and Visby Hospital. This innovation process had been running over several years, using participatory design practices and off-the-shelf technical components. Teleguidance had been used during development, and studied in a feasibility trial, and a decision was made to deploy it at four additional hospitals. At the point in time when I came into the picture, a clinical study was being planned to evaluate the outcomes of teleguidance, and there was a need to understand if differences between the participating hospitals might contribute to outcomes, or affect how teleguidance was received. My research role was to find ways to understand the implementation context, and identify factors which might affect the use of teleguidance.

This setting required collaborating with people from different professional and academic backgrounds, in a problem area where there is a great deal of knowledge, which is fragmented across research disciplines and perspectives. This work would not have been possible without my forbearing supervisors, who contributed with their different perspectives, and to whom I owe a debt of gratitude:

Kicki Groth was responsible for the overarching telemedicine program at the Innovation Center at Karolinska University Hospital: she welcomed me into the teleguidance project, and with her research background in Computer-Supported Cooperative Work, she was supportive of my research approach.

Urban Arnelo was head of endoscopic surgery at Karolinska University Hospital: he was essential for my initial understanding of ERCP procedures and the clinical setting, and a key for gaining access to clinical settings and busy specialists.

Sebastiaan Meijer, whose optimistic coaching and interest in real-world complexity helped me cross the finishing line.

Elina Eriksson, who gave me invaluable advice for surviving as a PhD student.

List of appended papers

Paper 1

Hedvig Aminoff, Sebastiaan Meijer, Urban Arnelo, Susanne Frennert *"Telemedicine for Remote Surgical Guidance in Endoscopic Retrograde Cholangiopancreatography: Mixed Methods Study of Practitioner Attitudes"*. JMIR Formative Research. Accepted 27/10/2020

Paper 2

Hedvig Aminoff, Sebastiaan Meijer, Urban Arnelo, Kristina Groth *"Modeling the Implementation Context of a Telemedicine Service: Work Domain Analysis in a Surgical Setting"*. JMIR Formative Research. Accepted 04/30/2021

Paper 3

Hedvig Aminoff, Sebastiaan Meijer *"Context and Complexity in Telemedicine Evaluation:Work Domain Analysis in a Surgical Setting"*. JMIR Perioperative Medicine. Accepted 11/06/2021

Paper 4

Hedvig Aminoff, Sebastiaan Meijer, Kristina Groth, Urban Arnelo *"User Experience in Remote Surgical Consultation: Survey Study of User Acceptance and Satisfaction in Real-Time Use of a Telemedicine Service"*. JMIR Human Factors. Accepted 07/05/2021

Contents

Acronyms

CSE Cognitive Systems Engineering. 23

CWA Cognitive Work Analysis. 33

ERCP Endoscopic Retrograde Cholangiopancreatography. i

RCT Randomized Controlled Trial. 1

TAM Technology Acceptance Model. 29

Chapter 1

Introduction

Digital health technologies are widely promoted for their potential to improve healthcare, for example by enabling access to treatment and care, improving quality and reducing costs [1]. However, many promising innovations fail to be adopted, and as a consequence do not deliver the anticipated benefits [2]. While there is consensus that introducing new technologies into healthcare requires attention to social and organizational factors, it is a challenge to gain a proper understanding of complex sociotechnical environments, and there is a need for better ways of coping with sociotechnical complexity throughout the systems development lifecycle [3].

Policy push and optimism about improving existing healthcare and creating new modes of service delivery has contributed to a great deal of innovation in health information systems and telemedicine. Since quality and safety are essential in healthcare, it is important to establish that these new ways of working are safe and effective. While controlled, experimental studies such as Randomized Controlled Trials (RCTs) are seen as the gold standard for evaluations in healthcare, this type of study design does not provide insight into the social and organizational factors that often play an important role in acceptance and use of new technologies [4]. Changing healthcare services by introducing technology is a complex endeavor that often creates social and organizational reverberations, which also need to be addressed during implementation and assessment (ibid.).

Today there is increasing awareness of the complexity of healthcare, and a need for methods for systems development and evaluation that can cope with this complexity. Experiences from engineering complex sociotechnical systems in safety and mission-critical domains such as aviation, the nuclear industry and the military have shown that successful human-technology integration is needed in order to reap the benefits of new technologies [5]. Sociotechnical systems perspectives offer methodologies that can support human-technology integration in complex work systems, but are not widely used in healthcare [6]. Hence, there is a need for examples of how these types of methods can be applied, and how the insights can contribute to the development and introduction of new digital health technologies[7].This thesis investigates how a complex sociotechnical work system can be analyzed in the face of technological change, through the example of a telemedicine service that was to be introduced in surgical settings.

The following section describes the digital heath innovation that is the focus of this thesis: a telemedicine service for surgical mentoring that had shown promise in a pilot study, but where there were many remaining questions about how it would be received when it was scaled up to more hospitals.

1.1 Teleguidance: surgical telementoring during ERCP

In 2013, surgeons at Karolinska University Hospital, and the in-house Center for Innovation, collaborated with Visby Hospital to develop teleguidance, a surgical telementoring solution that could support practitioners at smaller hospitals when they conducted advanced endoscopic procedures.

> Surgical telementoring - "the use of information technology to provide real-time guidance and technical assistance for surgical procedures from an expert physician at a different geographical location" [8].

This new way of working showed positive learning effects and improved clinical outcomes in a pilot study [9], and a health economic model showed additional types of benefits [10]. A year later, there was a decision to introduce the service at additional hospitals.

Teleguidance was a professional-to-professional telemedicine service for video collaboration during a highly specialized endoscopic procedure, called endoscopic retrograde cholangiopancreatography (ERCP). ERCP is used for diagnosing and treating serious ailments in the biliary and pancreatic ductal systems. Often the aim of an ERCP is to remove stones, or to place a stent in the case of a stricture, which may be due to tumor growth in the area. When ERCP is successful, it can quickly relieve certain serious and painful conditions. However, the procedure also has the potential for painful or even life-threatening complications for patients who already have serious underlying health issues.

Increasing therapeutic use of ERCP and growing procedural complexity has raised the level of expertise required for ERCP [11] and created new training demands among practitioners. ERCP has a long learning curve, and requires advanced technical skills and decision-making. Traditionally, surgical skills are learned by working together with experienced surgeons, progressing from shadowing to increasingly independent work. In addition to medical expertise and technical skill, behavioral aspects of performance in the operating room are also explicitly and implicitly included in training. This includes the cognitive and social skills [12] that are necessary components for trust and collaboration in clinical team work.

Sustaining already acquired skills requires regularly performing enough cases. At smaller hospitals in Sweden, many individual ERCP practitioners and clinics have an annual procedural volume which is below the recommendations for sustaining and advancing skill [13]. Hence, patients do not always have access to the best possible expertise, especially if unusual conditions or complications should arise during the procedure.

In response to regional disparities in treatment quality, there has been a trend to concentrate “difficult” cases to leading centers. An unintended consequence of this centralization is that specialists at low-volume hospitals have even fewer opportunities to uphold and expand their expertise. This is compounded by the rapid development of new surgical techniques, clinical evidence and guidelines, combined with policies that demand that hospitals run at maximum efficiency. Training and mentoring require provisions in time, as does “keeping up” with technical and clinical advances.

It has been suggested that ERCP specialists with lower levels of expertise should not attempt complex or difficult ERCP cases without the assistance of a more experienced endoscopist [14]. Similarly, serious outcomes can be avoided if there is an option to cooperate with other highly specialized colleagues, in the case of adverse events [11]. At larger hospitals, a doctor needing advice in the midst of a difficult procedure often has a colleague on call, who can provide advice or assistance. This is not always possible at smaller hospitals, and instead practitioners sometimes use the telephone to reach a colleague for support.

Teleguidance was developed to enhance this practice, through videoconferencing and simultaneous transfer of high-quality surgical imaging between smaller clinics and a high-volume clinic at a university hospital.

While the results from the pilot study were promising [9], it was unclear if these positive results could be reproduced at other hospitals. Teleguidance had been shown to work in conditions where the users had a long-standing professional relationship, and where the two clinics involved already had established organizational collaboration. These two clinics belonged to the same administrative region, and patients were regularly referred from the regional hospital to the central university hospital.

The new sites where teleguidance was to be deployed did not have the same type of established relationships or collaboration, and there were possibly other types of differences, for example in work processes, resources, and priorities. There was also the possibility that communication styles, and factors relating to hierarchy and autonomy [15] might contribute to how teleguidance was received.

Figure 1.1: Teleguidance from the university hospital

In addition, the need for telementoring, as well as the content of sessions, would most likely differ depending on the expertise and ability of the participants.

Thus, there were many unknown technical, social and organizational factors which potentially could influence how teleguidance would be received by clinical staff, and how it might come to be used at the participating hospitals. Any of these factors might ultimately affect the adoption and outcomes of the service. When new technology is introduced without careful attention to the context of use, there can be unexpected mismatches with work demands and emergence of new vulnerabilities [16]. Hence, to support the implementation but also to be able to understand outcomes, it was necessary to find ways to understand the implementation context at the participating clinics.

Figure 1.2: Teleguidance at the regional hospital in Visby

However, the implementation of technology in healthcare settings is an intersection between many professions and practices, as well as different research traditions. It is common that promising digital health innovations fail to be scaled up and adopted, and there has been considerable effort to understand why this is the case. While there is a large and diverse body of literature about implementation and adoption of digital health technologies, central questions about how to break apart the complexity of highly specialized clinical work settings, and consider the implementation context effectively remain unresolved.

1.2 Structure of this thesis

The background section, chapter 2, starts out by describing a central challenge in digital health: that many promising innovations fail to be adopted. After that, prevailing perspectives towards assessment of new technologies in healthcare are described, along with the suggestion that sociotechnical systems perspectives can contribute to a better understanding of the introduction of technology in healthcare. Chapter three describes the research purposes and research questions, and provides methodological background. Chapter 4 provides a summary of the studies. Chapter 5 revisits the research questions, and chapter 6 is a synthesis of knowledge and experiences from the work.

Chapter 2

Background

2.1 Digital health and telemedicine

Digital health services such as telemedicine are hailed as a key to solving global healthcare challenges, through their potential to improve access to treatment, increase efficiency and decrease costs, and to achieve sustainable development goals [1]. Yet despite a high innovation rate, the implementation and adoption of health information technologies has been slow and challenging [17][2][18], and it is often difficult to show how these innovations contribute to health care outcomes [19][20]. At the same time, the rapid rate and unprecedented extent of technological change in healthcare is changing the domain in fundamental ways and contributing to increased work system complexity.

The World Health Organization (WHO) emphasizes the importance of both developing digital health innovations, and also becoming better at integrating these technologies into existing health services. There is growing consensus that this requires attention to the relationship between the technology and the social and organizational context which leverages its effects [21][22]. This message is echoed in patient safety research, which emphasizes the need for knowledge about how new technologies affect individual performance, group behavior, and organizational conditions in order to avoid unintended outcomes [23]–[25]. Clinical research methodologies mainly focus on establishing cause-and-effect relationships by controlling for contextual, social and organizational factors, rather than investigating them. These conventional approaches to ensure quality and safety in healthcare are not well adapted to the rapid pace of technological development, and lengthy evaluation is often bypassed by quickly moving from a prototype stage into deployment. In effect, many questions about the social and organizational aspects that impact the use and adoption of digital health technologies remain unanswered [26].

Telemedicine is a subset of digital health, involving remote diagnosis, treatment and monitoring. Just like many other types of digital health, telemedicine is considered to have great potential to improve healthcare, and there are many telemedicine innovations and pilot projects which have demonstrated feasibility and effect [1].

Digital health - information and communication technologies for e.g. mobile health (mHealth), health information technology (HIT), wearable devices, telehealth and telemedicine, and personalized medicine.
Telemedicine - the delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and the continuing education of health care workers, with the aim of advancing the health of individuals and communities [27].

Telemedicine solutions have shown prospects of improving health outcomes, increasing accessibility to treatment, and optimizing the use of resources in many clinical fields [28]. However, telemedicine is also associated with persistent challenges: it is difficult to show how it contributes to healthcare outcomes, and many promising telemedicine innovations fail to become part of regular practice.

2.2 Paradoxes of telemedicine

There are many types of telemedicine services, such as tele-dermatology, tele-pathology, and tele-radiology, and they are used in a variety of clinical settings, in the industrialized world as well as in low-resource settings [29]. On top of this variety, there are many implementation strategies and reporting standards, which makes it difficult to appraise and synthesize findings from individual case studies as is the practice when accumulating clinical evidence [30][31]. So, despite a vast amount of telemedicine cases described in published research, the clinical evidence for many telemedicine applications is still considered limited [28]. Another recurring problem within telemedicine is that few innovations survive beyond the project stage [32][33][2]. The discrepancy between the promise of telemedicine and the lack of successful implementation has been described as a "paradox of telehealth" [34][35][2]. Similar patterns - difficulty to generate clinical evidence, and difficulties to establish sustainable services - apply to surgical telementoring, the type of telemedicine service which is the focus of this thesis.

> Surgical telementoring - "the use of information technology to provide real-time guidance and technical assistance for surgical procedures from an expert physician at a different geographical location" [8].

Surgical telementoring allows surgeons in an operating room to be connected to a consultant at another location. Numerous case studies, the earliest dating from the 1960s, have shown that telementoring can be a safe and efficacious way of providing mentoring during surgical training, and that it also can also be used to support already practicing surgeons in safely learning new techniques [36]. Despite these benefits, telementoring is rarely used as a daily tool in clinical work [37].

Despite a strong international and national policy push for digital health, and many promising innovations having been developed, there are substantial challenges in moving past the initial innovation stage, where a digital health service demonstrates effectiveness in one particular set of circumstances, and to show that it also works and can generate benefits in different locations, over time. Another challenge in the development of digital health innovations is that there are many stakeholders - development and industry, healthcare policymakers, and clinical researchers and practitioners - and that these stakeholders have varying perspectives and interests.

2.3 Telemedicine as a clinical intervention

Describing telemedicine as an intervention emphasizes its role as a mode of delivery for clinical processes, i.e. as a service with a clinical aim.

> *Clinical intervention* - an intentional action designed to result in a health-related outcome [38].

There are several key areas through which digital health interventions achieve results, and different phases of development, such as monitoring that the intervention and implementation is working as intended, and at a later stage that the desired effects are achieved [39].

A shorthand description of the technological development process for a digital health intervention can be as follows: performance-related issues in a work setting lead to ideas that technology can support performance, and a designed solution that embodies a hypothesis or prediction about the technology's usefulness for addressing the problem [40]. When a proof of concept for a digital health solution, e.g. a prototype, has been established, the next step is often a feasibility trial, to show that use of the technology can contribute towards a certain effect, as part of an intervention. Deploying the technology in additional settings, and examining how this works, makes it possible to gain insight into how the innovation fits into workflows, how the design answers to user needs and what is needed in order to perform similarly in other settings. If a solution can be successfully implemented, it can provide outputs, such as adoption and improved performance. Once an intervention is adopted, it can be monitored and evaluated over time to assess if outcomes can be attributed to the technology-based intervention. Outcomes can be distributed across patients, staff or the organization, and can be measured e.g. through changes in knowledge, or clinical impacts (efficacy/effectiveness) and costs [39].

Recommendations for how healthcare providers should assess digital health technology frame it as a clinical intervention, and suggest that clinical effectiveness should be demonstrated through experimental or quasi-experimental studies of the product's use and economic impact [41]. Evidence-based medicine (EBM) methodologies have shaped the current norms for evaluating clinical interventions [38]. The methodology can be seen as a cycle of activities to generate scientific "evidence" upon which standards for clinical practices and guidelines can be established. The activities include comparative effectiveness studies, rigorous standardized reporting, and systematic literature review (ibid.).

The gold standard for clinical effectiveness studies is the randomized, controlled trial (RCT). This is a type of experiment which is designed to assess the effect size of a particular intervention, such as a drug, under controlled conditions. This type of clinical study strives for control of contextual factors and high internal validity, which allows the overall effect of a type of intervention to be estimated by pooling results from individual evaluation studies, through systematic reviews. However, the need for adequate pre-trial data and achieving appropriate sampling and randomization makes it difficult to conduct RCTs in fields of practice such as surgery [42] and rapidly developing fields such as digital health [19]. RCT methodology is continuously being refined, for example by developing strategies for sampling and for correcting contextual differences between different sites, or baseline differences in a sample [43]. Yet this type of study is not designed to yield information which can help determine which conditions lead to a certain outcome, whether the results are possible to reproduce in another setting, or if it is likely that the same configuration of a service can be replicated at another site [43].

While RCTs are well-suited for pharmaceuticals, it is more difficult to achieve the level of control required to attribute a measured effect to a specific cause when there are many intervening variables, such as social and organizational issues, and when the "active ingredient" is difficult to define [44].

> *Complex intervention* - an intervention involving multiple components, causal pathways, feedback loops, synergies, and/or mediators and moderators of effect. [45]

Complex interventions have many components, behavioral or organizational aspects, as well as many types of outcomes [46]. The complex intervention methodology provides a framework for iterative development and evaluation of such interventions, recommending mixed-methods approaches, e.g. formative process evaluations to be conducted alongside the RCT cycle, to assess the activities during implementation and their effects on outcomes, and thus help explain variability in clinical results [47]. Process evaluations and implementation research can help practitioners or policymakers determine what is needed to transfer an intervention into a practice, by providing information about resource requirements such as time or training needed, and the process necessary for implementing the intervention with high fidelity [48].

> *Implementation science* - the scientific study of methods to promote the systematic uptake of research findings and evidence-based practice into routine practice, to improve the quality and effectiveness of health services and care [49].

There are also a range of implementation guidelines, models and frameworks which are intended to support implementation and research about implementation [50]. However, existing frameworks generally do not account for the interactions between social factors and technology [51].

While it seems clear that digital health interventions should demonstrate clinical efficacy and cost-effectiveness, there is currently no shared agreement on the appropriate level of evidence, or how this evidence should be generated before wide-spread implementation [20]. However, even if there is some degree of clinical evidence for a digital health intervention, clinical trials do their best to control for contextual factors, and most process evaluations and implementation studies do not report contextual factors [48], or use narrow descriptions and definitions of what should be included as context [52]. So evidence about clinical efficacy does not amount to knowledge about how a digital health intervention works, or if and how it will become adopted and used. Today, many digital health services in the real world succumb to *NASSS: Non-adoption, Abandonment and failure to Scale up, Spread and achieve Sustainable use*, despite clinical evidence of clinical benefits [53].

While the level of clinical evidence for new technologies is considered to affect physicians' willingness to adopt new technology [54], it is also important that a technology is effectively adapted to the local context, which encompasses end-users and other stakeholders, and organizational and technical factors [39]. However, the technical development process often has its own set of stakeholders, priorities and constraints, and adds yet another dimension to consider when trying to understand the introduction of new digital health technologies.

2.4 Understanding the use of technology

Digital health technologies are means to achieve healthcare system objectives: they are generally designed in order to improve the delivery of existing health care, by improving access and quality of services through the use of technology [39]. During the early stages of technical development, the focus is commonly on technical feasibility, and the safety and “ease of use” of a single product in a specified setting (ibid.). This generally does not extend to evaluating the use of a product, or trying to understand if and how the use of a product helps contributes towards a certain outcome in a larger healthcare system. In addition, the understandings and definitions of quality used by developers, standards, or regulators of medical devices do not necessarily match healthcare providers' needs, or correspond to their definitions or methodologies for assessing quality, effectiveness or safety.

Garvin [55] describes several aspects of product quality from a supply-side perspective: consumer preferences; manufacturing quality (design and production quality related to price); operations-management perspectives, and the quality of certain product attributes. Each perspective represents different design priorities and evaluation interests.

Industry and organizations with stakes in digital health products continually develop standards and guidelines for design and evaluation, and digital health technologies which are classified as medical devices also need to show compliance with regulatory demands, such as the EU Medical Devices Regulation [56], and international standards such as IEC 62366-1 [57].

The classification of medical devices is determined by the technical complexity of a product, its “intended use” and the level of clinical risk associated with its use. However, some digital health technologies are not classified as medical devices, for example if they are defined as communication modules. This can allow for rapid development, but agile methods can be problematic in mission- and safety-critical domains, if this approach is not informed by adequate knowledge about users, their tasks and the context of use [5] (p. 34). Avoiding classifying a digital health technology as a medical device lessens the burden for suppliers, but also makes it more difficult for procurers or end-users to know how safe and reliable a product is.

The certification process, which is a prerequisite for bringing a medical device to market, includes providing documentation for manufacturing quality, according to standards such as the ISO 9000-series. While these steps are important for managing the development of large products, following and documenting these procedures for certification purposes, essentially only means that the end product lives up to specifications, which in itself not a quality measure of the product.

Usability is another quality which is highlighted in regulations and standards. In the medical device domain, usability is conceptualized as a product quality, and usability engineering as a part of the manufacturing process needed to achieve this quality [58]. Usability engineering includes activities such risk assessment, which is grounded in "intended use" scenarios and "reasonably foreseeable" hazards. Other common activities include definition of user requirements specifications for user interface design, and formative and summative evaluation to demonstrate safe use of the product (ibid.).

However, the degree to which these steps actually ensure high usability depends on whether the usability specifications actually capture relevant features of the users and the context of use, which requires insight into the challenges users face in their work. Similarly, the definitions of intended use and identification of hazards might only be arbitrary if designers lack insight into human behavior and the conditions in which a product will be used. Scenarios for "intended use" which are defined by designers or engineers in an early development phase might be subject to the "designer's fallacy" [59]. This is analogous to the psychologist's fallacy [60], but where instead it is a designer who mistakes her own needs and preferences with those of the end user. What a designer or engineer imagines, or the results from early, "quick and dirty" usability evaluations during prototyping, might not be representative of how a product will be used in a messy, stretched healthcare setting where there are many technical systems, concurrent tasks, conflicting priorities and organizational pressures. It is also important that developers distinguish between consumer preferences, and the needs and expectations that drive professional use of technology.

From a healthcare provider perspective, the fact that a product fulfills manufacturing quality or product quality criteria for usability can be misleading: technical validation of technical requirements, or assessment of the "ease of use" of a specific user interface under "intended use" conditions does not necessarily mean that the product is usable or useful in real-life conditions. The consequence may be that systems fail to be adopted, or that they are adopted despite their deficiencies, because they offer capabilities that users require [5].

In the medical device domain, usability is defined as a product quality aspect. This contrasts to the predominant perspective within the fields of Human Centered Design and Human Factors, where usability generally refers to "quality in use" - a high level design objective which is generated over time. This view of usability is represented in software product quality standards such as ISO 25000, as well as Human Centered Design standards [61], where usability is a measure of the extent to which real-life use of a product allows users to achieve their goals with effectiveness, efficiency and satisfaction. These use-centered definitions of usability emphasize the importance of designing and adapting technologies to specific local human and organizational requirements, a perspective which also characterizes sociotechnical design methodologies.

2.5 Sociotechnical systems perspectives

Ever since digital health began to transform healthcare and to this day, it has been clear that implementing new technologies in healthcare is a difficult task, and can lead to unintended consequences or different kinds of failure [24], [62]–[66]. Yet, there is a tendency to underestimate the complexity of healthcare through a narrow focus on the new technology, rather than on its use and if/how it contributes to work processes [66]–[68]. Recurring problems with implementation and adoption also indicate how the introduction of digital health solutions is an interesting opportunity to investigate the relationship between technology, and the organizations and people that are intended to use it or benefit from its use.

Sociotechnical systems approaches, which were developed for analysis and design of work systems in complex, high-consequence domains, have been suggested as a way to improve the design, implementation and evaluation of new digital health technologies [6], [69]–[74]. While there are many methods for sociotechnical design [75] a shared feature is the practice of grounding design in a deep understanding of underlying work structures, in order to design technologies that users accept and that can be successfully integrated into organizations.

Large hospitals can be as defined as complex, adaptive sociotechnical systems [76][70], where adaptation signifies that the system's behavior changes as a result of interactions among components with and the environment. This is a way to describe systems that have a high degree of technological and organizational complexity, a rapid rate of change, many potential hazards and different layers of scientific uncertainty [77]. Conceptualizing a hospital as a complex, adaptive sociotechnical system acknowledges the variable and irregular nature of healthcare work, and that interactions among technical, human and organizational elements all contribute to outcomes.

What is a system? Simply put, a system consists of several parts that interact to achieve a common overall purpose. How well the system works depends on how well each part works in conjunction with the other parts, and with the system's outer environment. A system can have many parts and be complicated, but still be predictable and possible to control and describe through rules, if the system's response to a given impulse has a linear behavior.

Complex, adaptive systems are more difficult to predict, since they are flexible in their ability to achieve goals. In a complex, adaptive sociotechnical system, social, organizational and technical factors interact, and agents (human or machine) strive to maintain goals such as safety and performance by monitoring the system and adapting to changing circumstances [76].

Adaptive behavior on the micro-level, or "inner environment" of a system, contributes to emergent, macro-level system behavior which is difficult to assign to a specific entity, as it is the result of interactions rather than a controller who is in charge [78]. This emphasizes the role of independent agents, who can have conflicting goals and behavior, but who also adapt to each other [79]. This perspective is valuable in settings such as healthcare, where there is a high degree of collaboration among experts with different roles and perspectives, who require means to solve problems in a flexible and creative manner.

This goal-directed adaptive behavior contributes to performance and safety, and to the system's self-organizing capacity, which can makes these work systems resilient [23] (p.356). Goal-directed adaptive behavior can also explain why a new technology is less likely to be used or adopted if it impedes workers' performance or their efforts to sustain safety, for example by creating workflow interruptions.

The adaptive behavior that can make a work system resilient, also makes it intractable to describe or analyze all possible paths of action for every task [80][81]. An alternative approach is to focus on actors' goals and the context to which they are adapting [80], [82], [83].

Simon's parable of the ant on the beach is a useful analogy for how the behavior of adaptive systems can be understood and described without reducing inherent complexity [80][82]. An ant's path on a beach may appear irregular or complicated, yet it can be understood as goal-directed, adaptive behavior in a complex setting:

> *"An ant, viewed as a behaving system, is quite simple. The apparent complexity of its behavior over time is largely a reflection of the complexity of the environment in which it finds itself." [80] (p. 52).*

The ant's goal-directed, adaptive behavior shapes its trajectory, and if obstacles come in the way, the ant will adapt its path accordingly, to make its way home. While the beach provides many choices for action, the ant, viewed as a behaving system, is quite simple [80] p.52, and the beach is also "a relatively stable object that can be analyzed" [82]. Thus, the ant's behavior can be anticipated and described through information about the ant's goals and the lay of the land.

This analogy suggests that system behavior can be described and understood by focusing on the forces that contribute to an actor's behavior: the contextual constraints, and the actor's goals. This provides an alternative to attempting to capture a system's behavior through a descriptive or normative account.

Sociotechnical perspectives have provided conceptual and methodological foundations to successful approaches to patient safety [77], and sociotechnical methods have been described as a way to overcome obstacles and risk when introducing digital health. A sociotechnical perspective shifts the focus from linear causation models and variable-focused research [84], which are the norm in clinical and technical studies, and instead turns the focus towards identifying and accounting for the dynamic interactions that occur during technological change in healthcare settings.

This has conceptual and methodological implications for the design, implementation and evaluation of new technologies [85]. Still, social and organizational influences are often underestimated or overlooked in design, implementation and evaluation of digital health technologies [7]. Hence, there is a need to understand how sociotechnical methods can be applied in the design and assessment of digital health [7][86].

Chapter 3

Method

3.1 Research purposes

The main interest among the clinical practitioners who were involved with teleguidance was to evaluate clinical effectiveness, and they prioritized the collection of clinical data such as cannulation success, duration of procedures, and adverse events, to compare cases with teleguidance to those with in-person consultation. This reflects a common approach in clinical evaluation of this type of telemedicine service [87]. There was also an interest in investigating the conditions for teleguidance at the participating hospitals, as this contextual information is important for assessing complex interventions [47].

Teleguidance was intended to have an impact on expert performance and collaborative practice, and was also bound to interact with social and organizational factors at the implementation sites. Yet this implementation context was difficult to understand, with layers of technology, many roles and competencies, and a variety of concurrent and competing tasks and priorities. Work processes and organization varied between the hospitals, and there were constant reorganizations going on. There were also many stakeholders, with varying perspectives and interests, both within the teleguidance project, and at the hospitals.

Gaining a meaningful understanding of how teleguidance would work in these conditions required a way to identify relevant features of practitioners' behavior and of the sociotechnical context, which was likely to require multiple converging studies [88]. Therefore, the first hurdle was to identify appropriate methodology and techniques.

There is a wealth of research about telemedicine development and evaluation. Yet the literature is dispersed across research disciplines and domains, with varying conceptualizations and terminology, which makes it a difficult field to navigate [89]. However, there were a number of recurring unanswered questions and methodological challenges regarding telemedicine (see text box):

Rapid innovation, low adoption and unclear evidence
Numerous clinical case studies and systematic reviews show that there is an abundance of telemedicine innovation, yet many innovations are not adopted or accepted [33], [90]–[92], and it is often unclear how these services contribute to improved outcomes [31], [93]–[97].

Contextual factors shape use and contribute to outcomes
Traditional research methodologies in healthcare are not well adapted to the rapid pace of technological development. In addition, they generally focus on establishing cause-and effect relationships by controlling for contextual, social and organizational factors, rather than investigating them [98]. In effect, this leaves many questions about social and organizational aspects in the use of digital health technologies unanswered[26].

Systematic description and analysis of sociotechnical complexity
Many studies and several extensive systematic reviews point to the need to pay attention to a wide range of social and organizational issues in order to understand how digital health innovations such as telemedicine contribute to outcomes, and how they can be integrated into work practices [68], [90], [99]–[101]. However, often the sociotechnical context is not analyzed or described systematically, which makes it difficult to transfer findings to other contexts, or to bridge research and design, by using findings to inform design processes and evaluation.

Due to the many challenges outlined above, and increasing recognition of the complex and dynamic nature of healthcare, researchers and guidelines are highlighting the need to view healthcare as a complex system [4], [6], [47], [102], [103]. Hence, introducing technology to change healthcare demands attention to how the change generates technical, social and organizational adaptations, and awareness that outcomes emerge over time as a result of these interactions. This message is echoed in patient safety research, which emphasizes the need to support performance and avoid unintended effects through more attention to how new technologies affect individual performance, group behavior, and organizational conditions [23]–[25]. Consequently, it is beneficial to complement traditional clinical studies and technical validation testing with non-experimental and mixed-methods approaches that can account for interactions between technology and human and organizational factors when new technologies are introduced [98][44].

However, the trend to refer to "complexity science" and "systems thinking" is often limited to borrowing terminology and concepts as explanatory tools, or to sensitize discussions and workshops [104][105]. Yet, a systems perspective has deeper methodological implications, and offers alternatives to the traditional mechanistic logic [86] that shapes clinical and technical approaches to understanding digital health.

Hollnagel distinguishes between complexity that is due to a large amount of elements and relationships, and dynamic complexity, where analysis and description is difficult due to continuous change, rather than the amount of parameters [81]. Assuming that a system is complex due to the amount of parameters, implies that a complete system description is possible: principles of functioning can be fully known; the system can be decomposed into meaningful elements; events into individual acts, and the sequences of events are orderly, linear and can be predetermined. This might be the case in work that is routine and highly regular, where work can be prescribed and understood in detail. In contrast, a description of a complex adaptive sociotechnical system would have to be rich and elaborate to capture details of unplanned and irregular events, and yet the system is likely to have changed before a description can be completed: due to dynamic complexity the description will therefore necessarily be underspecified. For these reasons it is useful to define a complex adaptive sociotechnical system as a set of coupled functions - what the system *does* in its characteristic performance, factors of context and sources of variability - rather than to describe it as interconnected parts - what the system *is* in terms of its components, causal linkages and the probabilities of events (ibid.).

Presently, there is a need for practical examples of how methods which accommodate sociotechnical complexity can be applied in the design and assessment of digital health [7][4].

The overall objective of this research is to demonstrate how the implementation context for a digital health intervention in a hospital setting can be understood as a complex, adaptive sociotechnical system, by using systems-oriented methods.

The published papers which are included in this thesis are a set of theoretically informed empirical studies with emphasis on uncovering how teleguidance answers to users' needs, as well as to demands from the organizational context. The aim was to investigate the ways in which teleguidance was useful for practitioners, given the problem space and the sociotechnical context within which they work. The goal was to understand the factors which would be likely to contribute to if and how teleguidance would be used.

3.2 Research approach

Insights from previous research that was presented in chapter 2 suggested that the design and evaluation of the telemedicine intervention required insight to the conditions for teleguidance at the participating hospitals, and that this implementation context could be characterized as a complex, adaptive sociotechnical system.

Human Factors as well as Human-Centered Design approaches focus on understanding user needs and the context of use, and on designing to match these needs and contexts. A central idea is that technologies that are not usable, useful or that are not adapted to the context of use, e.g. that interfere with established practices and professional roles, are less likely to be accepted. From these perspectives, designing or evaluating a new technology requires an understanding of human capabilities and limitations (usability) as well as the functionality that is required to support work (usefulness) [82]. What is usable and useful will also depend on the conditions in which a technology is used: the context of use.

> *Context of use* - a combination of users, goals and tasks, resources, and environment [106]
> *Usability* - the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use [106]
> *Usefulness* - the functionality that is required to do a particular job effectively [82]

Sociotechnical systems approaches similarly emphasize the need to design for human capabilities and the context of use, but explicitly include the organizational context, and the work system's environment. From this perspective, understanding the context of use includes: understanding the tasks users perform; the types of situations that arise; patterns of communication and collaboration; users' motivations and strategies, and the physical, technical, organizational and political environment into which a technological system will be integrated [5][16].

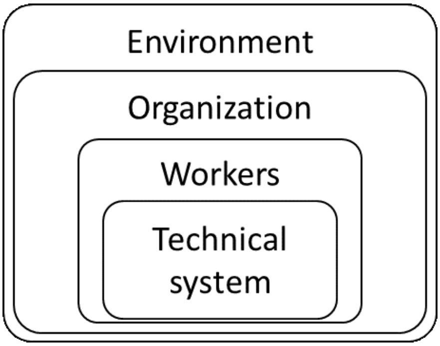

Figure 3.1: A schematic image of a sociotechnical system

This thesis proposes that systems-oriented methods can be used to proactively identify challenges to the scale-up of a digital health intervention in a complex hospital setting. The usability and usefulness of designed artifact, and its match with the context of use, can be expected to relevant for successful implementation. However, the research approach needs to be wider than "users interacting with a technology", as teleguidance is intended to affect expert performance and collaboration in a highly technical, rapidly changing, tightly coupled clinical setting. This requires insight into a complex, adaptive sociotechnical system.

The overall research aim was therefore to find a way to investigate a complex, adaptive sociotechnical setting to identify factors that are relevant for supporting implementation. In complex organizational work settings, there is no simple way to identify which behaviors are important for a design solution, or to single out and measure individual variables to assess the outcomes of introducing a new way of working [102]. This is especially true regarding the quality and safety of products and services which function across multiple settings [70], such as telemedicine. Investigations of work settings often combine observations, interviews and questionnaire surveys to provide situation specific descriptions of context and behaviors [107]. However, these methods can lead to large quantities of qualitative data, with subsequent challenges in analyzing and synthesizing findings [84][108]. Hence, studying behavior in busy real-world settings requires ways to capture sociotechnical complexity and also to make sense of it in a structured way.

Qualitative research in healthcare is influenced by interpretative, descriptive traditions in sociology, e.g. phenomenological approaches [109][110]. While sociological approaches, such as ethnomethodology, have sometimes been favored for qualitative investigations of technological work settings and practices, it has proven difficult to extrapolate what is relevant for a new design from rich descriptions that are bound to an existing configuration [111]. In contrast, behavioral science provides theories and methodologies that can inform studies of work and work settings by helping to identify phenomena which are relevant for a design problem, and supporting systematic data collection and analysis [112].

3.2.1 Behavioral science and technological development

The research approach in this thesis is influenced by fields of research that focus on technological innovation and the relationship between humans and technology. Research in subfields of Human Factors, such as Engineering Psychology [113] and Cognitive Systems Engineering [76], as well as Information Systems [114], is characterized by complementary cycles of behavioral science - to create knowledge about needs, uses and the impact of technology and information systems, and design - generating solutions to problems, and learning about these solutions and problems through design and evaluation [114][115].

Using behavioral science methodology to investigate technological developments is motivated since technology is often justified by its presumed impact on human performance [59]: teleguidance was designed to enhance expertise and coordinated activity, and thereby contribute to better patient outcomes. Behavioral science can contribute to hypotheses about the mechanisms that contribute to a design's outcome, which can help devise design principles, and also support evaluation of technological interventions [116].

The links between behavioral science and information technology is pervasive, e.g. in the cross-fertilization between cognitive science, and developments in various computer science fields [117][118][119][120]. Knowledge about perceptual and cognitive processes has for example been integrated in conceptual and computational models of human behavior, to predict human-machine performance in realistic settings [121]. The exchange between experimental psychology, computer science and naturalistic studies of human performance has led to significant developments in fields of application such as aviation, transport systems and human-computer interaction (ibid.). Concepts about human behavior have shaped human-centered design approaches, which emphasize the importance of knowledge about user needs and the context of use to create useful and usable systems [61]. Knowledge and methodologies from behavioral science are widely used to help elucidate design problems, and to predict and explain the use and impact of a design [114][122].

Behavioral science shares an epistemological basis with the natural sciences [107] and contrasts to social science through a more controlled systematic structure to guide research, e.g. a more rigorous approach to operationalization of theoretical concepts and definition of variables [123].

Behavioral studies which aim to understand how work is conducted in a naturalistic setting, e.g. Cognitive Task Analysis [124], often involve iterations of rich data collection balanced by reduction and pattern building, and as such the process is an interplay between induction and deduction [84]. In this way, critical problems can be explored through cycles of data collection, combinations of induction from empirical findings and abstraction with the aid of theoretical constructs, and developing theory from found regularities [125]. This combination of using theoretical constructs and qualitative data makes it difficult to earmark the research as either inductive or deductive, and the overall mode of inquiry can better be described as a search for patterns, which is a type of reasoning used to uncover and explain phenomena in naturalistic settings [126] by "demonstrating the connections of a puzzling item with other items and the whole pattern" [127]. Similar modes of reasoning are used in explorative organizational research focusing on patterns of behavior in complex work settings, such as organizational ethnography [84], and in design practices such as human-computer interaction and in the design of automation in complex human-machine environments [128][129][130]. This is a way to define generalized behavioral patterns which can be expressed in many situations, and which can transfer to the design of other products and work environments [130]. Identifying patterns is a type of abstraction which helps create functional descriptions which are decoupled from current system instantiations [108][131], which is a more valuable format for supporting novel design than rich, context-bound descriptions [111]. Focusing on human behavior makes it possible to move beyond the particular in "the unending variety of technology and particular domains" and identify regularities that stem from human behavior [132].

Cognitive Systems Engineering (CSE) is an approach which developed from studies of complex sociotechnical settings, and which also involves complementary cycles of design activity and empirical investigation, to gain insight into human cognition and collaborative practices which underlie the use of technology [59]. From a CSE perspective, introducing a designed technological artifact into a workplace represents a hypothesis about the relationship between the technology and human cognition and collaboration, i.e. a hypothesis about what is useful (ibid.).

Woods [115] describes the interaction between research and design during technological innovation as a combination of understanding and influencing. This involves exchanges between ideas and knowledge about how human performance can be supported, and technological advances - which affect performance, resources and organizational factors. Introducing a new technology into a realistic setting is an opportunity to test and refine a product, and also to build knowledge about the sociotechnical system and about how performance can be supported. New technology will generate new capabilities and unexpected reverberations, and hence, new opportunities for behavioral research.

These cycles of design and research rely on behavioral science methods to generate new explanations about phenomena, and being equipped with knowledge about human behavior enhances the ability to identify and abstract patterns that are valuable both as input into a design cycle, but also to understand its impact and use. This knowledge also helps a researcher avoid of becoming lost in "surface variability" of complex sociotechnical settings. Behavioral studies during technological development also contribute to innovation through "seed concepts" about what could be useful and what the best leverage points are for achieving a certain effect on people, technology or work (ibid.).

Likewise, Hevner [114] describes information systems research as being characterized by two paradigms: behavioral science, which contributes with knowledge about human and organizational behavior, both as input for design, and for evaluation purposes; and design science, which is concerned with the process of design and the designed artifact.

3.2.2 Design science

While there are many definitions of design, Simon describes design as devising "courses of action aimed at changing existing situations into preferred ones", which involves as a search process among alternative means for achieving a certain impact in a complex outer environment [80]. This process, of weighing design alternatives and devising means to achieve a certain objective, requires knowledge about initial conditions and patterns of behavior. Since the consequences of design lie in the future, the design process also involves forecasting, which in complex problems requires theoretical understanding of phenomena as well as information about the starting conditions (ibid.).

According to Simon, the main concern of design science should be the design process for creating effective artifacts [80]. Design science research entails addressing important problems through invention or improvement of products, processes, services or ideas [133]. The design science process involves intentionally incorporating knowledge about human capabilities and an application environment, along with new or existing designed tools and methods, into a specific design process [112]. The outputs of the design science process can be on a continuum from a physical artifact to "design theory" [134] which gives prescriptions for design and action [133].

From this perspective, the overall viewpoint of this thesis can be defined as a design science approach: it aims to address a known problem - the challenge of understanding how a digital health intervention will come to fit in a complex setting; it prescribes a means - that this challenge can be met by using methodologies developed for design in complex work settings; and generates artifacts that embody this prescription [135], in the form of the individual studies that were conducted as part of the thesis. The studies are examples of behavioral research to inform the implementation of a designed solution, where the discovery of salient findings was guided by concepts grounded in theory about human behavior and sociotechnical systems.

The overall rationale for the studies in this thesis was shaped by theory about complex, adaptive sociotechnical systems that suggests that complex work systems can be described and analyzed by focusing on actors' objectives and priorities, and the technical, social and organizational factors which characterize the setting [76]. The sociotechnical complexity of the clinical settings motivated a bootstrapping approach [88], and triangulating through multiple methods and data sources [84], to progressively gain a deepening understanding of the conditions for teleguidance, and how these conditions can come to shape the adoption and use of teleguidance.

3.3 Research questions

The overarching research question was: how can a complex, adaptive sociotechnical work system be adequately analyzed and represented in the face of technological change? The research approach followed a rationale that this could be done through investigation of the users' problem space, relevant features of the wider social and organizational environment, and how the technology matches this overall implementation context.

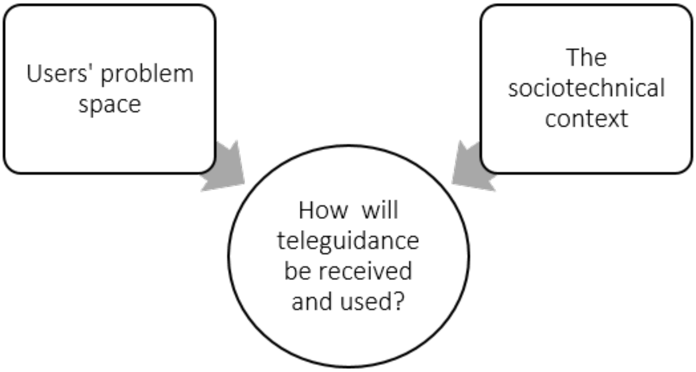

Figure 3.2: Conceptual framework for the research approach

The research questions were:

- What aspects of users' problem space are relevant for the use and adoption of teleguidance?
- How can the sociotechnical setting be systematically described and analyzed?
- How can the implementation context come to impact the use and adoption of teleguidance?
- In what ways does teleguidance contribute to ERCP procedures in practice?

The first step was to investigate ERCP practitioners' performance needs and how teleguidance could support their work. This step is reported in paper 1.

The second step was to investigate the technical, social and organizational factors that shape ERCP practice. These steps correspond to paper 2 and 3.

The third step was to assess factors related to the usefulness of teleguidance, based on perceptions and responses to using teleguidance during ERCP procedures. This was addressed in paper 4.

The following image shows the overall path of the research effort, and how a progressive understanding of ERCP work and teleguidance evolved:

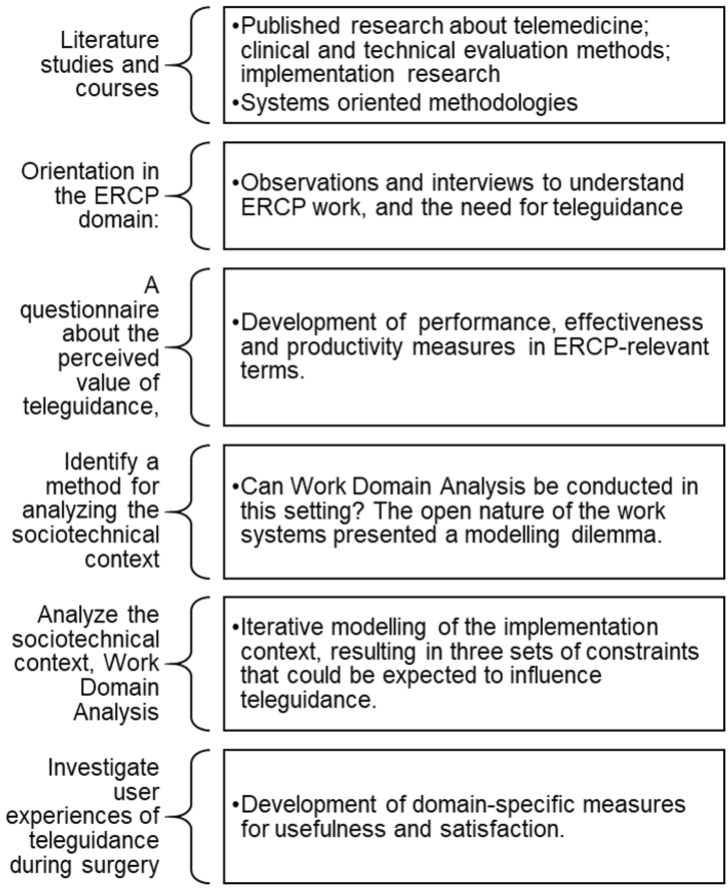

Figure 3.3: Overall path of the research effort

3.4 Data Collection

The main unit of analysis was the group of staff that collaborate to make ERCP procedures happen. This included surgical staff involved during surgery as well as in the planning of procedures. Young and less experienced nurses and surgeons, as well as highly experienced staff, were included. Managers and staff with planning functions were also represented.The selection of sites and participants was subject to availability, which was determined by key clinicians and the good will of managers and staff.

Written information about the research was provided in advance, and also provided verbally immediately prior to interviews, and consent was obtained from all participants. There was no compensation for participation.

Data throughout the studies consisted of: field notes; transcribed interviews; survey responses; images, audio and video recordings of the work being done in context. A significant proportion of recorded material were transcribed, and linked to supporting photos, videos and notes.

Data collection followed a sequence which is common in studies of complex organizational settings: gaining initial orientation in the domain from documents and informal interview observations of facilities and procedures and interviews, after which more directed, in-depth data collection is conducted [84][131]. During data collection and analysis, there was access to healthcare practitioners who could support understanding and verify interpretations.

There were 3 cycles of data collection, using a sequence of techniques, and moving from a general “rough” level of description and understanding to a finer grain. Each cycle included observations and video recordings of clinical work, interviews with staff, and questionnaires.

Cycle 1- what is ERCP, and how is ERCP is performed at the central hospital? Aim: to become familiar with essential aspects of the domain and to understand the clinical procedure: terminology, processes around ERCP work, responsibilities, roles etc. This phase included 80 hours of low-structured observations of ERCP procedures and clinical work, and 10 interviews with different categories of ERCP staff, technical and administrative staff. This step was crucial for structuring the consecutive data collection and enabling productive rapport with busy domain practitioners.

Cycle 2 – how is ERCP conducted at the remote hospitals? What are the needs and expectations among various stakeholders, regarding teleguidance? Aim: to gain deeper insight into local practices, organization and physical settings. Interview findings informed the design of a questionnaire, which was used to elicit information about the perceived value of teleguidance from a wider group of ERCP specialists. This phase included 5 observations, 15 semi-structured interviews with key practitioners and 5 interviews with technical and administrative staff.

Cycle 3 – early experiences of using teleguidance. Aim: to gain insight into how practitioners experienced the use of teleguidance, Data was collected from clinical case report forms filled in by surgeons before and after teleguidance sessions.

In the following sections, the analyses of interview material, which laid the ground for papers 1-3, are described in detail to illustrate how theoretical concepts guided the work.

3.4.1 Linking empirical data to theoretical concepts

The social sciences generally acknowledge that researchers have orientations and root assumptions that guide methodological and individual choices in their work [136]. Hence, it is important to state underlying disciplinary approaches and assumptions, since this shapes the interplay between theory, concepts and data: how data is displayed and reduced for analysis; how meaning is assigned to data, how analytical themes are formulated and how findings are linked to other research [136][137].

In the studies included in this thesis, underlying assumptions are made explicit through the theory and conceptual frameworks which guide the study design and the inductive analysis of qualitative data. As is common in behavioral science methodology, theoretical constructs have been operationalized to allow for observation and measurement, and empirical data have been linked to theoretical concepts. The validity of these leaps is strengthened by being explicit about how this deductive reasoning and inductive abstraction was achieved [108].

Paper 1 focused on attitudes that could be relevant for acceptance and adoption of teleguidance, and used constructs from the Technology Acceptance Model (TAM)[138] to guide the analysis. Papers 2 and 3 used constructs from Work Domain Analysis [131] as themes, to help organize the coding process and the display and interpretation of findings. In Paper 4, central usability themes were used to investigate perceptions about using teleguidance.

All interviews were transcribed and subjected to thematic analysis, using NVivo. Thematic analysis is an umbrella term for methods which seek to identify patterns in qualitative data, and does not denote a particular theoretical approach. However, Clarke and Braun [139] describe a widely cited generic analytic process in which themes, which are defined inductively or from theory, are used to describe patterns in the coded data. The thematic analysis in the included papers involved deductive elements, as the search for patterns in the material was guided by theoretical concepts[140]. In addition, the analysis remained on a descriptive, semantic level, which contrasts to constructivist and interpretative sociological methodologies (ibid.).

The analytic process involved multiple readings of the transcripts for familiarization, and several iterations of inductive coding, where utterances which reflected common work practices, and various types of constraints and challenges during ERCP were coded inductively. After a cycle of coding, the text extracts were collated and studied, and codes could be renamed or redefined. In the next phase, inductively generated codes and excerpts were examined to find potential subthemes, which were finally linked to overarching themes derived from theoretical concepts which were relevant for the research question. The first round of coding was a movement from domain descriptions, to groups of findings which could be directly linked to the data, yet without linkage to the theoretical concepts. The next step of abstraction was to identify subthemes. These were less context-specific, but could be traced to the empirical data through clustered examples. Linking subthemes to theoretical concepts was the final stage of generalization, finalizing a connection between context-specific findings and general theoretical constructs. This process reflects the inductive abstraction process, which is described by Xiao [108].

In paper 1, the aim was to identify drivers of practitioner behavior in ERCP work which could come to influence the acceptance of teleguidance. The questionnaire used theoretical constructs from the Technology Acceptance Model (TAM) [141], which were operationalized for this particular context. The operationalization of the TAM concepts was based on findings from deductive thematic analysis of the interviews.

While TAM is generally considered applicable to telemedicine, there does not appear to be any optimal TAM version for use in telemedicine [22]. Despite numerous attempts to widen TAM to include more variables [142], TAM questionnaires fail to fully explain technology acceptance in healthcare [143], or acceptance of telemedicine [96].

The central TAM constructs *perceived usefulness* and *perceived ease of use* were intended to be transferable across different technologies and users [144]. It is important to recognize that their definition and operationalization were originally derived from theory and prior research about behavior in the domain of office information systems, and that the questionnaire was originally designed and validated for situations such as prototype usability testing or system selection [141]. The parsimony of the original questionnaire and the operationalization of the constructs was justified for this particular type of system and environment [145], yet individual decisions about whether to use a certain software in an office setting contrasts to the many types of considerations which define decision-making in complex and collaborative health care work.

Central TAM constructs such as usefulness and ease of use are situational and context dependent, which implies that if the model is to be used in a different setting from where it was originally developed and validated, it is important to pay attention to how the constructs are operationalized, and thereby secure the match between scale items and the actual concept being studied [146][147]. Holden posits that acceptance studies in healthcare benefit from using a broad set of perceptions and adapting the variables to the context [143].

The fundamental steps in designing a behavioral questionnaire is to understand what is to be measured, e.g. through contact with domain experts and analysis of prior research in the relevant behavior domain, and then constructing items that capture aspects of the specific domain [148]. Theory and conceptual frameworks can be useful for guiding data collection and analyses when studying complex work settings [149][125]. Since physician acceptance is generally considered to be one of the most important factors for the success of telemedicine [32][150], and TAM has strong theoretical underpinnings yet has been shown to have weaknesses when applied in this domain, it was warranted to take a deeper look into what the TAM concepts actually mean in regard to teleguidance during ERCP, and how these constructs should be operationalized to match the setting.

Despite its shortcomings in healthcare settings, TAM showed promise as a valuable conceptual framework by providing construct definitions that were used to guide analysis of the interviews, and the preparation of test items. Figure 3.4 shows examples of coded text extracts, subthemes reflecting patterns from the inductive coding, and how these were linked to themes reflecting "Perceived Usefulness" a central theoretical construct in the Technology Acceptance Model [141].

Theme	Subtheme	Example of coded text extracts
Individual and team performance	Extracts related to clinical experience and team work, technical skills and learning	Less experienced ERCPists were expected to need help with technical aspects of interventional procedures: advice about choosing and maneuvering equipment etc. Experienced ERCPists were expected to discuss clinical assessments.
Productivity	Extracts related to the types of cases and how many cases are performed	Several practitioners expressed a desire to perform a greater number of complex ERCPs locally, thereby reducing the need for referrals to larger hospitals.
Effectiveness	Extracts related to patient outcomes and work processes	Some ERCP work methods and processes were described as being in need of redesign. Teleguidance was believed by some to be a way to motivate new ways of working.
Context and facilitating factors	Extracts related to social, technical & organizational context	Staff were aware of administrative and reimbursement issues that could crop up in collaborations between healthcare organizations, and that management support was necessary for successful implementation.

Figure 3.4: Themes and subthemes in the analysis

In this way, findings from the interviews were used to define and formulate contextually relevant questionnaire items about issues that had been identified as pertinent for the acceptance of teleguidance.

This reflects deductive thematic analysis, where previous research or theory guides the search for patterns [140]. The link between specific empirical findings and theoretical constructs strengthens the ability to generalize and use the findings to other cases or domains [108].

Thematic analysis was also used for analyzing the interviews upon which the Work Domain Analysis (WDA) in paper 2 and 3 was based. WDA is a method within the Cognitive Work Analysis (CWA) framework [76][82], which provides leads for how patterns of behavior in complex sociotechnical work environments can be identified and represented. WDA focuses on functional structure of a work system: the context which provides the reasons and resources for actors' behavior [131]. WDA includes social, cultural as well as physical aspects of the environment. Modelling the environment through WDA provides a way to reason about any number of situations and to understand why workers behave in a certain way. WDA is typically represented as a means-ends matrix, where the higher levels show intentional, purposive concepts, and the lower levels show physical concepts.

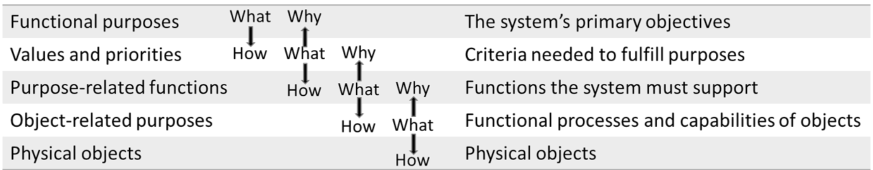

Figure 3.5: The how-what-why structure of an abstraction hierarchy

Representing work in complex settings in this how-what-why model is an approach developed from research into how workers reason about work demands in relation to their situated context [131]. The strength of modelling abstracted constraints rather than, for example, describing sequences of activities, is that the abstraction makes it possible to represent many patterns of interactions, which makes it useful for predicting interactions between humans and technology in systems which are undergoing change or have not yet been instantiated [131].

The CWA methodology is grounded in research about how humans reason about complex work in naturalistic settings, and WDA focuses on why things are done and the alternatives for how things can be done [76]. However, people generally do not describe their work in terms of how the environment shapes their strategies. Instead, it is more practical in interviews to ask subject-matter experts for an account of common activities during a day or in a particular process, and to ask about reasons, objectives and resources for activities [131]. It is also important to include a range of different stakeholders, as workers often are not well acquainted with all aspects of a complex sociotechnical system.

Analyzing interviews for a WDA requires moving from accounts of what actors do, to a model which shows why they do something and how this can be done. This transition requires interpretation of interview material to identify constraints at different levels of abstraction. In the WDA described in papers 2 and 3, thematic analysis was used to identify constraints mentioned in the interviews.

Naikar provides a useful list of prompts and keywords [131] (p. 182), which were used to help identify text extracts which could be coded and grouped, and then linked to the themes, which were predetermined and corresponded with the abstraction levels in the model. The prompts and themes are shown in figure 3.6.

Themes (abstraction levels)	**Prompts**
Functional purposes	Reasons why the work system is needed.
Value and priority measures	Factors by which performance and outcomes are assessed, or which contribute to the functional purpose.
Purpose-related functions	Typical functions the team members would perform during an ERCP session, or functions that were related to or performed in conjunction to the procedure.
Object-related processes	How physical objects were put to use during ERCP.
Objects	Physical objects necessary during ERCP.

Figure 3.6: Prompts and themes derived from the WDA framework

3.5 Conditions for the research, and limitations

Gaining access to study workplaces in healthcare settings can be difficult, and understanding expert performance requires time to be able to discern patterns of behavior amid the messy details of clinical work and the adaptations with which skilled professionals handle complex situations. The primary subject, a senior expert in ERCP, was key to being able to perform the studies, acting as a main informant during the first data collection phase, and also acting as a gatekeeper to other practitioners, which opened access to a broad sample of domain practice.

The research did not assess the usability of the technical solution, or investigate which aspects of the design or functionality of teleguidance were sufficient or necessary for the intended changes to be brought about. There was no intent to quantify relationships or causal links.

There was no opportunity to make practical use of the research findings to support the implementation process, or to inform clinical evaluation of teleguidance.

Chapter 4

Summary of appended papers

The starting point for this research was a telemedicine solution for surgical telementoring called teleguidance, which had shown promising results [9]. There was an intention to scale up the practice to more hospitals and to study the outcomes. However, telemedicine implementation regularly fails, which is often attributed to a lack of insight into sociotechnical issues. These studies were an effort to understand sociotechnical issues that might contribute to the use and adoption of teleguidance.

The first study focused on gaining insight into clinical practitioners' performance needs during ERCP, and how teleguidance could support their work. Physician acceptance is often described as one of the most important factors for the success of telemedicine [32], and is related to how useful they believe a service will be. This appeared to be an adequate first line of inquiry.

A series of observations and interviews about ERCP work provided input for a questionnaire, with measures of "usefulness" and "ease of use" that were adapted for the ERCP setting. Paper 1 describes this process and provides details about common challenges in ERCP practice, and workers' beliefs about how teleguidance might support their work. During the design and analysis of the questionnaire, the sociotechnical complexity of the domain became apparent, indicating that further investigation required an approach which could cope with this complexity. Work Domain Analysis (WDA) showed to be a method which could allow a structured and accountable analysis of the sociotechnical context, by modelling the conditions for teleguidance at the various sites (paper 2). While the importance of considering the implementation context is receiving increased attention in research about new technologies in healthcare, WDA contrasts to methods which are commonly used in healthcare settings. It was therefore warranted to explicate this methodological choice (paper 3). The last study investigated clinical practitioners' experience of using teleguidance, in order to gain more specific measures of how teleguidance answered to users' needs during ERCP (paper 4).

Paper 1:

A Mixed Methods Study of Practitioner Attitudes towards Teleguidance

Over the years, the low adoption rate of telemedicine has spawned research into "technology acceptance", a concept which is often described as a determinant for technology adoption [151]. The popular Technology Acceptance Model (TAM) [141] was originally grounded in behavioral research about how beliefs and attitudes influence behavior, and hypothesizes that people are more likely to use a technology if they start out with a belief that it will be useful and easy to use. The model was developed as a way to gain early user feedback to help designers identify and evaluate strategies for improving design in order to enhance user acceptance of office information systems [144], However, the central constructs "perceived usefulness" and "perceived ease of use" were intended to be transferable across different technologies and users [144]. The original TAM and various extended versions of the model are broadly used in healthcare [152][147] and especially in telemedicine [153][147]. However, in healthcare, the model is often used in efforts to confirm that future users are positively inclined toward a system, rather than a means to investigate if a system matches users' needs. In addition, the model has repeatedly proven to have a low predictive power in this type of setting [154][143][146].

While TAM has shown considerable weaknesses in healthcare, the model has strong theoretical underpinnings, and concepts that can benefit from using a broad set of perceptions and being adapted to the context [155]. This made it warranted to use TAM to help understand users' problem space, by investigating users' performance needs and goals during ERCP, and how teleguidance could be useful in this particular setting.

After an initial phase of open-ended observations of ERCP procedures and open interviews, a series of semi-structured interviews were conducted with intended users of teleguidance. The interviews were designed to elicit information about what staff considered important for performance during ERCP, and their expectations regarding teleguidance.

These interviews showed that many practitioners were interested in finding ways to improve their technical skills, but also to develop better works flows so that patients could receive the best possible treatment as fast as possible. Teleguidance was seen a way to develop individual skill, especially through support during certain phases of the ERCP procedure, which are considered difficult. Collaborating with the prestigious central clinic was also seen as a way to gain support for work process improvement. However, there was also concern that teleguidance might cause practical problems or introduce new types of risks.

Thematic analysis of the interviews laid the ground for a TAM-influenced questionnaire, which focused on perceptions about how teleguidance could contribute to performance, effectiveness and productivity, in terms that were adapted for ERCP work.

The "ease of use" items that are typically included in TAM questionnaires did not adequately capture the practitioners' concerns. Hence, they were replaced by items relating to the implementation climate and how compatible teleguidance might be with current ERCP work conditions and processes.

ERCP practitioners at 15 ERCP clinics responded, and the results indicated that ERCP practitioners' roles and level of experience reflected differences in how they weighed the value of teleguidance. A majority of the less experienced surgeons viewed teleguidance favorably, agreeing that it would be useful. However, there were senior experts who expressed concern that teleguidance might add burden to both clinical and administrative work practices.

One suggestion which grew from these findings was that it would be valuable to define incentives for experts to use teleguidance, and also designate time and resource allowances for staff participating in teleguidance. Framing teleguidance as an explicit training effort could be a way to avoid inadvertently challenging the power and autonomy of incumbent experts, and well-defined educational objectives might increase incentives to participate as well as increase management support of telementoring.

These insights about ERCP practitioners' work, and how teleguidance might support it, contributed to knowledge about how teleguidance could be useful and gave indications about workers' attitudes about how teleguidance could answer to their needs. This led to suggestions about how implementation of the service could be supported. This research process also contributed to the consecutive studies, since the effort to elicit users' performance needs and expectations, also revealed the sociotechnical complexity of the domain, which became the focus of paper 2.

Paper 2:

Modeling the Implementation Context of a Telemedicine Service: Work Domain Analysis in a Surgical Setting

The study leading to Paper 1 had provided insight into ERCP as a highly specialized procedure, which is conducted as a team task in a setting where there was a rapid rate of change, and high pressure for performance, safety and efficiency. Practitioners had expressed positive expectations about teleguidance, but also concerns that it might interfere with workflows and administrative issues. It was clear that teleguidance was more than a technology, it was a service which would change the distribution of work and expertise, bridge several stakeholder domains in each organization, and bridge hospitals across administrative regions. This setting was difficult to grasp intellectually, and it was unlikely that it would be possible to gain complete information about all the factors that might contribute to cause and effect during work. It was unclear what set the implementation sites apart, how to analyze this, and how to represent the findings in a way which could be useful for stakeholders.

Thus, the next step in the research required a way to describe the conditions for the implementation, in a manner which could include interactions among technical, social and organizational factors. The complexity of the implementation context also made it important to allow for multiple stakeholder viewpoints and interpretations.

Technical systems have social consequences [67]: teleguidance could be expected to affect communication and relationships, and its use would also be contingent with factors in the wider organizational context, such as managerial support. In this sense, social systems have technical consequences (ibid.): aspects of the context were likely to determine how the technology would be used. These interactions among technical, social and organizational factors would make it difficult to understand the introduction and use of teleguidance by separately focusing on the technology, on individual users, or on social and organizational mechanisms. In addition, the scope and the variety of factors that were involved made it intractable to try to describe the context by listing constituent components.

Linear models of causality imply that an event in a certain set of conditions can be expected to lead to a subsequent event: for example, that technology, which is validated and verified according to requirements, can be expected to improve efficiency and quality. While this perspective is sufficient for simple products and environments, the complexity of the clinical setting demanded a more realistic approach: tracking a number of easily identified conditions and events might lead to missing systemic factors which are not so apparent at a first glance.

Work environments that have a rapid technological rate of change, a high degree of computerization, and many integrated and interconnected processes can be characterized as complex adaptive sociotechnical systems [76]. These systems' ability to adapt can lead to reverberations when new technology is introduced, which makes it difficult to trace causal links between a new technology and changes in the overall system [156]. The ability to adapt also generates emergent phenomena, i.e. that the system as a whole acts in a way that could not be predicted from the individual components. The interactions make it difficult to understand outcomes from introducing new technologies by focusing on individual components, and also makes these systems difficult to specify and analyze.

Greenhalgh [157] stresses the need to acknowledge complexity and to address it systematically in order to understand technology implementation in healthcare. The NASSS model, which was developed to help explain the problems of "Non-adoption or Abandonment of technology by individuals and difficulties achieving Scale-up, Spread and Sustainability" shows six dimensions of complexity in technology implementation in healthcare, three of which are related to the implementation context: in the adopter system, in the organization and the wider system [4]. Sociotechnical systems methodologies can provide the "complexity lens" needed to understand the context in complex healthcare settings such as hospitals.

A sociotechnical perspective marks a shift from a "variables paradigm"[158], which focuses on discrete factors that can be defined and measured, to instead focus on identifying and accounting for the dynamic interactions that occur during technological change in healthcare settings [159]. The sociotechnical perspective provides theoretically informed methods that support design and evaluation of sociotechnical work systems [160]. This perspective shifts the focus from linear causation, and provides means to investigate interactions among technical, social and organizational factors [85].

A systems perspective provides an alternative to studying a system by breaking it down into its individual components. This alternative view is that system behavior can be understood and anticipated through attention to the forces or goals that generate interactions among system elements, and by understanding the context to which the functional parts are continually adapting [80][82].

Work Domain Analysis Work (WDA) is a method which is used to model complex work systems in the face of technological change, typically during the design requirements and specifications phases, or ahead of system development or acquisition [161]. WDA is developed for complex targets, which by their very nature are resistant to deterministic analysis. WDA is a both broad and deep method for analyzing and representing work place structure. It shifts the usual focus on technical properties or human activities, to instead model the constraints that shape the system's behavior. By idealizing and modelling categories of social, organizational and physical constraints, rather than examples or instances, the models can serve as relatively compact representation that still reflect the complexity of the real world.

WDA appeared to be a useful and feasible approach to account for the implementation context for teleguidance. WDA is a way to create abstracted functional models, which could be a way to investigate the "organizational fit "of teleguidance. A broad Work Domain Analysis could provide a systematic description of the factors shaping regular ERCP work at one hospital, including macro, meso and micro levels of the system, which are commonly analyzed and represented separately [53]. Modeling and representing the implementation context through WDA could provide insight into how the affordances of physical objects interact with functions towards system goals, and how expanding the work with new components may affect the system as a whole [162].

The common WDA representation is a type of model, which in its simplest form is a matrix called the abstraction hierarchy. This matrix can be used as a tool to systematically trace how introducing new technology and work processes can interact with numerous aspects of work. The graphical format could serve as a useful artifact to help to contrast the work systems where teleguidance was to be implemented, and to proactively identify how the telemedicine service might interact with work at the different sites. In this way, WDA could also support prediction of change and unintended consequences, which is a central aspect of complexity-informed evaluation [85].

As the intended benefits of teleguidance had been expressed in terms of clinical, economical and training outcomes, it was reasonable to take a wide approach to system definition, and to let the system description be built through findings from fieldwork and interviews, e.g. practitioner references to factors that shape daily work in the surgical setting. Data were collected through observations of clinical work, and semi-structured interviews with potential users of the telemedicine as well as other stakeholders. The focus was on gaining insight to challenges and needs in current ERCP practice at the hospitals where teleguidance was to be introduced. The transcribed interviews were analyzed through thematic coding [139], using predetermined categories and prompts from the WDA framework. The studies made it evident that many staff members have a variety of tasks, roles and priorities, and that they continually weigh trade-offs between medical/clinical work, and organizational demands such as resource efficiency, which sometimes conflict with clinical priorities.

Due to the open nature of the work systems, the scope of analysis was very wide, but also deep: many causal (physical) and intentional constraints (goals, priorities etc.) were identified. Some constraints were conflicting, for example policies which might cause trade-offs between clinical performance and economic efficiency.

Over multiple modelling iterations, three abstraction hierarchies were developed. The clinical environment was characterized as having three *facets*, which represent distinct sets of constraints that affect ERCP work. Clinical work was the primary field of interest, and administration and development were seen as complementary fields of the domain, which provide resources for clinical work. The three facets are distinguished through the nature of tasks, and aspects such as organizational departments, competencies and roles. The functional facets were defined as follows:

The *clinical facet* represents the constraints that shape the ERCP team's work with regard to the functional purpose "Patient diagnosis, relief or cure through ERCP".

The *administrative facet* was conceptualized as the part of the domain that provides the resources for "primary", clinical work. This facet is largely shaped by intentional constraints: institutional objectives; organizational and management policy; legislation, and regulations.

The *development facet* is distinguished from the administrative facet due to its focus on training, research and quality management which characterizes advanced clinical practice.

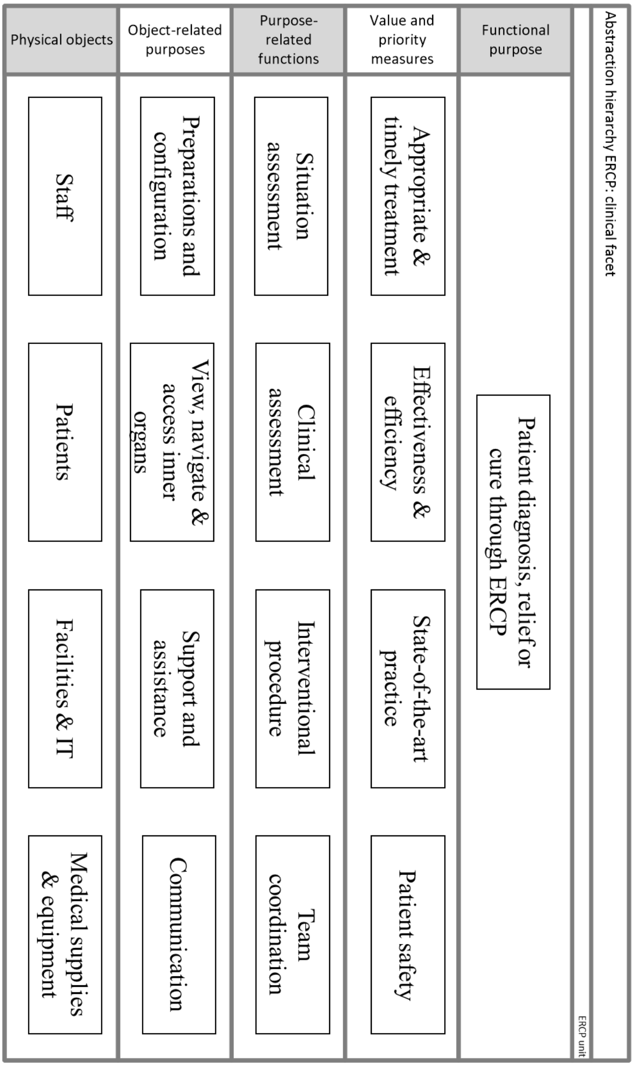

Figure 4.1: The clinical facet

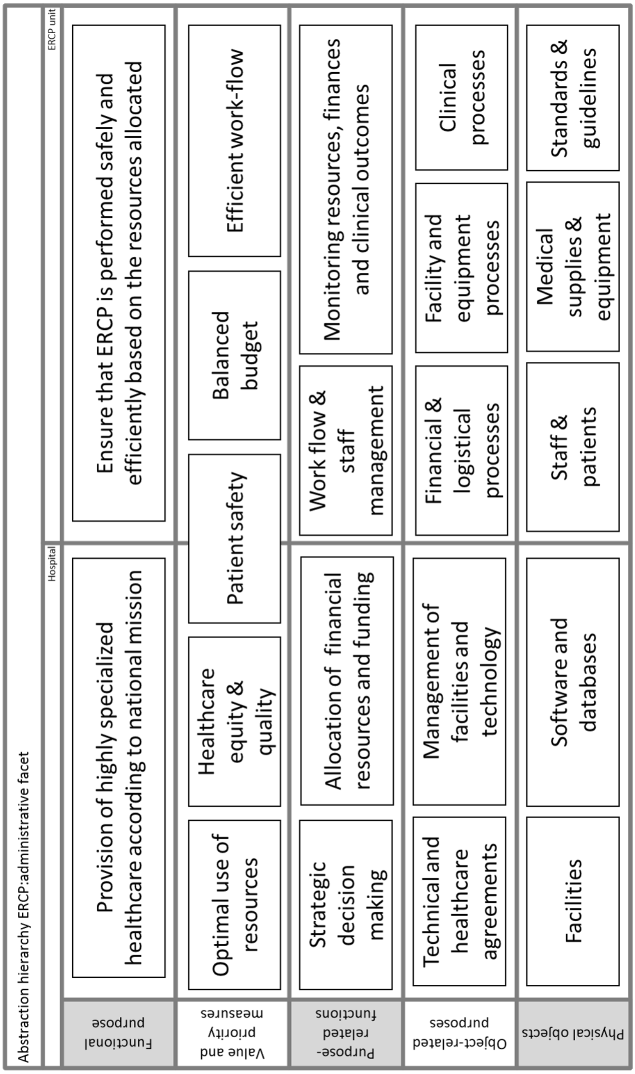

Figure 4.2: The administrative facet

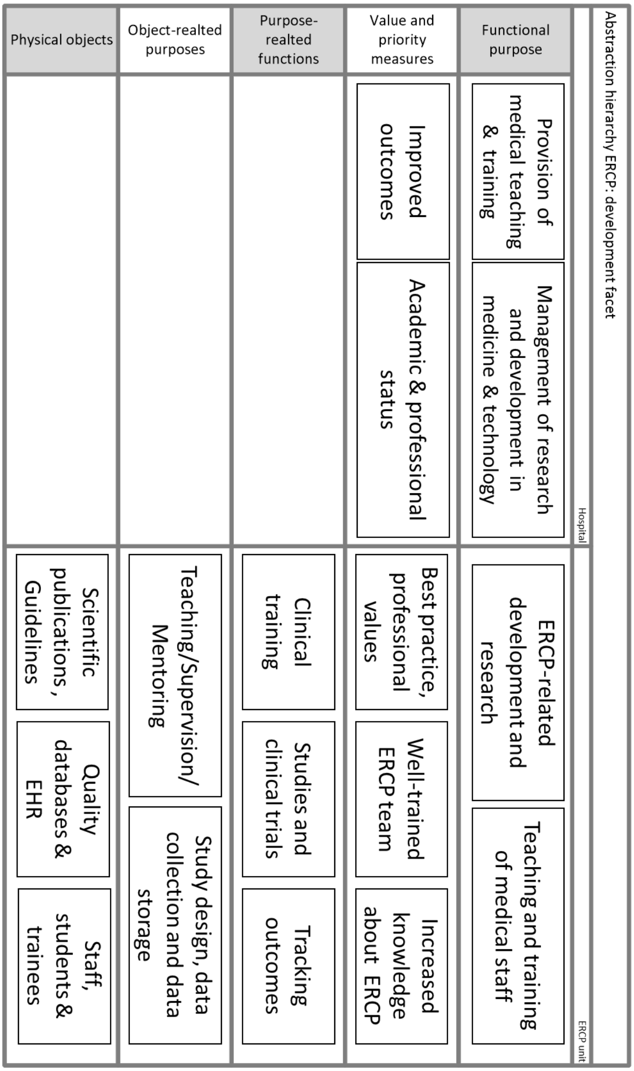

Figure 4.3: The development facet

WDA provided means to analyze and visualize the ERCP work system in a way which displayed multiple sources of complexity. This proved to be a powerful way to investigate multiple aspects of the telemedicine service's "organizational fit ", not only in material terms, but also with regard to functions, goals and priorities across different parts of the organizations. Modelling the three facets separately highlighted how ERCP staff continually deal with multiple considerations.

The model of the clinical facet showed constraints that shape cognitive and collaborative processes during ERCP procedures. The "secondary" facets of the domain showed parts of the work system which provide resources and set constraints on the "primary" clinical work. Issues in these secondary facets, such a technical responsibility for the service or reimbursement issues, may play out over time, and affect use and adoption of the telemedicine service, even if the clinical facets of collaborating hospitals are well-aligned. One example was that the development facet was decidedly more prioritized at the university hospital, and that users at the smaller hospitals may not have the time and resources necessary to handle the awkwardness of work process adaptations, even if teleguidance was of value for clinical work.

Using WDA to model the implementation context was an effective way to analyze and represent these complex settings. This can be a way to support the transformation required when telemedicine is implemented at a hospital, when dynamics between the incoming new technology and the organizational dynamics can be expected to lead to mutual adaptations [62]. However, CWA originated in analyses of well-defined, tightly coupled causal systems, i.e. engineered systems that are constrained by natural laws and technical factors [76]. Some have claimed that WDA is not well-suited for healthcare [163][164], where work systems are open, and system behavior is characterized by intentional constraints, such as actors' goals, values, priorities and shared rules of practice. Another concern was that WDA is not well known within healthcare, and that it contrasts to current approaches to understanding the implementation context or how technology can change healthcare. Paper 3 is a methodological article which focuses on these issues, and also describes some practical challenges of applying the method.

Paper 3:

Context and Complexity in Telemedicine Evaluation: Work Domain Analysis in a Surgical Setting

It is generally acknowledged that health technology implementation and outcomes are affected by contextual factors, but the preconditions for implementation are rarely accounted for in a way that captures the inherent complexity of healthcare, or in a fashion which can inform design and evaluation. There were many methodological challenges in understanding and describing the implementation context for teleguidance. One issue was the need for a format that could accommodate the complexity of the work systems but also support communication among various stakeholders such as designers, researchers, clinical staff and managers. Work domain analysis is not well known in healthcare settings, and there were also modelling dilemmas due to the nature of the loosely bounded system.

Modelling the work systems through abstraction hierarchies provided a way to gain a deep and shared understanding of how the ERCP procedure is conducted, and how this can vary among different clinics. The strong theoretical grounding of the method and the focus on modelling constraints and affordances for work made it possible to avoid conceptual dilemmas about what should be regarded as context or setting, and also provided compact graphic representations that supported communication between researchers, clinical practitioners and other stakeholders.

This shows how WDA is an effective, proactive, "complex systems" approach to mapping the implementation context, which can serve as an alternative to currently common approaches, which focus on identifying and measuring variables, which often are characterized as determinants, barriers and facilitators. In sum, WDA can support telemedicine projects towards achieving intended effects on clinical practice and/or patient outcomes, and avoiding unintended effects on overall system performance and safety.

From a systems perspective, the effects of teleguidance would not necessarily surface immediately during implementation, rather they can be expected to be emergent, as users come to experience the pitfalls and the potential of the new way of working. While there was no possibility to track the use of teleguidance over time, there was a window of opportunity to capture user feedback through piggybacking on a study which was being planned to investigate the clinical outcomes of teleguidance. Paper 4 describes the results from questions about surgeon's expectations and experience of using teleguidance which were included in case report forms in a clinical study of teleguidance.

Paper 4:

User Experience in Remote Surgical Consultation: Survey Study of User Acceptance and Satisfaction in Real-Time Use of a Telemedicine Service

Teleguidance had shown potential to improve ERCP when it was used within the pilot project [9], and it was interesting to assess how a wider group of practitioners experienced its quality in use. There was an opportunity to gather data in direct conjunction to teleguidance sessions. This particular study came to focus on clinical practitioners' expectations about how teleguidance might contribute to procedures, and also whether these expectations were met during the teleguidance session. The aim was to gain further insight into user expectations and needs regarding surgical consultation and how teleguidance contributed to ERCP procedures.

The ISO standard 9241-10 [106] is a tool to support human centered design processes, which also provides definitions regarding usability and user experience. Usability evaluations commonly include combinations of *effectiveness, efficiency* and *satisfaction* measures [106]. According to the ISO definition, satisfaction is a measure of how well user experience during actual use meets the user's needs and expectations. Understanding user experience therefore requires an understanding of user perceptions prior to use, and the level of satisfaction that results from system use (ibid.).

Satisfaction is generally considered to be a key component for telemedicine success, and is often included in evaluation of telemedicine services [165]. However, in health services research, satisfaction measures often refer to staff or patient satisfaction with treatment or care [166][167], which is not the same as satisfaction with the use of a technology.

Similarly, *usability* and *user experience* bear certain resemblances with the concept of *technology acceptance*, which signifies users' expectations of how a technology will impact job effectiveness, efficiency and performance [168]. However, technology acceptance commonly refers to the behavioral intention to use a technology, rather than end-user satisfaction grounded in actual use [143]. Another common confounder in healthcare services research is that the terms acceptance and acceptability are often not well-defined, and generally are used to describe the extent to which staff or patients consider a treatment to be appropriate [169]. Hence, there is a need for careful definition and operationalization of these types of measures.

This study therefore represents a human-centered design approach to assessing teleguidance. Users of teleguidance were asked to provide subjective ratings of their estimated need and expectations for consultation during the procedure, through measures of the support they were expecting to gain through teleguidance. After telementored procedures, satisfaction with teleguidance was measured through participants' ratings of the ways in which teleguidance contributed to their performance and to the outcomes of the procedure.

The results showed that there were positive expectations in a high proportion of cases, and that the anticipated need for teleguidance increased with the level of procedural complexity. Also, there was increased interest for teleguidance prior to certain types of interventions, and when certain clinical indications were present. Accordingly, the expected, or perceived usefulness of teleguidance was higher in cases that could be expected to be challenging.

Regarding satisfaction with teleguidance, it mainly contributed through the practical advice that operating surgeons received from the consulting specialist, as well as the support they received with assessment and decision-making. In addition, teleguidance was considered to have helped avoid failed procedures in a considerable number of cases.

One interesting result was that satisfaction after using teleguidance was higher than pre-procedure beliefs about usefulness. This indicates that it is difficult for practitioners to predict the benefits of a novel way of working, and that user beliefs and attitudes towards teleguidance can be expected to change with first-hand use. These results therefore represent an interim judgement of the usability of teleguidance.

Chapter 5

Conclusion

This chapter revisits the research purposes and the research questions presented in section 3.3, in relation to the findings in the papers included in the thesis.

While digital health has considerable potential to transform healthcare and there is a great deal of innovation, many digital health interventions fail. The WHO's Global Strategy on Digital Health 2020-2025 [1] states that it is important to find effective ways to scale up and assess digital health interventions, and that feedback about implementation and use is a path towards attaining higher levels of adoption.

When a promising innovation is to be deployed or scaled up, it is often not clear how it might play out in other settings, or what adaptations are required to create a good organizational fit [39]. This means that digital health innovation should not end with a pilot project: often, additional assessment and adaptations is required before an innovation can be scaled up to additional sites and be adopted. Aligning the design and implementation of a service with user needs and organizational resources, in order to ensure that it is usable and useful, requires an understanding of user and stakeholder needs, as well as of the wider organization (ibid.).

There are many sources of complexity in digital health, not only due to the sociotechnical setting, but also because how a technology is designed and implemented plays a role in achieving health related outcomes. Sociotechnical complexity makes it difficult to design and carry out clinical evaluations of digital health technologies [26]. The complexity of healthcare settings also makes it challenging to implement promising innovations, and failed human-system integration is a common but often underestimated product and project risk [5]. The common "paradoxes of telemedicine" show that despite policy push and great optimism, most services do not achieve sustainable use. Little is known about the reasons why this is the case, and common ways of assessing digital health are often incongruent with the ways in which systems development occurs [20], and fail to provide insights which are relevant for design and implementation [26].

Researchers and policymakers underline the need to accommodate complexity when introducing digital solutions to drive change in healthcare, which requires understanding how interacting technological, organizational and social factors contribute to use and acceptance of digital health services [98][170][171].

The overall research aim in this thesis was to provide examples of how a complex, adaptive sociotechnical work system can be analyzed to better understand the introduction of a telemedicine service. The research approach was shaped by theory about complex, adaptive sociotechnical systems. This provided a conceptual foundation for how to understand the implementation context where teleguidance was to be introduced.

Constructs such as usability and usefulness guided the search for relevant aspects of user behaviors. Abstracted functional modelling through Work Domain Analysis was an effective way to structure a large amount of qualitative data, and also helped guide the analysis of the implementation context. The abstracted format of the models was valuable, because it enabled comparison of work settings which were configured in different ways and which also were undergoing change. These models of the context of use generated information about how the solution could work in different settings, which can be important feedback during development and deployment, but also serves an important role in evaluations.

Paper 1 provides details of how practitioners weigh the usefulness of teleguidance, attitudes which can have practical implications for implementation. The findings from the WDA (papers 2 and 3) hold clues for what can be important to consider when planning implementation, and also when designing late-stage final assessments. For example, the models identified functions during the ERCP procedures which were most likely to be affected by teleguidance. Similarly, investigating early reactions to using the telemedicine system (paper 4) provided details about how users assess the value of teleguidance, and that it may take some time for users to appreciate the contributions of the new way of working.

5.1 Research questions revisited

In this section, the research questions formulated in section 3.3 are addressed and discussed in light of the research findings.

RQ1 What aspects of users' problem space are relevant for the use and adoption of teleguidance?

Concerns that teleguidance might disrupt current workflows made it clear that workers assessed the usefulness of teleguidance with regard to the wider work system, and not just within the frame of an ERCP procedure. However, despite the daily pressures of ERCP work, many had positive expectations of learning new techniques or gaining support in difficult ERCP cases. This also included ERCP assistants, who play an important role during procedures.

The studies showed that the problem space differed for the guiding surgeons and the surgeons at the remote sites, which reflected their different roles during teleguidance, but also differences due to levels of expertise and interest. The studies also uncovered how the intended users of teleguidance not only had to balance demands in the clinical work, but that their behavior was also shaped by constraints from the wider sociotechnical context. All clinical staff were deeply committed that their patients should receive the best possible treatment, but effectiveness and efficiency were also primary concerns among all the interviewed ERCP staff. It was therefore important that teleguidance did not add to workload or disturb workflows, neither with regard to activities in the operation room, nor the planning and coordination required for effective staff and patient logistics.

ERCP can have both diagnostic and therapeutic objectives, and the common aim is to gain access to obstructions in the biliary and pancreatic ducts, to take biopsies or alleviate blockage. Particular challenges are interpreting endoscopic and fluoroscopic imagery, correctly identifying physiological features, and making decisions about the appropriate method and equipment.

Clinical assessment and decision-making. During ERCP, it is not unusual that surgeons are confronted with unusual physiological features or new findings, and that pre-operative plans are reassessed during procedures. The expertise that the mentoring surgeons contribute with during teleguidance was expected to support reassessment of indications and diagnosis, as well as adaptation of the clinical task in the midst of ERCP, e.g. the choice of equipment, supplies or technique, or settings and adjustment of the fluoroscopy. The highly experienced surgeons were expected to have a better ability to detect variance and complications, and also have more skill in projecting consequences and anticipating events.

Situation assessment. The ERCP team continually control and monitor the patient's condition and the progress of the procedure. Important information about the situation is communicated through speech and also through explicit and tacit signalling. While the guiding surgeons' understanding of the situation would be supported by high quality transmission of medical imagery and sound from the operation room, they also wanted to have a video feed of the operation room, as this would show the configuration of the remote team and equipment, and also provide clues to how the procedure was progressing through patterns of movement among the staff. For a guiding surgeon joining a procedure already in progress, it would be important to quickly understand the case and the immediate situation. Both the guiding surgeons and the surgeons at the remote sites expressed that verbal exchanges in combination with the medical imagery would suffice for these purposes. However, communication breakdowns in surgery are strongly linked to patient safety risks, hence it is important to understand the processes in understanding the situation and how to avoid breakdowns in teleguidance [172].

Team coordination. ERCP is a time-sensitive procedure which requires intensive team coordination and shared understanding. It was therefore considered important that the entire ERCP team could listen in on a teleguidance session. This was especially important for the assistants, who need to anticipate the ERCPist's actions and needs, and who contribute to the outcome of the procedure through a wide range of tacit and "soft" skills. There are general routines, conventions and practices that shape how ERCP was conducted at the various hospitals, and a common shared goal of helping the patient on the operating table, which could be expected to make the team members' activities predictable to each other, to a certain degree [173]. However, procedures also involved competing and sometimes conflicting goals, e.g. whether to persevere in a case where it was difficult to cannulate, or to resort to other procedures. This meant that it would be important for the mentoring expert to have background information about the patient, insight about the level of skill of the surgeon and the team at the remote site, as well as about the available resources and constraints, e.g. medical equipment and supplies, and time pressures.

Teleguidance can be expected to change the "costs" of grounding communication [174] and coordination [173]. While there are generic mechanisms for achieving and sustaining the common ground that is necessary for coordination [173] this aspect is important, and understanding how it is achieved and how it can be supported in surgical telementoring is worthy of attention.

Interpersonal relationships, social interactions and trust are factors that affect coordination in teams [175]. Some surgeons at the remote sites were well acquainted with the guiding surgeons, from educational and professional encounters, while others did not know each other.The university hospital from which teleguidance was being offered has a prestigious and popular fellowship program, during which important skills and practices are transferred for aspiring ERCP surgeons. It is likely that practitioners with established relationships and similar ways of working, for example fellows, will have a lower threshold to collaboration through teleguidance than practitioners who have no established relationship.

Preparations. Planning for ERCP is tightly coupled and often conducted by highly experienced nurses, and includes securing access to adequate facilities and equipment, and balancing changing patient needs with the scheduling of surgeons, anesthesiologists, and assisting staff. From this perspective, it was important that teleguidance would not delay procedures or disrupt planning. In addition, staff were generally stressed and appeared to be constantly struggling to work more, with fewer resources. It was therefore pertinent that teleguidance should not add workload to overburdened staff, for example by demanding extra time and effort for rigging the teleguidance equipment, for setting up a connection, or for getting technical support. The smaller hospitals had fewer resources for training and development, and would have more difficulties in accommodating a telemedicine service that is not tailored for the local conditions.

Administrative issues. Many practitioners anticipated lack of management support or reimbursement problems, which would affect teleguidance over time even if it was useful during procedures.

Development, training and research. For individual surgeons at the remote sites, teleguidance was seen as a way to gain access to new knowledge about physiology and pathologies, and also about new or advanced tools and techniques, and to learn to use them under supervision. This would not only benefit patients, but also progress in their professional specialization, and serve the overall quality and safety of treatments at the respective hospitals. Many of the less experienced doctors also expressed that collaborating with the university hospital clinic was a positive step for their careers, both for learning new skills but also for strengthening professional relationships. Some specialists were interested in finding ways to participate in research, and teleguidance was a way of connecting with senior practitioners involved with studies and development of medical technology.

The collaboration with a prestigious clinic was also seen as a possible way to raise the status of ERCP at smaller hospitals, and thereby gain better access to resources such as operating theaters and staff. Similarly, the collaboration was seen by some as a way to gain leverage in efforts to develop more effective work processes.

From the perspective of the university hospital, teleguidance was a means to address disparities in treatment and to attain a larger number of well-trained specialists in the field of ERCP. It was also a way to spread knowledge about surgical guidelines and best practice, and to increase the level of reporting to national quality registries.

RQ2 How can the sociotechnical setting be systematically described and analyzed?

WDA is a Cognitive Systems Engineering [76] method that made it possible to represent the implementation context for teleguidance, in the form of a model of the work domain. By representing the functional structure of the sociotechnical system, the models define constraints on actors' behavior, which is a way of showing possibilities for action, and also for understanding the rationale for behaviors. The models are event-independent and abstracted from their instantiation, which makes them useful for many situations and also makes it possible to use the same models to analyze differences between hospitals. Creating models enabled systematic analysis and allowed for a compact representation format, which was a useful alternative to creating detailed narrative accounts.

There were some challenges in applying the method, which were partly due to the open, loosely bounded nature of the work system, which made it difficult to set clear system boundaries or create a distinct hierarchical system decomposition. The focus system and its boundaries were not defined by physical or organizational entities. Instead, the system was demarcated by the problem of interest: conducting ERCP procedures, and elements were included based on their coupling to ERCP, in this case through their mentions in interviews.

Different stakeholders - clinical staff with and without administrative roles, managers, technical staff etc. - presented overlapping but different concerns with ERCP and teleguidance. It became apparent that administrative and clinical roles and tasks were highly interwoven in ways that were not necessarily reflected by formal roles or organizational boundaries. Similarly, development work, such as research and training, was generally not represented in the organizational structures. The interactions between clinical work and organizational demands made it challenging to define a meaningful part-whole systems decomposition of the hospitals and their subsystems. This was finally solved by creating multiple models of the domain, which allowed more detailed modeling of the elements. The three facets represent sets of constraints that have different purposes but which shape every day ERCP work, and can shape the use of teleguidance.

Each facet had certain functional purposes, and values and priorities which shape the behavior of various parts of the overall work system. Details about functions and processes were also included in the models, which serve as detailed maps of the implementation context. The structure of the models made it possible to reason about how teleguidance would introduce new affordances and constraints, and how these could propagate throughout the work system.

WDA contrasts to reductionist methodological approaches in implementation science which attempt to break down a context into constituent parts, often classifying these elements as barriers or facilitators, without addressing interdependencies among contextual determinants [52]. WDA provides a way to include causal and intentional constraints, and interacting technical, social and organizational factors, thereby serving as an alternative way to analyze and represent implementation context, instead of identifying contextual factors and their relevance for implementation through lists of "determinants" (ibid.).

RQ3 How can the implementation context come to impact the use and adoption of teleguidance?

The work domain analysis served as a framework for reasoning about how teleguidance would interact with constraints on multiple levels of the work systems. Teleguidance was not expected to change the functional purposes of the work systems, but rather to affect the constraints through which these purposes are achieved. Teleguidance may cause differences in intentional constraints to surface, such as variations in the values and priorities among clinical practitioners or between organizations. One example, which shows how values and priorities are linked to objects and object-related processes, was how the strong research focus at the university hospital shaped priorities, since many practitioners are involved with quality work such as collaboration regarding clinical data and standards. This shaped daily practice, such as the decision that all ERCP procedures at the university hospital should be conducted with anesthesia. As a result, all ERCP are conducted with the patient in a supine position. However, at some smaller hospitals, sedation was used instead, as this often was quicker, required simpler facilities and fewer specialized staff. However, sedated patients are kept in a recumbent position, which alters the orientation of the patient's anatomy in relation to the surgeon. This could lead to serious misinterpretation of imagery and skewed instructions if the consulting surgeon is not fully aware of this difference. There was a hope at the university hospital that teleguidance might influence more practitioners to follow the best practice of using anesthesia during ERCP.

There were also causal constraints which could affect the use of teleguidance over time. Some examples are provided below.

Daily work pressures, such as staff and patient logistics, technical issues, and the need to keep to a tight schedule were all factors that shaped every day ERCP work. Many of the smaller hospitals are tightly stretched, and did not have much allowance for a service that was not well adapted for their work.

Differences in the hospitals' facilities, such as the size and layout of procedure rooms, or that facilities were not dedicated for ERCP might affect the ability to use teleguidance effectively. Also, different types of medical equipment and supplies were used at each site: the type of x-ray equipment or the range of ERCP-specific supplies available at a site could affect the ability to perform the advanced interventions teleguidance was intended to support.

If teleguidance disrupts these everyday considerations in ways that outweigh staff's perceptions about its benefits, it can be expected that it will not be used over time.

In addition to the constraints set by clinical work, the administrative facet also shaped the conditions for teleguidance, for example through efficiency demands, which were weighed against clinical priorities during procedures. All hospitals were under considerable pressure for increased efficiency, and in constant reorganization. IT-infrastructure and IT-support varied among hospitals, and there were concerns that reimbursement processes did not cover development projects such as teleguidance. As a consequence, it would be difficult to provide swift technical support during teleguidance sessions. Another illustrative example, which instead might increase the demand for teleguidance, was a management directive at one of the participating hospitals: that ERCP candidate patients generally should not be referred to hospitals outside the region. This had the effect that less experienced ERCPists needed to take on challenging cases that they previously would have referred to a tertiary center.

Contrasting the development facets at different sites highlighted how the participating hospitals had different priorities and resources for training and research. If development activities are not a priority, then there is a risk that users will not have the time and resources necessary to handle the awkwardness of the work process adaptations required to accommodate teleguidance. This could show as reduced ability to accept teleguidance, and also as a risk that organizational demands for efficiency and effectiveness might be prioritized over the long-term quality outcomes provided by the telemedicine. Hospitals where the development facet was weak were also the places where individual novices expressed the strongest need for support in their own professional development, and also voiced a need to develop work processes.

However, the development facet was also a point of entry to the hospital work systems: teleguidance may be framed as an explicit training effort directed at novices. Well-defined educational objectives might serve as incentives for novices to participate in teleguidance, as well as increase management support of telementoring. This could be a way to avoid inadvertently challenging the power and autonomy of incumbent experts.

RQ4 In what ways does teleguidance contribute to ERCP procedures in practice?

Conducting the WDA proved to be a way to structure and represent growing insights about how teleguidance would come to affect ERCP work. From the WDA it was possible to see that teleguidance could be expected to mainly affect functions such as clinical assessment and interventional procedures, by consultation about how to enhance or interpret imagery, or providing specific suggestions for the interventional procedure, such as placing a stent or handling cannulation, which often can be a tricky phase during the procedure. However, it could also be expected that knowledge about new surgical supplies and techniques can be disseminated through teleguidance. Experienced practitioners can be expected to have considerable knowledge about potential courses of action, and an ability to project risks and consequences which they can contribute with to a less experienced team.

The telemedicine service may create challenges for situation assessment and team coordination during ERCP. Situation assessment will change in some ways during teleguidance sessions because team members will be in different locations, and there are risks that the remote surgeon and on-site team might perceive the situation differently (e.g. the guiding surgeon may miss information that is apparent to the on-site team). Team coordination may be affected as the guiding surgeon becomes part of a geographically and organizationally distributed clinical team that requires cognitive, practical, and administrative coordination. Trust is also an important aspect of team coordination, which needs to be considered.

The investigation reported in paper 4 gave further details about how teleguidance contributes to ERCP in practice. The demand for teleguidance was more pronounced in cases with a high complexity rating, where cannulation was expected to be difficult and for pancreatic procedures. Teleguidance contributed to intervention success and helped avoid more invasive procedures, or having to repeat the procedure. Practitioners benefitted more from practical advice than they had initially expected, but overall they experienced the most benefit from support with assessment and decision-making. The findings indicated that doctors may become more cognizant of how teleguidance can support important clinical and development/training aspects in ERCP with hands-on use, but also that they require some time before they assimilate teleguidance into their practice. When planning the evaluation of an intervention, where its effectiveness is contingent on changes in human behavior, it is important to consider the time between implementation and maturity of effects [176]: this is the case with teleguidance, which relies on a new form of collaboration. and is intended to support learning.

Chapter 6

Discussion

The research included in this thesis shows pragmatic ways to unpack the complexity of a highly specialized hospital setting in the face of technological change. Teleguidance had been successful in the settings for which it was initially developed, but when it was to be scaled up, it was necessary to have an adequate image of the conditions at the other hospitals, in order to support deployment and evaluation. This was a daunting task due to the complexity of the clinical work and the wider organizational context. Systems theory and sociotechnical systems principles provided important guidance for how to accommodate the complexity of these work systems, suggesting that focusing on user goals and mapping the implementation context would provide insights into factors that would shape the use and adoption of teleguidance. The studies converged on understanding user needs and stakeholder interests, as well as the environmental constraints that the telemedicine service had to be compatible with. The thesis demonstrates how sociotechnical complexity can be accommodated when assessing the implementation context for a digital health intervention.

6.1 Reflections about the research findings

While the data collection generated large qualitative data sets, the theoretical grounding helped guide analysis and distinguish elements and patterns that are relevant for implementation of teleguidance, and also patterns that may be characteristic of this type of hospital setting facing introduction of new digital health services.

The research showed that the deployment phase can be an opportunity to gain insight into the local adaptations which are generally necessary to support adoption of digital health interventions[39]. Papers 1 and 4 showed how it is possible to gain effective end-user feedback prior to and during deployment.

Papers 2 and 3 showed how charting the implementation context through WDA is a way to identify potential problems proactively. The work illustrates means to build a progressive understanding of how a digital health intervention will be accepted and contribute to healthcare outcomes, an activity which is important throughout the lifecycle of digital health interventions [39], and where there has been a need to find ways to accommodate sociotechnical complexity.

Planning and conducting evaluation of digital health interventions requires insight into the conditions for an intervention and the mechanisms which generate outcomes [39]. The research shows effective ways of analyzing the implementation context and user needs and behavior. Paper 1 uncovered prioritized aspects of clinical work in order to define usefulness in ERCP-relevant terms. One finding was the concern among practitioners that teleguidance might disturb team coordination, or that it might disrupt planning. If teleguidance causes these types of disruptions, staff can be expected to become less positive towards teleguidance over time. These examples also suggest how insight about user needs can provide a basis for defining representative tasks and scenarios for pre-implementation testing but also post-market monitoring.

WDA was an effective way to analyze and represent the implementation context. This helped to understand the initial conditions, and project what changes can be expected or how change will be achieved. WDA is a theoretically informed and structured method, whereby the identification of relevant data was guided by a clear rationale, justifying which factors were included in the model. Using a formal method and creating a shared diagrammatic representation was also a way to clarify what has been considered in the analysis. In addition, the simple and epistemically transparent format of the model enabled shared interpretation among researchers and practitioners.

The models show factors which can determine the "survival" of the service over time, and therefor also contribute to outcomes. Thus, WDA can be useful for developing theoretical understandings of complex interventions and to model likely change processes during development and before full-scale evaluation, an activity which is recommended for complex interventions [46]. This type of detailed analysis and planning prior to implementation and evaluation of telemedicine is currently rare [177].

WDA can contribute to clinical effectiveness studies of complex interventions, such as digital health solutions in complex healthcare settings, as the method can help analyze and describe the conditions for implementation, the mechanisms and conditions of change, and identify sources of variability or bias. One issue which was identified in Paper 1 and also surfaced in Paper 4 was that the level of experience among practitioners affected how they perceived the value of teleguidance. This suggested that they would use the service in different ways. Paper 1 also identified a group of practitioners which were consistently negative towards teleguidance. Paper 4 gave insight into certain mechanisms of change, showing how perceptions of teleguidance developed when practitioners gained first experiences of using the service. These examples show sources of bias and variability which are valuable to consider in later evaluations.

Another way in which WDA can contribute to clinical studies is by helping determine characteristics which are relevant for matching experimental and control sites in multi-site studies of digital health solutions, which is a current challenge [20]. The WDA described in papers 2 and 3 show how the work systems are shaped by clinical, administrative and development constraints. Each of these facets represent dimensions along which to reason about similarities and differences between sites. An example of how this can be done is included in paper 3.

In the example, the model shows how adding additional equipment at the deployment sites might cause increased workload by affecting both logistics processes and preparations, resulting in less time for the configuration of the operation rooms. At certain sites, it was therefore likely that teleguidance would affect the total time required for an ERCP procedure. More details about work processes and functions that could set sites apart were included in the disaggregated models, which are not included in the papers.

Many organizational case studies of complex settings use rich, story-like narratives to account for work practices and the implementation context, a format which can make it difficult to link observed patterns to other research or inform implementation [86]. If the context in which an intervention has been studied is not adequately defined and described, it is difficult to synthesize findings from different sites, for example in a systematic review, or to transfer findings from a particular case study to different settings. By instead representing the implementation context as a model, it is easy to discern how the system of interest, the "context of use" or "implementation context" has been defined, and what is included in the analysis.

Modeling through WDA answers to calls for systems complexity-oriented methods [44], acknowledging the dynamic nature of the work systems involved. This is also a way to avoid the notion that "context" is a fixed, stable entity which can be understood through its constituent components and described by compiling variables or events, which is problematic in complex, dynamic environments. In this sense, modeling provides a better way to identify issues requiring attention when planning or evaluating implementation than for example using determinant frameworks [50], which risk directing attention to a limited number of components, without deeper understanding of their mechanisms or interdependencies in a certain context.

The WDA model serves multiple functions: it represents knowledge which was gained through the studies in paper 1 and 2, and also serves as a useful artifact. By isolating aspects of the target domain which are relevant for understanding the factors that shape ERCP work, the model can bear important similarities to the domain and yet be simple, tractable, and transparent. Ordering and displaying empirical findings as a model, supports the process of discovery, with the aim to infer beyond the empirical findings to provide new insight into the target, and in this way help anticipate and proactively meet challenges during implementation. The models help answer to *the envisioned world problem* [59] of understanding how a technology matches user needs in a changing environment, and how the technology can come to transform practice. WDA offers a way to represent a system in an object- and event-independent approach. This makes it possible to represent a system which is undergoing change, and shows paths for how workers can deal with a wide variety of situations. It also shows how various components interact.

WDA can accommodate many sources of complexity and can be used to model and analyze other similar clinical work systems. Many of the functions and constraints which were identified in Paper 2 and 3 may be typical to surgical settings and hospital environments. The three functional facets of the domain (clinical, development, and administration) which were modelled in the WDA represent generic sets of constraints which can be expected to be present in other hospital environments, and are likely to affect other technology implementation projects.The development facet was of particular interest because it was not reflected within the organizational structures, yet is a central aspect of the work domain. The aspects of the work system included in the development facet appeared to be important drivers of behavior: motivating staff to gain new knowledge and skills; to teach, train and conduct research; and to gain professional status and uphold professional networks in the constantly evolving field of ERCP. Lacking awareness of this facet can be a significant problem, since quality work, training, research, and design of medical equipment are pervasive aspects of daily work that need to be considered during design of technologies and work processes.

Together, the studies and the results provide examples of how methodologies for complex sociotechnical systems can guide research to illustrate work practices and how actors behave in a domain. This was a way to provide insight into many social and organizational aspects that could affect the use of the telemedicine service, for example to identify local adaptations, which is generally a necessary activity for achieving successful implementation of digital health interventions [39]. The research illustrates that it is possible to conduct and represent a multilevel systems analysis of the implementation context, including macro (e.g. guidelines, directives, policies), meso (e.g. organizational norms, values and expectations) and micro (e.g. team and individual staff needs, attitudes and resources) levels [52], and how it interacts with an intervention, which is a methodological challenge in case study research about complex interventions and digital health [178][105].

6.2 Methodological reflections

The thesis links design science and sociotechnical design methodologies to the field of digital health interventions. The research is transdisciplinary, proposing that behavioral science and design methodologies developed for complex, adaptive sociotechnical settings can help understand the conditions and behaviors that can be expected to contribute to the outcomes of a digital health intervention.

From the predominant healthcare research perspective, the research would most likely be positioned as qualitative and descriptive, yet the studies do not fit into the common categories of qualitative research in healthcare, such as: narrative research, phenomenological research, grounded theory research, ethnographic research, historical research, or case study research [179]. These qualitative approaches reflect epistemological traditions that emphasize interpretative analysis, and richness and depth of description, and seldom use higher-level theories to organize data, or connect it to other research [180]. The studies included in the thesis are qualitative in the sense that the data is largely qualitative rather than quantitative: here "qualitative" describes the type of data, rather than an epistemological stance [181], as is implied in phenomenology and interpretative sociological methodologies [182]. The theory-guided empirical investigations involved both inductive and deductive processes, where specific empirical findings are linked to theoretical constructs during analysis, a process of abstraction that supports cumulative building of knowledge from empirical data, which is has been described in cognitive engineering research [108].

In behavioral science, it is common to use both mechanistic and functional theories about causes and reasons for individual, group and social behaviors [183]. Rather than being used as universal laws of nature, from which specific behaviors can be deduced, behavioral theories describe causal mechanisms as patterns, or relational rules among theoretical constructs, that help explain how and why phenomena arise. Behavioral research often involves multiple, complementary methods, and iterations of inductive and deductive processes, where the choice of approach and focus is shaped by knowledge about observations and theory in a field, and empirical findings are interpreted in light of a chosen theory (ibid.).

Hence, the research contrasts to common research approaches in healthcare. Healthcare research is characterized by reductionist scientific thinking [102] and positivist approaches to evaluation, which prioritize establishing quantitative relationships between decontextualized variables, and face challenges in establishing causal links when there are many intervening factors [26].

Digital health projects often have multiple sets of goals, and outcomes are context-dependent; they may even be difficult to articulate and operationalize as quantitative measures (ibid.). In addition, both technological development, and the settings in which the technology is to be used, are moving targets as they continually undergo change and mutually affect each other [156]. Conventional positivist evaluation methods in research about complex interventions have been critiqued due to the focus on individual variables and controlling for contextual variability, as these approaches do not contribute to understanding how and under what circumstances interventions bring about change [44][184], and may even cause oversimplification and a risk of seeing causality which might not really be there [81].

Information systems design and other fields of technological innovation allow for other research priorities than qualitative estimates of effectiveness, and several fields of research describe technological innovation as cycles of learning and development, a perspective that can be transferred to research and development of digital health interventions. Behavioral science can also support scientific discovery and justification with regard to digital health interventions, by helping to develop theories that explain how or why the intervention works in a certain context, and helping to identify the data required to produce scientific evidence to support or refute these theories. In this way, behavioral science can contribute to the process of establishing that new ways of achieving health impacts are effective and safe: it might even enhance the ability to make good and testable hypotheses through a better insight into the mechanisms and variables which contribute to outcomes.

The "normal science" [185] of the predominant healthcare research paradigm, is shaped by natural science and focuses on "how things are" [80]. Natural science strives for justified descriptions and explanations that are consistent with observed facts [135], and scientific process is often equated with the hypothetico-deductive method [186]. In contrast, design science focuses on "how things ought to be in order to attain goals" [80], and offers prescriptions for design and artifacts that embody a certain intent [135]. As designed artifacts are loaded with intent, their study is qualitatively different from the natural sciences [187]: an artifact's intended or actual use must be considered, and the situatedness and complexity of technology interacting with humans in particular settings makes it difficult to construct generalized theories, or to deduce a detailed design proposition from general, scientific knowledge [186]. The rate and complexity of technological change also contribute to the challenge of generating cumulative knowledge and higher-order design theories (ibid.).

From a design science perspective, this thesis can be seen as proposing a "nascent design theory"[134]: that the implementation context can be analyzed and represented by investigating users' problem space and the sociotechnical context. This type of theory is distinct from a natural science theory for analyzing, explaining or predicting, as its purpose is to support design and action [188]. The proposal of the thesis was prescriptive [188] but underspecified, as the object of study is an intractable system which cannot be specified in detail or decomposed to constituent parts in a meaningful way [81]. Instead, a general approach was suggested, with recognition of the challenges of definitively formulating wicked problems: understanding requires knowing the problem's context, and a search for the information required for a solution needs to be guided by a solution concept [189]. The overall approach was guided by the proposed design theory, which enabled a deepening understanding about the problem space and the solution space to evolve in parallel, for example, the service blueprint which was devised prior to the Work Domain Analysis (paper 2), was a way to represent a tentative understanding of the work processes during ERCP, but also provided clues for how to start modelling the WDA. The individual research articles included in the thesis can be viewed as instantiations which demonstrate the feasibility of the approach, and these instantiations show details about the decisions and rationales that have shaped their design. The design theory of the thesis is a generative statement, and the studies together provide testimony that the approach can be fruitful.

From a natural science perspective, this would hardly serve as confirmatory evidence, however, design science does not seek to verify theory [190], but instead assesses products in terms of value, which is related to the importance of the problem, and the novelty and utility of the approach [135][191]. From this perspective, the research contributes by proposing and demonstrating an innovative way of tackling a ubiquitous problem in digital health implementation - that of analyzing and representing the implementation context in a way that accommodates sociotechnical complexity. The approach provided insight into the sociotechnical systems, which are relevant for: understanding responses to teleguidance; identifying adaptations that are conducive for adoption, and for understanding variability in summative evaluation. The explicit focus on context of use also contributes to design science, in which context has a significant role, yet seldom receives direct attention [192].

While this research can demonstrate value from a design science perspective, it is reasonable to expect challenges in integrating a novel approach in healthcare research. The research bears similarities to traditional formative evaluations [193], which essentially embody the objectives of design research, and provide feedback to the development process [194]. Formative evaluation is a study approach for investigating determinants of behavior and system change at an early stage of implementation, to identify contextual factors and the need for adaptations [193]. Formative evaluation is an accepted research approach in social and behavioral interventions [195] and fields such as educational research [196], and is recommended for digital health interventions [39]. The WHO describes a logical framework for development and evaluation of digital health interventions[39], which includes feedback loops between technical development and studies into how the technology impacts performance.

The work in this thesis fits into this framework, as a type of formative evaluation, which explicates the input to the telemedicine intervention. Defining the input to a digital health intervention requires knowledge about the functionality of the technology and the application environment, including organizational factors as well as user needs and responses [39]. This step is necessary for identifying necessary adaptions between the intervention and local contexts, and is also central for subsequent monitoring and evaluation of the intervention's outcomes and impact (ibid.).

While formative evaluation is a design science approach, and systems perspectives often are mentioned, many frameworks for formative evaluation do not attempt to account for interactions among technological and social factors [51]. Instead, it is more common to employ an approach which implies pragmatic complexity, rather than dynamic complexity [81], by seeking to identify "all the variables of interest that affect dependent variables" [194], which quickly can become unwieldy and labor-intensive in a complex, adaptive work system, which is witnessed by the scale and scope of several formative evaluation frameworks, e.g. [194][51][157].

This thesis presents an alternative approach due to its basis in theory about complex, adaptive sociotechnical systems, where it does not prescribe a method for comprehensively specifying the implementation context in terms of its components, but instead suggests inquiry into users' problem space and understanding the work system in terms of its functions. This approach is fitted for digital health interventions in complex, adaptive sociotechnical settings, and may not have the same utility for large-scale behavioral interventions, or interventions in less adaptive environments.

Formative evaluation has shown difficult to integrate in RCT studies, as local adaptations of an intervention can conflict with the ambition to achieve intervention fidelity across different implementations [193]. They also face the challenge of being regarded as "merely" qualitative, and lacking in rigor. However, understanding the implementation context is important for supporting cross-site comparisons, and adaptations which are important for success can be motivated if the information gained from this type of investigation is relevant for the intervention purposes and generated in a rigorous way, especially if there is a plan for how local adaptation of an intervention can be addressed in statistical treatment of the results of a study (ibid.).

However, formative evaluation of digital health interventions does not necessarily have to be in the context of an RCT, especially in cases where there already is evidence for a treatment, and the objective of the digital health intervention is to optimize delivery. In these cases, where the main focus of evaluation is to understand the added benefit of e.g. a telemedicine solution, an innovative approach may be considered less incommensurable with the "normal science" of healthcare settings.

The studies are examples of behavioral research to inform the design of a telemedicine intervention, where the approach was influenced by a sociotechnical systems design perspective, and where the discovery of salient findings was guided by concepts grounded in theory about human behavior and cognition. In-depth context of use analysis is strongly emphasized in literature about how to support the introduction of new technology in complex settings [5][16]. This thesis shows how systems oriented methods which are common in design environments can be used to understand how a telemedicine solution can interact with a complex surgical setting. The studies generated context-specific insights about the problem space, and artifacts to help project the consequences of the designed solution.

Insight from the research can support a number of further development and research activities within the intervention:

- identifying the conditions in which the intervention works (or not)
- identifying variables and indicators to include in summative effectiveness evaluations, to understand which changes can be attributed to the intervention
- identifying issues that affect implementation fidelity when comparing results of an intervention at different sites
- further investigation and definition of the mechanisms of change (i.e. the actual processes responsible for improved performance)

The research also identified design challenges that could benefit from further behavioral research:

- What background knowledge about cases is important, and what information and knowledge is needed to deal with unanticipated situations?
- How do practitioners maintain important mechanisms for teamwork, such grounding, coordination and shared situation awareness [173] during teleguidance?
- How issues of trust and autonomy affect the use of teleguidance?
- What is the role of established interpersonal relationships during teleguidance?
- What factors affect surgical learning during teleguidance?
- Does teleguidance between experts and novices differ from teleguidance between peers?

The research contributes to the field of digital health through examples of methodologies from outside the conventional healthcare research paradigm that can contribute to the design and evaluation of digital health innovations, and also be part of a hybrid evaluation strategy, an approach which is recommended for digital health interventions[39], and for complex interventions [184].

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Chapter 7

Appended papers