Traceability in Healthcare Innovation
Maintaining the Relations Between Needs and Solutions

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Licentiate Dissertation in Applied Health Technology

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To my wonderful, supporting and entertaining “muppet family”
Tobias, Tilde, Linnea and William.

Vad vore jag utan era andetag?
“People do not care how much you know until they know how much you care”
- John C. Maxwell
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Madeleine Larsson
ABSTRACT
Healthcare is an important arena for improvement and innovation and the use of e-health solutions has great potential. However, many obstacles exist, such as insufficiency in interoperability and usability. One reason for this problematic situation is that the development process has been inadequate. A majority of Swedish healthcare serves under regulations for public procurement. Hence, almost every e-health solution has to be procured to prevent an orientation towards an illegal direct award of contracts. Specification requirements that explain what the customer and users need and why is one of the most critical parts of that process. The customer gets what is asked for, but the requirements are often on a high level of interpretation and not explicit or traceable enough. This prevents interoperability and usability from being a vital part of the prioritizing activity.

Today knowledge about requirement processes and traceability is fragmented, and often more based on ideal models than on practical, real life experiences. The aim of this work is therefore to understand how traceability is managed and how it can be improved. I investigate who is most suitable to perform the “traceability activity” and, maybe even more important, the skills needed to fulfill that task. With a practice-based and ethnographical approach several studies have been conducted in different healthcare settings in Sweden, all closely connected to the design- and development process in e-health projects.

The research shows that traceability maintains the relation between needs and solutions by providing a reality check for every step in the procurement and development. To accomplish that, requirements must be made explicit and interpretable for different stakeholders. The actors best suited for this “traceability activity” must have a holistic approach and know how to identify needs and relate them to the context. This requires a domain-specific knowledge about the healthcare setting and an understanding of how the organisation works practically and politically. It is also crucial to be skilled at usability, design, development and procurement. In addition, the implementation of IT in healthcare cannot be separated from business development.

I argue that it is time to update the way healthcare development is managed and by whom. First, healthcare management must pay more attention to usability and the crucial role that healthcare professionals have as change leaders and needfinders to strengthen existing initiatives. Second, the design community must match existing initiatives and roles in healthcare with the designers’ special knowledge to support innovation and design processes.

KEYWORDS
Traceability, usability, needfinding, requirements, healthcare, e-health, interaction design, development, innovation, procurement
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1 INTRODUCTION

Like many other countries Sweden is implementing information- and communication technology (ICT) as a strategic effort to improve healthcare. The Swedish government has set up high demands regarding the increased use of such e-health solutions. The purpose is to create user-friendly, visible and tangible improvements for three main stakeholders: the individual (patient, citizen, service user, family member), the healthcare professional (caregiver, doctor, nurse) and the decision maker (management) (Ministry of Health and Social Affairs, 2011). This means that the goal is to provide accessible and quality assured health information to individuals so that they can be offered individualized service and interactive e-services in order to exercise participation and self-determination on their own terms. Healthcare professionals should also have access to effective and interoperable electronic decision support that ensures a high quality and safety while facilitating their daily work. Necessary and structured information will be available as a basis for decisions about interventions and treatments. Decision makers should also have appropriate tools to continuously monitor the quality of activities and safety. They must get current and comprehensive decision support regarding management, planning and resource allocation (Ministry of Health and Social Affairs, 2011; Government Offices of Sweden, 2011).

Using technology to improve healthcare to this extent is a complex thing.

When the digitalization began conditions were different from today. It was not paramount to exclude a holistic approach and implementing ICT did not include interoperability the same way as in the current situation. Today, the game plan is completely different. Healthcare is among the most complex and highly collaborative domains of work practice in the world (Reddy et al, 2010) and has become more complex in terms of its use of different ICT products (Ministry of Health and Social Affairs, 2011). Earlier, only a few systems were used in a hospital but today there can be up to 300 different systems. This means that a nurse must handle up to twenty different systems in a day to be able to fulfil the task needed. The quest for availability has opened up for patients and citizens to also use systems and interact with the healthcare by using technology instead of face-to-face meetings. At the same time the healthcare domain is seen as a promising arena for innovation and economical growth. The Swedish Governmental Agency for Innovation System (VINNOVA) is moving towards a challenge-driven strategy. The rationale for this shift is the globalization of knowledge, technology and capital flows. This has enabled new sources and forms of competition and opened up new markets and opportunities for the creation and delivery of innovations. To remain competitive, Swedish industry, like that in many other countries, has been forced to move up the value chain and embrace innovation, entrepreneurship and collaboration in new ways. VINNOVA identifies health, wellbeing and medical care as one of four social challenges, which drive the development of innovations with international potential.

The content of this thesis is designed for a wide audience, i.e., people with interest in design and health technology research or the design and healthcare practice. The introduction presents the problem area, background and motivation for my work followed by the objectives and research questions. In the second chapter, the research context and study setting are presented in order to give an overview of the projects and healthcare settings in which this work has been conducted. Chapter 3 describes the methodology used in this thesis and how the research work has been performed in relation to the context and setting. Related research areas, concepts and definitions that I have chosen as a basis for my research are discussed in detail in chapter 4. Chapter 5 is a summary of the appended papers, and explains their relations to the thesis. The answer to my research questions, findings and results are discussed and declared in chapter 6 and concluded in chapter 7. A chapter with a description of future work followed by references and the appended papers concludes the thesis.
1.1 Problem Area

Despite the opportunities of combining healthcare and technology in an innovative way, there are a lot of challenges. Still, many obstacles exist such as insufficiency in interoperability and usability. One reason for this problematic situation is that the development process has been inadequate. There is a lack of user involvement in the development process and users are constantly exposed to solutions that they consider illogical and inconsistent. This causes stress and tension (Userawards, 2010). These problems constitute a security risk and can lead to fatal mistakes and should therefore get full attention from decision makers.

A majority of Swedish healthcare is a part of public service, and serves under regulations for public procurement. Hence, almost every updated or new e-health solution has to be procured to prevent an orientation towards an illegal direct award of contracts. Simplified this means that the customer (healthcare sector) specifies a list of requirements based on what is needed and then the winning supplier develops a solution to meet the requirements of that list. This process is one of the most important and critical parts of the development process (Maguire, 2001). The customer gets what is asked for, but the requirements are often on a high level of interpretation and not explicit or traceable enough, i.e., explained in terms of what they represent, why they are needed, for which purpose, and if and how they relate to other requirements that must be considered. Especially requirements regarding usability are often on such a high level of interpretation that it is impossible to label them fulfilled or not fulfilled (Jokela, 2010; Artman 2002). That prevents usability issues from being a vital part of the prioritizing activity and the price tag for each requirement gets more attention than the requirement actually merits, given its contribution and value. There is an attempt to prevent these problems by suggesting more research on how to improve processes around requirement management, procurement, education, implementation, and the need for user representatives and patients to play a more active role in healthcare development (UserAward, 2010). To ensure that attention is paid to the user and accessibility perspective at a high strategic level, the government has put up a user forum (Government Offices of Sweden, 2011) to increase the usability and access to public e-services. They have also highlighted the lack of expertise and processes around requirements and public procurement and addressed that “it is important that knowledge and purchasing skills on accessibility and usability are strengthened in relation to public procurements of e-services” (Government Offices of Sweden, 2011). All of these suggestions and initiatives are of high relevance of course, but how can these improvements be accomplished in healthcare development?

Knowledge about requirement processes and traceability is fragmented, and often more based on ideal models than on practical, real life experiences. Unawareness of present conditions and possibilities can prevent the healthcare sector from moving forward towards preventing current obstacles. Therefore, a deeper understanding about how requirements are “made”, formulated and used in practice is needed for the future. How else can appropriate and beneficial use of actors, activities and processes be enabled to ensure healthcare innovation?
1.2 Background and Motivation

Applied Health Technology is a science that includes studies of how health directly, or indirectly, is affected by the implementation and impact of technology. It concerns supporting management or development processes as well as studying how technology can improve the quality of life for one specific patient or group. Applied Health Technology is an interdisciplinary research area (Nair et al., 2008; Creswell & Plano, 2011), since it combines the domains health and technology in a search for co-creation, but also because it opens up and connects to other research areas, such as management, design, social science, economic science etc. User-centred approaches like Participatory Design (Kensing & Blomberg, 1998), Human Computer Interaction (Carroll, 2002; Maguire 2001) and Computer Supported Cooperative Work (Reddy et al., 2010; Weerakkody & Ray, 2003) are commonly used to improve healthcare development. As designers we are trained in understanding the practice and context we intend to change and to suggest possible solutions. Often we become facilitators (Boivie et al., 2006) or mediators in the design and development process with the responsibility of identifying needs, interactions and use as a basis for development. The work of this thesis has been conducted through the lens of Interaction Design, a discipline that has a central concern in developing interactive products that are usable (Preece et al., 2002). That is why the objective in this thesis focuses primarily on how to get health technology applied in a favourably way, i.e. used, supporting, effective, efficient and satisfactory for users in a given context.

Over the last ten years, I have worked as an interaction designer and project leader (see chapter 4 Research Context and Study Settings) mainly in the area of e-health but also product development and distributed engineering. The work has been carried out within different research and development projects with collaboration between academia, municipalities, county councils and companies. In practice I have been the “needfinder” (see chapter 3.1 Needfinding) in these projects trying to understand, map and mediate processes, workflows (Dourish, 2001), interactions and needs in order to develop useful technologies for healthcare settings. This has given me the privilege of working together with researchers, designers, developers, entrepreneurs, students, teachers, healthcare professionals and citizens, but also decision makers at various levels. My long experience of working closely with these actors has given me invaluable practical knowledge of these communities in terms of understanding the healthcare practice, product development, procurement, political and organizational structure etc. This insight directed my attention towards two levels of interest in research. First, I became interested in how to support need-driven development and deal with the lack of interoperability and usability issues in healthcare innovation. Second, I wanted to understand why these important issues had such a low impact in development and procurement processes and often were left out of the political agenda. *Was there a lack in communication among stakeholders? Have we as designers and “usability promoters” failed in explaining why usability issues and need-driven development are important? Do we need to sharpen the arguments to make people listen?* All of these questions pointed my directions towards how usability work tends to be presented in practice. We talk about the benefits but sometimes forget to explain that the core of usability work is to read and show traces of needs, use, context, and interactions etc., almost like a tracker in the jungle guiding tourists. Our mission as usability experts is to make others notice and understand these traces. We want the traces to be a basis for development and taken into account before, during and after implementation. This reflection made me search for traceability and the meaning of that concept in healthcare innovation.
1.3 Objectives and Research Questions

The core of my research is built upon my needfinding/needfinder experience. Hence, it focuses on examining such roles and activities involved in the process of making requirements. This thesis investigates how requirements regarding interoperability and usability can be made explicit and traceable for different stakeholders in healthcare development and procurement, more specifically by focusing on the mechanism/role of understanding, interpreting, mediating and making people’s needs and interaction traceable in this process. The aim of my work is to understand how traceability is managed and how it can be improved. Further I investigate which actor/actors is most suitable to perform the “traceability activity” and, maybe even more important, the skills needed to fulfil that task. As a result of these objectives I have chosen the following research questions:

RQ 1: How is traceability managed in the process of healthcare innovation?

RQ 2: Who is best suited to perform the “traceability activity”?

RQ 3: How can traceability be improved in the process of healthcare innovation?
2 RESEARCH CONTEXT AND STUDY SETTINGS
Given the circumstances of working with applied research in close collaborative mode with the healthcare practice, an understanding of the context and study setting is important. This section describes the projects and different healthcare settings in which I have carried out my research. The relation of the project to the thesis work is presented as well as a clarification of my roles in these projects.

2.1 NeedInn
NeedInn (Needfinding and Innovation) was a research- and development project at Luleå University of Technology (LTU) (Larsson & Larsson, 2007). It was funded by the European Commission and lasted almost three years between 2005-2007. The project was driven by researchers at the department of Computer Aided Design at LTU. Other partners were the municipality of Luleå and Skellefteå, the company Alkit Communication, and the County Administrative Board in Norrbotten and Västerbotten. The goal for NeedInn was to create a method, a working process, which contributed to a need-centered product development process within e-health. To make this happen, we developed the NeedInn-process that combines needfinding and product development. Six different subprojects were conducted, each with the aim of developing a prototype in the area of e-health. The first two papers included in this paper were written as a result of this project. Together with researchers at LTU I participated in writing the application for the project. Further I worked as an interaction designer, project leader, facilitator, needfinder and researcher with the responsibility to perform all of the needfinding activities.

2.2 Nurse Gudrun’s Full-Scale Lab in Blekinge for IT in Nursing and Caring
Nurse Gudrun’s Full-Scale Lab in Blekinge for IT in Nursing and Caring (SGF) was a collaboration project between the County Council of Blekinge, BTH, Affärsverken in Karlskrona and the Municipality of Karlskrona (Blekinge County Council, 2011). The research and development project received financial support from the European Regional Development Fund 2008-2011. The basic idea for the project was to find out to what extent one can, through modern technology, make health- and medical care more accessible with unchanged quality for the individual and at the same time render the care more efficient. During the project Blekinge County Council set up a full-scale lab for the testing of IT solutions in real environments of nursing and care. In addition, BTH created a research lab for innovations and development. In several of the subprojects that are included in SGF, the research lab at BTH had a central role. This is where new technology, new solutions and new innovations were produced, examined and analyzed in relation to the technical conditions that existed in the full-scale lab of the county council. In SGF I worked as an interaction designer and subproject leader responsible for the research lab. I was involved in all of the subprojects in supporting the researchers and development process.

2.3 Centre for Telemedicine
Centre for Telemedicine (CTM) is an on-going research and development project, funded by the European Regional Development Fund. It started in 2010 and ends in September 2013. The project owner is a Blekinge County Council and project partner and co-financers are BTH, Telecom City, the Regional Council of Blekinge and Blekinge Research Foundation. The aim of the project is to provide a cost-effective development of sustainable e-health related services and products. The overall project objective is to establish an e-health centre in Blekinge with the purpose of investigating how e-health can lead to increased availability, new business in Blekinge,
examine various IT solutions for compatibility and establishing experience with other e-health centres. CTM consists of subprojects working with video communication, homecare, innovations and procurement, and digital radiology and pathology. In collaboration with researchers at BTH and people from Blekinge County Council I participated in writing the application for this project. I have worked as a researcher and part time as a subproject leader for digital pathology together with the chief of ward in the pathology department in Blekinge. Paper C and D are written as a result of the work in CTM.

2.4 Exchange of Diagnostic Imaging in Network

The on-going development project Exchange of Diagnostic Imaging in Network (ExDIN) is funded by the Swedish Governmental Agency for Innovation Systems, VINNOVA. It started in 2012 and ends in 2014. The project owner and main project leader is RxEye AB, a medical technology company working with remote reviewing of diagnostic imaging. Other partners and co-finance are BTH, the Royal Institute of Technology (School of Technology and Health), the County Councils of Blekinge and Stockholm. ExDIN will analyze more effective forms of collaboration, working in networks. The issue is complex in nature as it spans over different health care providers, specialties and processes. It also covers a number of areas such as technology, patient safety, legal and regulatory requirements. Starting with the web-based solution that RxEye is currently using today in radiology, the project is intended to create a co-operation platform in order to reach experts regionally, nationally, and even internationally, in order to provide reinforcement for local competencies. The efforts are focused on pathology, echocardiography and multidisciplinary teams. In collaboration with representatives from all partners I co-wrote the application for this project. I have worked as a researcher and part time as a subproject leader for digital pathology together with the chief of ward at the pathology department in Blekinge.

2.5 Elderly Care

In this thesis two of the subprojects in NeedInn are included, the The Nosphere (the FEE student project explained in paper A) and the Support for oral transmission of information (the project explained in paper B). Both these subprojects were conducted in collaboration with healthcare professionals and management at Ingridshem, an elderly home unit in Luleå. Depending on the degree of need for healthcare services, elderly people can either get homecare or move in to an elderly care unit to get support in their daily lives. Each unit is owned by the municipalities. At Ingridshem most of the elderly people had dementia or multiple diseases and were in great need of care. Each person living there had their own apartment even if they eat all the meals together in a large kitchen area. During the case study at Ingridshem I spent two weeks at one department, including 10 apartments. I was observing and helping out the same way as if I had been a nurse student. All the healthcare professionals working at each department were certified nursing assistants. They had two nurses to turn to for advice and help with the medical treatment since a nurse have a higher education with more responsibilities. There was a special office space for the nurses in the building. Regarding the use of ICT, Ingridshem was quite a typical unit in the municipality. They had one computer in each department that was used for administrative work only. The nurses had their own computer, which they used for ordering medicine and documentations in a healthcare record. The elderly had safety alarms that were set off if they fell or in form of a watch that they could set off themselves if they needed help. Otherwise there was a low use of ICT.
In NeedInn I also worked with case studies at a homecare unit in Gammelstad in Luleå, an elderly home unit in Skellefteå, with a group of physical therapists at the county council in Västerbotten working with rehabilitation (they visited and provided support for elderly people living at home). At LTU we had collaboration with Stanford University, which meant that during the FEE project we visited Stanford University to learn about elderly care in the United States. Researchers, students and healthcare professionals from Ingridshem and Gammelstad all went together. We visited elderly care homes, a homecare unit to exchange experiences. We also visited the Center for Longevity and Centre for Design Research at Stanford, IDEO, and the Geriatric Research, Education & Clinical Center own by Veteran Affairs.

2.6 Radiology

Paper C includes a study of radiology, which unlike the elderly care has a high use of ICT. During the last decade radiology has changed from using analogue pictures (film-screen radiography) towards using digital imaging and patient systems such as RIS (Radiology Information System) and PACS (Picture and Archive System). This has been a challenging journey for people working within this field, especially considering the change in workflow and increased use of ICT (Helgeson & Toft, 2010; Duyck et al, 2008). Besides being a high technology area, using several products and systems in the front end of development, radiology in Sweden has a back office function towards other departments/clinics/wards such as orthopaedics, surgery or primary healthcare units etc. Through referrals, these customers order different kinds of radiological surveys/investigations where the radiological department works as a service provider with the patient associated somewhere else. In addition to the high use of technology, professionals working at the radiology department tend to be involved in different development projects more or less all the time. It is common for radiologists and radiology nurses to work closely together in the same department since radiology nurses produce images while radiologists review, investigate and interpret them. Being a radiology nurse or a radiologist demands skills in using specific technical equipment that provides a wide range of diagnostic imaging services (modalities); CT scanning, MRI scanning, radio isotope scanning, ultrasound scanning, X ray etc. Besides radiology specialists, there are technicians, either employed at the radiology or medical technical department, who support the diagnostic imaging equipment and physicists who make sure that the radiation level is correct. Within CTM I have spent time at radiology departments in Växjö, Karlskrona and Skövde in my research. I observed the every-day practice of radiology and interviewed different professionals working in the area of radiology. In ExDIN we work with multidisciplinary teams and in those teams the radiologist has an important role. To understand the complexity of these teams I have observed their meetings and interviewed the experts involved.

2.7 Pathology

Pathology involves the study of cause and development of diseases and is primarily based on changes in the building of cells, tissues and organs. Pathology is quite similar to radiology since it provides images and serves as a back office function towards other healthcare units (wards). However, the way the images are produced is very different. The pathology department receives samples from other healthcare units and prepares those before the microscopic diagnosis can be performed. This is a complex process of cutting out small pieces from the sample, and then to embed these in paraffin. The embedded small sample is then sliced in a special machine to get tin slides that they can put on a glass for microscopes. Before examining the glass sample it has to be coloured so that the cells and tissue can appear. When it comes to the use of digital images in pathology in Sweden, the development process is ten years behind radiology. Another problem is the lack of expertise. Pathology departments are having trouble with finding pathologists,
especially in the rural areas. The pathology department at Blekinge County Council is developing the use of digital images. The work started as a subproject in CTM aiming at making it possible to transfer analogue samples into digital images. The purpose was to make it possible to review digital images at a distance within the organization. In ExDIN the digitalization process was taken further to also include reviewing images between different departments, outside of the organization. Together with my supervisor I have been studying the pathology department in Karlskrona (CTM and ExDIN) and the pathology department in Stockholm South General Hospital (ExDIN). We have observed the everyday practice and interviewed pathology experts involved in the projects. Our assignment has been to provide descriptions and analysis of workflows, interactions, use and technology.

2.8 Procurement
A majority of Swedish healthcare is a part of public service, and serves under regulations for public procurement. This means that every updated or new e-health solution has to be procured to enable completion for suppliers (Swedish Competition Authority). According to the regulation it is forbidden to give preferential treatment to one supplier over another and the procurement process is formal and should be equally performed in all public healthcare areas. Blekinge County Council procures services and products each year for over 800 MSEK (Blekinge County Council Procurement Policy). To make everyone use the same process a procurement policy has been produced. This policy describes the different types of procurement that can be used and the process in terms of activities, documents, responsibilities and roles involved. The procurement department plays an important role in this process, as they are responsible for the legal aspects. In one subproject within CTM we focus on how to enable innovation in the procurement process. This is done in collaboration with the procurement department. I have been involved in that project together with two other researchers and made literature reviews on how usability and traceability relates to procurement in healthcare. The more practical study of procurement has been through the development processes in the projects. In NeedInn, SGF, CTM and ExDIN we have developed products and for each of them the procurement departments have been involved one way or the other, depending on the type of product or cost. This has given me experience and knowledge both as a researcher, project leader and usability expert.

Working in applied research in close collaborative mode with the healthcare practice also gives opportunities of networking and strategic intelligence. Within NeedInn, SGF, CTM and ExDIN I have attended and participated in several conferences regarding e-health, locally, nationally and globally. I am also part of a graduate school for doctoral students in the Swedish Faculty for Design Research and Research Education. This has been invaluable for sharing experience and insights with researchers, designers, healthcare professionals, management and politicians etc., and helped me learn about the game plan and context of healthcare innovation.
Nevertheless, looking back in the mirror would not make me switch to another approach. I argue that projects, often makes necessary. Working in close collaborative mode with the healthcare practice, in research and development projects, often makes researchers hard to replace (Gunnarson, 2001) and that can be problematic. I have been moving in and out of different roles (designer, researcher, project leader etc.) and that has sometimes made it difficult to keep a research perspective and to stay on the right track. Nevertheless, looking back in the mirror would not make me switch to another approach. I argue

3 METHODOLOGY

To position my research on the epistemological map (Gunnarson, 2001), in relation to the research area and problem I wanted to address, I asked myself two important questions before designing my research, namely:

1. What kind of data do I aim for?
2. Why do I aim for such data?

I am aware that my experience, knowledge and beliefs have affected the answers to those questions and my research, both in embodiment, approach and analysis. With a background in interaction design, trained in ethnography and studying work practice, I learned that understanding people’s interaction with other people and/or artefacts within a certain context constitutes a crucial part of the design process. This has influenced my philosophical worldview (Creswell & Plano, 2011) in believing that human behaviour must be studied and addressed as a subset of a complex totality (holistic view) in tandem with a detailed and context-based understanding of people’s behaviour (deep view). That is, to understand what people actually do and not just say they do, or how they behave instead of ought to behave (Blomberg et al., 1993) and, to put that insight in relation to the totality.

The objectives and research questions I wanted to address demand for an approach that could highlight and explain important dependencies and patterns for a certain situation (Thuren, 2005; Åsberg, 2001). Hence, this meant understanding patterns and dependencies for activities and actors around traceability by searching for answers to questions like who? is doing what?, where?, when? and why?. To accomplish that, a holistic and deep view was needed. I used a practice-based and ethnographical approach to my research “…to obtain a valid understanding that reflected the experience of those studied and to observe the activities of everyday settings” (Kieliszewski et al., 2010). This approach does not aim at making generalizations based on facts but rather to put perspectives on a problem from real life experiences. A practice-based and ethnographical approach helps me understand “the big picture”, how the reality works, in an inductive way, which is to draw conclusions based on qualitative rather than quantitative data (Åsberg, 2001). Having this approach means that it was not enough to simply ask people how traceability is managed or by whom. Instead I had to put myself in the context of study and observe the reality to grasp the complexity of traceability, and to look for answers in words rather than numbers (Johnson & Onwuegbuzie, 2004).

Even though basing the research on a practice-based and ethnographical approach felt appropriate I am aware of the disadvantages. For one thing I have biases, because the findings are subjective and based on my interpreted values and pre-understanding (Thuren, 2005) pointing at specific situations with few individuals. However, all researchers have biases in one way or the other and thus need to reflect upon and be aware of that in their research (Creswell & Plano, 2011). Another issue is the researchers’ involvement in actual design and development work. My work has been highly influenced by Participatory Action Research PAR, considering that change and action have been embedded and critical element of my research (Walter, 1998). This means that I have worked in close collaborative mode with the healthcare practice and that demands being intimately involved. This has taken a lot of effort even though it has been both invaluable and necessary. Working in close collaborative mode with the practice, in research and development projects, often makes researchers hard to replace (Gunnarson, 2001) and that can be problematic. I have been moving in and out of different roles (designer, researcher, project leader etc.) and that has sometimes made it difficult to keep a research perspective and to stay on the right track. Nevertheless, looking back in the mirror would not make me switch to another approach. I argue
along with others that research aiming at a deep understanding of how the reality works, e.g., using a practice-based and ethnographical approach, PAR, Needfinding etc., is needed to prevent problems in healthcare.

In my research I have worked primarily with need-centred development (Ericson, 2007) and needfinding (Faste, 1987; Patnaik & Becker 1999). As explained earlier my roles as a researcher have been different even if all have related to the process of creating traceability. I have worked as a needfinder, coached needfinders, studied other needfinders and co-designed with other needfinders involved in identifying needs and making requirements in healthcare development.

### 3.1 Needfinding

Needfinding is a qualitative research approach created and developed over 40 years ago by Robert McNim, head of Stanford University’s product design program (Patnaik & Becker 1999). McNim wanted to find methods and a way to help designers get closer to the users since he realized that if designers wanted to have a high impact on product development they needed to be involved at the earliest stages of product definition. (Patnaik & Becker, 1999). Ever since then the science Needfinding has been commonly used in education and research (Faste, 1987; Patnaik & Becker 1999; Paper A), but also updated and redefined in response to the growing understanding of using qualitative research and methods in design and development (Patnaik & Becker, 1999). Needfinding is used as an important part of the design thinking approach (Brown, 2008) in encompassing the definition of a problem or opportunity through observation (Seidel et al. 2012). The scope for innovation includes not only physical products but also processes, services, interactions, entertainment forms, and new ways of collaborating and communicating (Brown, 2011). Designers are challenged by the most progressive organizations to be more strategic and create ideas at the outset of the development process, rather than making an already developed idea more attractive (Brown, 2011). This demands for insights that come from observing the actual experience of people as they improvise their way trough their daily lives.

In a Needfinding process it is important to understand people and the constraints they perceive, not to judge or correct them (Ericson, 2007). Needfinding aims at integrating qualitative research into the process of design and development, hence, collecting data through observations and interviews and to use video, audio, photos, drawings etc. to capture, mediate and reframe that data iteratively in the process. Needs can be perceived in one or two ways: either by the same person that experiences the need (the Needer), or by a person who is observing another person’s or group’s needs (the Needfinder) (Faste, 1987). The task of a needfinder is to study a real-life practice by using an ethnographical approach to understand and find answers to questions like who? is doing what?, where?, when? and why? In that sense Needfinding is not aiming so much at gathering information, rather it is intended to gain a gestalt understanding of current events (Faste, 1987).

The activity of “finding needs” might sound like an easy task or even a bit arrogant, if interpreted as an activity of collecting something tangible just lying around ready to be found (Hyysalo, 2003). That is not the case! Needs are usually embedded in other outputs/statements and hard to define, often expressed as functions, wants, wishes or even as specific solutions (Patnaik 2004). So why bother about needs? Well, needs last longer than any solutions (Patnaik & Becker, 1999). Needs are solution-independent, i.e., a need can be met with several different solutions depending on the situation at hand. Needs spur innovation and new ideas. Focusing on needs helps the needfinder/needfinders understand why an output/statement is expressed and that is the key factor to succeed in a need-driven process (Ericson, 2007). It is not the definition of needs itself
that is most important here, rather the perspective of searching for an understanding that goes deeper than what people express.

### 3.2 Working as a Needfinder

In the research and development project NeedInn we created a need-centred method (Paper A) based on the methodology Needfinding by designing and developing prototypes as a proof-of-concept. It was a learning-by-doing kind of project and consisted of six different prototypes. As an interaction designer I became the needfinder in our project working on understanding the problem space, the context and the user needs. Together with researchers in engineering and product development we worked in close collaboration with healthcare professionals and entrepreneurs and, with people from IT- and management departments. To get an insight into the healthcare domain we started out by entering the field and observe the everyday practice of healthcare (caregivers and caretakers). We spent several weeks at a time, studying different healthcare settings (Larsson & Larsson, 2007) and observed the on-going activities and actors of providing healthcare service. The purpose was to find workarounds and problem areas that could be supported with IT and serve as input to new innovations. We had a practice-based and ethnographical approach and used methods like onsite observations, field-notes and in-context interviews (Preece at al. 2002 pp. 394; Blomberg et al. 1993). Sometimes we used video and audio recording to make our findings easier to understand and mediate. The collected data was analysed in collaboration with the healthcare professionals (nurses, physical therapists, doctors etc.), IT department and management. The process was iterative and we developed several prototypes (from paper-mock-ups to physical) that were tested in real-life settings. The context for data generation consisted of participation in everyday work and staff meetings but also by organizing workshops and focus groups.

### 3.3 Coaching Needfinders

In the student project Future Elderly Environment (FEE) students in mechanical engineering from LTU and Stanford University worked together on an assignment provided by NeedInn. In the area of Designing for Wellbeing (Larsson et al., 2005) the student had to develop ‘something’ that would help increase the wellbeing of elderly people. The students had to use the P2I process, which is a hybrid of needfinding and product development (Ericson, 2007; Paper A). We gave the students a fuzzy assignment on purpose that had many different problems and possible solutions. The purpose was to force them to find out answers by themselves by making studies in real-life settings. As researchers we supported and coached the students in performing needfinding and product development. We showed them how to use methods like observations, different interview techniques etc. and how to make use of them in their design and development process. The students also got feedback on their findings and activities. Together we had project meetings and workshops both in Luleå and at Stanford. The meetings were physical/local and digital/global, e.g., using video communication systems. We had access to the student documentation and observed and interviewed the students iteratively in their process.
3.4 Studying Other Needfinders
In the project Center for Telemedicine (CTM) we studied the digitalisation of radiology. Focusing on needfinding and traceability activities led us to radiology nurses. They were responsible for identifying needs and making requirements in the process of digitalizing their department, e.g., moving from using analogue pictures to digital images. We spent several days observing the everyday work of radiology to understand what radiology work is all about. People at the radiology departments showed us how the process of producing and reviewing medical images works and the different modalities. We made literature studies on telemedicine, in general and digital radiology, in particular, because radiology was a new knowledge area for us. We also had access to requirement documents. Besides observations we made semi-structured interviews with radiologists, radiology nurses, medical technical engineers and had dialogs with management and entrepreneurs. This was more a descriptive study aiming at understanding the current conditions regarding the role of healthcare professionals and traceability activities.

3.5 Co-designing with Other Needfinders
In the current research and development projects CTM and ExDIN we currently work with three different subprojects, e.g., digital pathology, multidisciplinary teams and echocardiography. The aim is to develop IT support for effective analysis within medical imaging and networking structures. Digital pathology was the subproject we started with and therefore the only subproject included in this thesis. Our work within digital pathology has been to provide descriptions and analysis of workflows, interactions, use, needs and technology based on participatory observations and field studies. The descriptions and analysis have been used as an input to development and innovation for improving the use of digital images both locally and in distributed collaborations. With the purpose of making each step in the process explicit we used many context-related pictures to capture e.g., workarounds, a specific work environment, interaction or use-situation etc. The pictures were used to highlight the practice connected to the process and to serve as a basis for discussions on what the every-day work of pathology is all about. We used the pictures to prevent the workflow from becoming a stereotyped representation of a process separated from the pathology practice (Suchman, 1995). In the project we also produced use-stories (Moggridge, 1993) that described the work of reviewing medical digital images and the on-going interaction with IT-systems and viewers, by observing the work process and context-of-use. The use-stories were described both in text and visually. Our role distinguished itself from working as a needfinder because the healthcare professionals were equally involved and responsible for the outcome. Hence, we did not serve as a facilitator between users and developers, nor did we produce descriptions or analyzed them apart from the healthcare professionals. It was rather co-design e.g., designers and people not trained in design working creatively together in the design and development process (Sanders et al., 2008), even though we as designers provided the tools and methods used.
4 KNOWLEDGE AREA

In this chapter I present the concepts and definitions I have chosen as a basis for my research. My work is about traceability in healthcare innovation and that includes methods and tools regarding usability and the stakeholders involved. It also highlights the designer’s special knowledge in this process and relates to the development and procurement process. Hereby, I describe in more detail these concepts and definitions and declare my standpoint.

4.1 Usability

Usability is a well-known concept in design and healthcare development (Maguire, 2001; Gard & Wikman, 2012; Scandurra, 2013). The concept has its roots in the development of information and communication systems and Human-Computer Interaction (HCI) is seen as the study and practice of usability in system development (Carroll, 2001). Usability is referred to the international standard definition (ISO 9241-11:1998) as:

“\textbf{The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.}” (ISO 9241-11:1998)

Whenever usability is used in this thesis I refer to the ISO 9241-11:1998 definition of usability and all of its components. Besides a user perspective and an aim towards creating beneficial solutions that are effective, efficient and satisfactory, the context of use is considered important and as having quite an impact on usability work. Focusing on the context of use demands for an understanding of the context before, during and not the least, after implementation when the product is put in use. This means that usability work must be included in all steps of the development process. ISO 9241-11:1998 highlights the product and not only the system. This means that usability goes beyond the system to include also physical and tangible products.


- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.

These principles makes UCD characterized as a multi-stage problem solving process and the design team includes multidisciplinary skills and perspectives. That is why the activities, actors and responsibilities must be clear in this process.

4.2 Stakeholders

As a designer it is not enough to only focus on a single user in healthcare development because first of all there are multiple users with different interests and goals. Second, the processes of decision-making have many other valuable players that must be taken into account. It is therefore important for designers to get involved with the politics of the technology they seek to bring forth (Krippendorff, 1998). Stakeholders (users, management, developers, technicians, procurers, politicians etc.) involved in healthcare development have their own agenda and guard their interests. These can be about usability, security, interoperability, financial cost etc. In the process the stakeholders contribute with their specific knowledge and worldview as input but they
become sequentially relevant and irrelevant (Krippendorff, 1998) depending on which role they have in the project. Therefore it is important to have someone with a holistic view that can serve as a mediator (Paper C) to understand and relate each stakeholder’s input to the big picture. This responsibility can be a challenging position since the design work is done in collaboration with stakeholders that are not necessary pushing in the same direction (Krippendorff, 1998). On the other hand, such a responsibility can empower people through the opportunity to actually affect the design and outcome of the system. With respect to the complexity in healthcare development this thesis refers to stakeholders as people and roles that either have impact on the decision-making, or are affected by the outcome as a user.

4.3 Designers’ Special Knowledge
Usability work in design and development can be beneficial in many ways. It can enable increased productivity, reduce errors, training and support or improve acceptance etc. (Maguire, 2001). To accomplish these benefits an explicit role with knowledge in usability is needed to place usability on the agenda and make it visible (Boivie, 2006). Usability experts are trained to identify needs and make requirements but they are also skilled at the methods and techniques needed to enable those activities (Preece, 2002). Besides having the toolbox to perform usability activities, usability experts look at the user, artefacts, context, activities and interactions with a usability perspective (Hult et al., 2010). A usability expert also knows where to fit usability work in the development process. Experts in usability tend to use the same design methods (Maguire, 2001) and have a jointed interest in promoting usable products, even though they operate under different names, e.g., interaction designers, user-centred design facilitator, health informatics specialists, interaction architect etc. In the field of user-centred design, scholars talk about the usability expert’s role of being “a lonesome cowboy” (Boivie, 2006), working alone with no supports from peers or, as “the users advocate” (Eriksson, 2008) being responsible for championing human-centred approaches. For an interaction designer “users are whole people with complex sensibilities and design processes need to be conducted accordingly” (Lowgren, 2013) Further interaction design is described to be:

“...the design of everything that is digital and interactive and it includes the design of all the interactions that are enabled by digital technology, whether by computers, chips embedded in products or environments, services, or the Internet” (Moggridge, 2007).

This quite broad definition opens up for several specializations to be included under the label interaction design, such as HCI specialists, computer scientists, software engineering, cognitive scientists, sociologists, cultural anthropologists, and designers (Moggridge, 2007).

In the research field of Health Informatics, scholars work with “the understanding of medical and nursing problem situations and clinical work processes as well as insight into the strengths and weaknesses of different technical solutions” (Scandurra, 2007). It has been claimed that despite this focus on problems and processes, usability does not get much attention in HI (Scandurra, 2007). As a result of this gap, research on how to combine the two fields into a cross-disciplinary HI-HCI approach has been conducted in a project called OLD@HOME (Koch et al., 2005). Hence, a multi-disciplinary thematic seminar method (MdTS) (Scandurra et al., 2008) was created and tested to identify and transfer in-context user needs into requirements documentation in healthcare development. In this work the usability expert was a health informatics and usability (HI-U) specialist with a holistic view of the actual domain and work process, serving as an interpreter between multiple users and developers. For this it was considered critical to know the language of healthcare professionals and system engineers (Scandurra et al., 2008).
Users’ involvement in the development process is often discussed in terms of on what level the involvement should be. Participatory Design (PD) is:

“...an approach towards computer systems design in which the people destined to use the system play a critical role in designing it.” (Schuler and Namioka 1993). Further, PD is defined, in part “...by the techniques and methods used, namely strategies that allow for the direct participation of workers in project definition and design specification. A great deal of emphasis has been placed on developing and formulating these methods and techniques so that they can be adopted by others” (Kensing & Blomberg, 1998).

In other words this means that others could adopt and use PD without being experts in design if they have a strategy that allows for direct participation of workers and use PD methods and techniques. PD research includes studies of the balance and power relations between users/technical experts, workers/managers and takes a broader perspective on organizational and political change (Kensing & Blomberg, 1998). PD emphasises empowerment of workers while user-centred design (UCD) is limited to ensure the influence of specific users in a systems development process (Boivie et al., 2006). In some cases UCD can be performed even without end-users actively involved through e.g., personas (Pruitt & Grudin, 2003; Blomqvist & Arvola, 2002), user scenarios (Bodker, 2000) or user representatives, although practical user participation always should be preferred. In design practice the use of scenarios, personas and storyboards etc. are commonly used in usability work and development. However, many hours of observation, interviews, mapping, sketching, and iterations underlay the result of these representations. Even so, they still are representations and know matter how well-defined they are it is important to reflect upon the fact that in the wrong hands they might serve as stereotyped representations (Suchman, 1995).

Today design goes beyond products to also include designing services and processes (Gard & Wikman, 2012) an issue discussed in PD. As part of this change the concept of co-creation has evolved. Co-creation is “a creative design development process where designers and people not trained in design work together “ (Sanders & Stappers, 2008). This means that the usability expert works more equally with users instead of serving as a facilitator. In the field of UCD a facilitator needs to:

“...know about business targets and organizational goals and how to communicate with the users and communicate results from the field to the developers. In short, the facilitator must understand and communicate the context of use as well as the context of development” (Boivie et al., 2006)

In the connection of usability and procurement the “interaction architect” has been explained as a valuable role to include UCD competence in the procurement process. The responsibility goes beyond the development process since it also lies in securing quality issues of using the system before a contract with technical supplier is signed (Markensten, 2005).

The “designer’s special knowledge” lies in the skill of using design methods and techniques to perform usability work and make use of those in the healthcare development process and procurement. Many designers also speak the “language” of healthcare professionals and developers and know how to communicate, negotiate and interact with stakeholders.
4.4 Traceability

Traceability has derived from the word “trace” and according to the dictionary (Cambridge Business English Dictionary) trace can be described as the action to:

- follow the movements, progress, or development of something
- find someone or something
- describe the way in which something has developed

This definition highlights the fact that traceability is related to the history, presence and future of developing something. In software development and system engineering, traceability is a standard term used in the field of Requirements Traceability (RT), a sub-discipline of Requirements Engineering (RE). From a HCI perspective, requirements engineering is the “engineering discipline of establishing user requirements and specifying software systems” (Sutcliffe, 2013) and requirements is about “finding out what people want from computer systems, and understand what their needs mean in terms of design” (Sutcliffe, 2013). Hence, this means to “design the right thing” and that includes the process of identifying and mediating stakeholders and their needs as a basis for analysis, communication and implementation (Sutcliffe, 2013). In the context of requirements traceability, a very simple explanation of traceability is to follow relationships or links and that the information produced and used should be kept related (traceable) (Pinheiro, 2004). The definition of requirement engineering can be driven either by the purpose (what RT should do), solution (how RT should do), information (emphasising traceable information) or direction (emphasising traceable direction). Each of these definitions differs in emphasis and delimits the scope. To manage the fact that traceability is related to all of them and relates to the history, presence and future, researchers have redefined the definition. A common definition states that:

“Requirements traceability refers to the ability to describe and follow the life of a requirement, in both a forwards and backwards direction (i.e., from its origins, through its development and specification, to its subsequent deployment and use, and through all periods of on-going refinement and iteration in any of these phases.” (Pinheiro, 2004).

This definition addresses that it is important to describe a requirement in order to follow it but also that it must be described in a way that supports traceability in both a forward direction (Pre-Requirements Specification) and a backward direction (Post-Requirements Specification). In addition to the definition above it has been stated that traceability also is about identifying which traces to control and how they may be captured and followed. Further, elements of traceability comprise not only the technical artifacts such as specifications, diagrams, and code, but also people, policies, decisions, and even less tangible things like goals and concepts (Pinheiro, 2004).

The activities of RT are highly relevant for usability work and HCI given the similarities of purpose but unfortunately social-technical design is rarely mentioned in RE (Sutcliffe, 2013). This is lamentable considering that the purpose of developing systems is to satisfy some set of user or stakeholders needs and the time spent on understanding needs is some of the most valuable time you can spend in such a process (Leffingwell & Widrig, 2002). A quite simple description of how to perform RT in system development is put together as a generalized traceability model shown in figure1 (Leffingwell & Widrig, 2002):
I am aware that this is not a complete picture of RT and all of its activities but what I would like to pinpoint is that identifying stakeholder needs is crucial and sets the goal for every step in the process. In other words, no matter how well defined and structured a process may be, it can never compensate for a lacking input. Neither is the process a linear process of specifying-testing-implementing, rather an iterative and on-going exploration and evaluation in dialogue with stakeholders. The generalized traceability model consists of three phases, i.e., system definition, system test and implementation. The first phase shows that tracing requirements is performed in a specific domain/context, with a specific purpose but the model does not show that the traces are bidirectional. Traces can be used and should be used both backwards and forwards and they are interrelated as well as related to the real world objects and software artefacts shown in figure 2 (Pinheiro, 2004).
In this thesis I will use “traceability” as a concept for the act of making requirements traceable in the processes of design, development and procurement in healthcare innovation. By traceable I mean to understand and explain requirements in terms of what they represent, why they are needed, for which purpose, and if and how they relate to other requirements that must be considered. To be able to answer these questions, a lot of information and knowledge is needed about the context, stakeholders, interaction, use etc., along with an understanding of how traceability activities fit into these processes. It is also of high relevance to know how to produce and make use of the information in a beneficial way that supports usability and interoperability. Without understanding the processes and the game plan of healthcare innovation, traceability cannot be enabled to its full potential.

4.5 Healthcare Innovation
Innovation can be seen as the process of creating value. An innovation is not restricted to only being a product; it includes processes, organizational changes, services etc. as a wider range of definition. According to the Swedish government innovation is about:

“...new and better ways to create value for society, businesses and individuals. Innovations are new solutions that meet the needs and demands of everyday life and the world. The value occurs in the utilization and application of an idea. The value created can take many forms - economic, social or environmental values” (translated from Swedish by the author)

Healthcare is seen as an important arena for creating innovation and economical growth. As a result of this, efforts and research networks exist to promote innovation for healthcare. One such player is the Swedish PIEp network, a program for product innovation engineering. In one of their projects (InnoPlant), healthcare innovation was on the agenda. Researchers worked together with partners from the public healthcare sector and private entrepreneurs to create a workbook as a guide for collaborative healthcare innovation (Larsson et al., 2012) intended as a guide for stakeholders. In the workbook needfinding is used as a tool to identify needs and generate ideas and create opportunities for innovation. As explained in the methodology section of the thesis, needfinding is a part of design thinking, which is regarded as an approach to support social innovation (Brown & Wyatt 2010). Design thinking is a creative human-centred discovery process followed by iterative cycles of prototyping, testing and refinement (Brown, 2008). This design process has been proven successful in healthcare innovation (Brown, 2008).

Since the word “innovation” is a buzzword used by several people in different ways, I would like to declare that the concept “innovation” is used in my work in its broadest sense. This means that everything that adds value is an innovation, whether it is a product, process, service or change in organizational structure. Further, needfinding and design thinking are powerful tools and processes when aiming for healthcare innovation. Thus, qualitative efforts combined with creative thinking can lead to new and interesting ideas for products, services, and systems (Kolko, 2011).
4.6 Public Procurement

The majority of Swedish healthcare is a part of public service, and serves under regulations for public procurement. The Swedish Competition Authority, which controls the procurement process and ensures compliance with the act of law for public procurement states that:

“‘Public procurement’ is the measures taken by a contracting authority with the aim of awarding a contract or concluding a framework agreement regarding products, services or works. ‘Framework agreement’ means an agreement concluded between one or more contracting authorities and one or more suppliers, the purpose of which is to establish the terms for a later award of contracts during a given period.” (The Swedish Competition Authority)

To be able to follow the regulation, a process for public procurement is developed. As shown in figure 3, the process starts with activities related to identifying needs and requirements specifications as a part of the planning phase.

![Diagram](image)

Figure 3 The public procurement process (The Swedish Competition Authority)

Almost every e-health solution falls under regulation for public procurement. One of the problems with such innovations is that they often suffer from poor usability (Jokela, 2010). Either the call-for-tenders does not have any requirements for usability or if they do they are on a high level of interpretation. A typical example could be that requirements on usability are defined as “the software should have a modern and user-friendly interface”, or “errors should be avoided” (Jokela, 2010). It goes without saying that such requirements can never be objectively verifiable or classified as fulfilled or unfulfilled. If the aim is to procure usable solutions, then the call-for-tender must have usability among the requirements. Otherwise the supplier may not consider usability when preparing for tenders or if they do the supplier takes a risk of having a more expensive tender and might be less competitive (Jokela, 2010). It is also crucial that usability requirements are possible to trace and measure. However, requirements do not have to be documented and labeled as a usability requirement to be important for usability. Hence, a requirement can describe a feature without specifying why that feature is needed. If such a feature is excluded the usability might be affected. That is why usability work in procurement must go beyond the list of requirements to provide information and knowledge that can help trace the cause and effect for every requirement, i.e., create traceability. It has been claimed that
there is a gap in the current procurement process between the requirements that the procurement projects start from (the abstract and idealized business goals), and the requirements that it aims at specifying (the concrete and technical goals). This is shown in figure 3 (Markensten, 2005).

![Figure 4 Levels of systems requirements (Markensten, 2005)](image)

There is a strong connection between usability work and procurement (Lantz & Holmlid, 2010) and some scholars even claim that, “all usability professionals know that the results of their daily work are ultimately in the hands of the procurers” (Artman, 2002). This means that activities of creating traceability in healthcare innovation must adapt to the process of public procurement.

Suppliers delivering products for healthcare have started to recruit interaction designers and other usability experts to better bridge the gap between developers and their customers. But that is not enough. First, suppliers often come in after the needs and requirements are described and then there is no access to the supplier’s experts. Second, the health care sector needs someone who understands the benefits of user involvement and usability in order to explain, what they need and why they need this as a big part of the procurement process. In addition, the user, their tasks and the context in which the product is going to be used are only known to the buying organization. That is why usability work should be carried out in that known situation (Lif et al., 2005). Nevertheless, it has been argued that it is crucial to require that the supplier’s development process, competence and organization include usability (Thorén, 2005).

Within public procurement it is of high relevance that usability issues are formulated in ways that make sense to management or other stakeholders. “Only then will usability people gain the resources and respect they need in order to be able to do more then just scratch the surface “ (Artman, 2002). It is also important that the procurer is highly involved in the design process so that the organization can procure usable systems (Lantz & Holmlid, 2010). Further, the procurement process must include the follow-up after a product is implemented and starts being used, since it is hard to predict the future. It is not until a product is put in use that the result of usability will be visible. Therefore the procurement process and contracts must be open for iterations and updates to enable follow-ups without increased cost.
5 SUMMARY OF APPENDED PAPERS

This chapter summarizes the appended papers and states the relation to the thesis as well as clarifies the contribution by the author.

5.1 Paper A

Relation to thesis:
This paper describes and discusses the practical activities of needfinding and product development conducted by MSc students in mechanical engineering. It highlights the challenges and benefits with a need-driven approach and the work of developing innovations for healthcare. Further, the paper describes the roles involved in identifying needs and making requirements. The paper also explores how traceability can be obtained in terms of making needs tangible by using different ways of mediating the students findings to other stakeholders. This research was about coaching needfinders involved in design and development work to focus on maintaining the relations between needs and solution. We wanted to gain insights into the skills requisite for the performance of a need-driven product development process.

Author’s contribution:
I was the operative project leader for the project, giving the assignment to the students. I helped the students get access to the healthcare setting and coached them in using a needfinding approach. Together with researchers at the department for Computer Aided Design I took part in collecting, analysing and compiling the data through observations, interviews and workshops as a basis for this paper. I was responsible for creating the model we used to describe a need-driven product development process, even though it was done in close collaboration with the other researchers. I participated in writing the paper mainly by reviewing the model, data and result.

5.2 Paper B

Relation to thesis:
This paper discusses and describes the practical work of creating an innovation for healthcare with a need-driven approach. The project team consisted of researchers (needfinders and designers), management and healthcare professionals from an elderly-care home (users) and representatives of the product development company (developers). We combined needfinding and product development for a healthcare setting and developed the NeedInn process, which we used and redesigned iteratively in the process. By using the process in practice we could try the recognition of the potential benefits of that process. This paper explains how we collaborated with other stakeholders and the activities and methods we used to create traceability in healthcare innovation. We also elaborate on the benefits and challenges we experienced working with a need-driven approach.

Author’s contribution: I was the operative project leader for the project described in this paper and worked as a needfinder in collaboration with researchers at the department for Computer Aided Design. I was responsible for and directly involved in the development process and all of the
activities performed. Besides being the needfinder I served as a facilitator in the project team. I took part in collecting, analysing and compiling the data through observations, interviews and workshops as a basis for this paper. As a co-author I reviewed the paper regarding the way the project and practical work was described and the use of data and result.

5.3 Paper C

Relation to thesis:
Paper C is based on the results of studying other needfinders. The paper describes a study on healthcare professionals and their practical work as change leaders and needfinders. It highlights the important role that healthcare professionals have in healthcare innovation projects. In the projects radiology nurses were responsible for identifying needs and making requirements as a basis for development and procurement. In the paper we explain what the nurses did to create traceability and put their work in relation to the designers’ special knowledge. Further we elaborate on roles, activities and knowledge needed to ensure traceability in healthcare development and procurement.

Author’s contribution:
I collected, analysed and compiled the data used for this paper and observations and interviews with people from the radiology departments were performed by me. As the main author it has been my responsibility to write this paper. Constructive comments, reviews and advice have been provided by the co-authors since they have valuable knowledge about research regarding radiology, design, healthcare development and procurement.

5.4 Paper D

Relation to thesis:
This paper is a bit different than the others since it is done in the area of requirement engineering (RE) rather then design. Paper D is included in my thesis because it shows and reflects upon the complexity of the healthcare domain in terms of the organization structure, regulations and political issues related to development and procurement. RE is a big part of healthcare innovation, especially from a developer’s perspective. The work we did was a result of a case study aiming at understanding how to transfer an existing reference model (SPM Framework) used in requirement engineering to the healthcare domain. We wanted to investigate if it was possible to transfer knowledge from one domain to another and to measure the maturity level of making strategic business decisions on a long-term basis in healthcare. The SPM framework is commonly used to measure the business level of software product companies, which fall under different conditions than in a healthcare organization. For a County Council it is difficult to be strategic and make long-term decisions because of the economical conditions and organizational structure. The budget is set one year at a time and is based on the political agenda.

Beside myself, the research team consisted of one person from RE and one with a background in healthcare and system engineering. The work was done in two steps. First we translated and tailored the SPM framework to fit the healthcare domain. Based on that we created a
questionnaire to identify the maturity of the organization for strategic requirement engineering (SRE) in a healthcare organization. The questionnaire was first reviewed internally in the research team and then evaluated by the expert from the county council. In step two the questionnaire was used in interviews with stakeholders (project leaders, management, procurement, healthcare professionals) within the organization. The research team then analyzed the result. Our work was an eye opener for the county council and they made several improvements regarding their SRE process. A new position for a business analysis was created to have someone responsible for collecting needs from stakeholders and transform them into well-communicated and managed requirements. Further, a tooling project was launched for tracking needs and requirements, for increasing transparency of decision-making, and for identifying bottlenecks that lead to long procurement lead times.

Author’s contribution:
I was involved in the translation activity of the SPM framework and contributed with my experience in usability, requirement, healthcare development and design. It was my responsibility to translate the parts that related to requirement management. This involved questions regarding how that process was conducted, how needs and requirements were identified and validated, the actors involved etc. in relation to the SRE process. I participated in the evaluation of the questionnaire but the other authors did the interviews and analysis of data. As a co-author I participated in writing the paper mainly by giving feedback and constructive comments.
6 TRACEABILITY IN HEALTHCARE INNOVATION

One of the overall findings in this thesis is that traceability in healthcare innovation could be seen as an act of making requirements traceable in the processes of design, development and procurement in healthcare innovation. This perspective emphasizes the importance of understanding, documenting and explaining requirements in terms of what they represent, why they are needed, for which purpose, and if and how they relate to other requirements that must be considered.

Traceability maintains the relationship between needs and solutions by providing a reality check in every step of the development and procurement process. Unfortunately, this traceability act is not managed and used to its full potential. First, usability experts do not label their work as “creating traceability” and still that is exactly what usability work in healthcare development is all about. Hence, usability experts are trained to find out what people want and to understand what people’s needs are in terms of design. They know how to follow the movement, progress, or development of something, in this case, work processes, interactions, context-of-use etc. in healthcare innovations. Further, they can identify, understand, explain and provide the traceable information needed to follow relationships and links regarding usability and interoperability. To label usability work an act of creating traceability could strengthen the arguments for making usability the basis for development. It could also facilitate the communication with developers considering that traceability is a well-established term used in requirement engineering.

A second concern regarding traceability is that usability work does not pervade every step of the development and procurement process. This makes the traceability process inadequate and incomplete because traces can only be found if they exist. The generalized traceability model in figure 2 is based on stakeholders’ needs but it does not show how those needs have been identified, understood or mediated. Again, without information explaining the significance of those needs, there is no trace to follow. Thus, no matter how well defined and structured a process may be, it can never compensate for lacking input. It is not sufficiently to make requirements that state that the software should have a modern and user-friendly interface, or errors should be avoided. These types of requirements can never be traceable, evaluated or validated. That prevents usability issues from being a vital part of the prioritizing activity and the price tag for each requirement gets more attention than the requirement actually merits, given its contribution and value. Explicit and measurable usability requirements are important for an overall perspective. But it is also important to understand that all requirements are related to usability in one way or the other. Features are based on stakeholders’ needs and must be evaluated and validated accordingly. A traceability process is not linear, rather iterative and an on-going exploration and evaluation in dialogue with stakeholders.

In strategy and policy documents for e-health the flow of health information and solutions property aims to be accessible, effective, supportive, useful, necessary, structured, interactive, and appropriate (Ministry of Health and Social Affairs; 2011; Government Offices of Sweden, 2011). The meaning of all of these attributes is context-related: in order to fulfil them they must be interpreted and understood in relation to the context. What is useful for one person might not be useful for another, and whether a system is appropriate or not depends on the situation. This paves the way for usability work in development and innovation, since usability experts can provide such an understanding. They know how to transform fuzzy and unstructured information and make it explicit.
Paper A showed that the efficiency of a needfinding process is dependent on the designers’ training and experiences in qualitative needfinding activities, as well as being confident in the flexibility of the process. This means that it is not the quality of the process itself that makes for good results but rather the possessed skills people have using that process. In chapter 4 we state that the designer’s special knowledge lies in the skill of using methods and techniques to perform usability work and make use of those in the healthcare development and procurement process. Designers also speak the “language” of healthcare professionals and developers and know how to communicate, negotiate and interact with different stakeholders. However, involving more designers (usability experts) does not solve all of the traceability problems in healthcare.

It has been argued that there is nothing magic about design (Kolko, 2011) and that there are methods to help designers or others to move forward through different stages in the design process. This means, to “jump” from gathered data and turn the data into information, knowledge and wisdom with the aim of making meaning out of data, experiencing frame working and to get empathy and insight (Kolko, 2011). Some people argue that “design has become too important to be left to designers” (Brown, 2008) and that people’s personality profile and commitment are more interesting than their profession. The design thinker’s personality profile is claimed to include properties, e.g., empathy, integrative thinking, optimism, experimentalism and collaboration skills (Brown, 2008). Paper C argues that healthcare professionals are a part of what could be classified as designers’ “territory”. Without any specific training in design or development processes, the radiology nurses were responsible for identifying needs and establishing requirements, which is fundamental in healthcare development. The radiology nurses were mediating and negotiating with other stakeholders and balancing between practical, organizational, technical and political issues that had to be taken into account. To cope with that the radiology nurses had to shift roles to work as mediators, project leaders, user representatives, needfinders, change leaders and designers.

The challenge we want to address is how the design community can find a way to match the role that radiology nurses had in the projects, a role essential to design. It is time to update the way design work is done and by whom according to current conditions. In paper B we found that in the context of innovative products, the identification and definition of customers and their needs is a non-trivial and difficult exercise. It involves not only needfinding but also the definition of ‘those who might need the product’, users and customers to co-evolve iteratively in the early phases of design. Within the projects CTM and ExDIN, we as designers work co-creatively with healthcare professionals for a mutual benefit. All of us work together equally as needfinders to identify, understand, explain and provide the traceable information needed to follow relationships and links regarding usability and interoperability. As usability experts and designers we provide the process and tools but use them together with healthcare professionals at the pathology department. This kind of collaboration is one way for designers to match existing initiatives taken by healthcare professionals and combine the skill needed to create traceability.

The time spent on identifying, understanding and “tracing” stakeholders’ needs is some of the most valuable time spent in a development process. To improve the traceability in healthcare innovation usability work has to be acknowledged by management, and be put on the political agenda. It is also crucial to understand that implementing IT to improve healthcare affects the whole organization and cannot be separated from business development. The decision-makers’ attitude and perspective must change. Making innovations usable must be seen as something more than using “common sense” (Eriksson et al. 2008). It is easy for people to understand and claim that usability is needed but much harder to actually make decisions or to know how to do create usability. To accomplish that, experts in usability must be involved in the development and procurement process and provide information and knowledge needed to trace the cause and
effect for each requirement i.e., create traceability. It is also important to specify the activities, actors and responsibilities in that process.

In addition, the process of creating traceability in healthcare development must adapt to the process of public procurement in order to be used to its full potential. Usability must be included in the call-for-tenders because that is the information channel used for communication between customers and suppliers. Without asking for usability the supplier might not consider usability important and if they do they risk having a more expensive tender and thus be less competitive. This has to change. The healthcare sector must be a better purchaser and demand solutions that fulfil stakeholder’s needs in terms of usability and interoperability, requiring that the supplier’s development process, competence and, organization are pervaded by usability.
7 CONCLUSIONS

This thesis argues that traceability in healthcare innovation could be understood as an act of making requirements traceable in the processes of design, development and procurement. That includes understanding, documenting and explaining requirements in terms of what they represent, why they are needed, for which purpose, and if and how they relate to other requirements that must be considered. Despite great opportunities traceability in healthcare innovation is not managed and used to its full potential. Usability experts do not label their work as “the creation of traceability” even though that could provide arguments for making usability work visible, and facilitate the communication with developers. Also, the development and procurement processes are inadequate, i.e., not need-driven and pervaded by usability.

The people filling up the role/roles best suited for the “traceability activity” must have a holistic view as well as a narrow and deep understanding about stakeholders’ needs and context. This requires domain-specific knowledge about the healthcare setting and an understanding of how the organisation works practically and politically. It is also crucial to be skilled at usability, design, development and procurement to know the game plan of healthcare innovation.

To manage and improve traceability in healthcare innovation the decision-makers’ attitude and perspective must change. First, usability work should be used and labelled as the act of creating traceability. Second, usability work has to be acknowledged by all stakeholders and the process of implementing IT in healthcare must be incorporated with business development. Third, experts in usability must be involved in the development and procurement process. Another improvement would be if the healthcare sector acted as a better purchaser and demanded usability in communication with suppliers (requirements specification, call-for-tenders etc.).

Finally, these suggested improvements will not be accomplished without a strategic plan where the roles, activities and responsibilities are detailed and clear. Thus, it is time to update the process of healthcare innovation and the roles involved according to current and upcoming conditions and such a task requires people who know the game plan.
8  FUTURE WORK

Due to the complexity of the healthcare innovation process I would like to make use of my findings and continue working with more empirical studies on how to create traceability in different development and procurement projects. One important and interesting area for future research is the work of usability experts in healthcare innovation projects of today. I want to compare and understand the difference between usability experts working as external consultants and in-house usability experts in healthcare projects. It would be interesting to study if and how they differ in terms of roles, responsibility, skill or acceptance. The procurement process in relation to usability work, decision-making, validation and stakeholders involvement is also of high interest for future studies. Is it possible to be strategic and make long-term plans and decisions based on stakeholders’ needs given the current circumstances? How does the private sector purchase and develop healthcare innovations compared to the public sector that serves under regulation for public procurement? In the nearest future I will be focusing on how to create traceability and match my own design skill with healthcare professionals and other stakeholders involved in developing innovations for pathology, multidisciplinary teams and echocardiography.
9 REFERENCES


ISO 9241-11:1998. Ergonomic requirements for office work with visual display terminals (VDTs) -- Part 11: Guidance on usability


Madelene Larsson, Traceability in Healthcare Innovation – Maintaining the Relations Between Needs and Solutions


Need driven product development in team-based projects
NEED DRIVEN PRODUCT DEVELOPMENT IN TEAM-BASED PROJECTS

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ABSTRACT
In this paper, practical activities of Needfinding - an intertwined approach to identifying needs and to visualizing idea concepts in early design - are described and discussed. This is done primarily to gain an increased understanding of the various representations of user needs that are fed into the fuzzy front-end activities of team-based product innovation projects. The empirical basis comes from a study of an eight-month collaborative product development project, performed under realistic conditions by MSc students in close collaboration with their client.

Focusing closely on customers and their needs is encouraged within the conceptual framework of Integrated Product Development and is increasingly highlighted as a key enabler in the design of truly innovative products. Despite the fact that identified customer needs are considered as the initial and primary input into such an innovation process, it can be argued that the design teams do not commonly have a sufficient understanding of customer needs and they do not normally interact with customers in their environment. Besides focusing on measurable aspects of user behaviour and requirements, a traditional approach to identifying and managing customer needs usually includes several interpretive stages before being handed over to the design team. In the context of innovative products, the identification and definition of customers and their needs is a non-trivial and difficult exercise. It involves, we suggest, not only Needfinding but also the definition of ‘those who might need the product’, users and customers to co-evolve iteratively in the early phases of design.

Keywords: Product Development, innovation, Needfinding, engineering design

1 INTRODUCTION
The business environment is going through a shift towards service provision, which is likely to affect how products are designed and developed. Contemporary companies on a global market are experiencing constantly changing business demands and increased competition. The situation is described by a company as: “There is fierce competition out there, which means we require the best supply chain, the strongest finance operation, the most creative deal-makers, the greatest customer focus and the finest engineers to help take us into the future” [1].

To meet competition, companies invest a great deal of money and effort into the development of new products. Despite that investment, nearly nine out of ten products fail within two years of release [2]. One possible explanation for this is that the products do not actually solve a customer need [2]. An additional dimension to that situation is that failures in market uptake can actually have its explanation very early in the product development process; engineers lacking a profound knowledge concerning who might use the product they are developing: “The engineers involved assumed that because they personally would like to own and use such state of the art devices, everyone would. They were wrong” [3] (p.422). It can be argued that the engineers probably would describe themselves as customer focused, since they assumed that the customers preferred the same devices as they did. However, the attitude ‘we know our customers’ is not the equivalent of focusing on customers [2]. Focusing on customer needs involves both thinking and acting activities [2].

A tendency to focus on a product that designers might want to use themselves often leads to a product that is too complex [4], as well as a focus on a particular product or solution in early design phases often hampers innovation and new product development. Finding and understanding people’s needs
are at the heart of developing innovative products [5], and Needfinding is a needs-focused approach, which encourages designers to keep all possible solutions open for consideration and helps them avoid a premature delimitation of the design space [5]. The investigation of people’s needs and designing activities should be seamless; this means that engineers have to be closely involved in the Needfinding activities to truly understand people and their needs. It is proposed that focusing on customer and their needs is a way to manage the fierce competition [2], but to design innovative products that actually meet people’s needs the whole product development process has to be driven by those needs.

One task for a technical university is to educate and train future engineers to meet the companies’ expectations, and to possibly even exceed those expectations by providing engineers that are particularly well equipped for need driven product development. Our university is no exception; in line with an earlier quote, we aim to provide the future engineers with a greater customer focus and make them the finest engineers. Our experiences are that applying a Needfinding approach in early phases of product development makes the engineers aware of that they are developing products for somebody else [6], and aids them in the transformation of that awareness and understanding into products that are better aligned with actual customer needs. In today’s product development world, by tradition bound to deal with physical problems and hard facts, this approach has initially proven to be a rather hard sell. Zooming in on customer needs actually widens the scope of the product development domain, calling for multidisciplinary, team-based creativity and new methods for aligning design and development activities more closely and continuously to the outcome of an iterative Needfinding approach.

1.1 Purpose

The product development process which is put into practice by the students at Luleå University of Technology is named Participatory Product Innovation (P²I). It supports the process in team-based product innovation projects and, we find, not only allows user needs to drive and affect the design activities, but actively encourages it [6]. The integration of Needfinding in P²I is perceived as a virtue for the practice of need driven creative product development. However, dealing with people’s needs in relation to innovations means that we are also dealing with fuzzy front end information. As the word ‘fuzzy’ implies, this is a phase of innovation projects where it is very difficult to find evidence concerning whether or not the project outcome will be a success or a failure. The activities when handling fuzzy front end information are normally not straightforwardly captured into guidelines or models, yet they are taught and promoted as a set of capabilities that professional designers and engineers should be able to put into practice. Identification of fuzzy front end information, such as people's needs, might be a characteristic for innovation opportunities, since “Needs are opportunities waiting to be exploited, not guesses at the future” (p.38) [5].

The purpose in this paper is to describe practical activities of Needfinding in the early phases of a team-based product innovation project to gain insights into what the fuzzy front end is about and how designers and engineers can develop the adequate skills in performing need driven product development.

1.2 Innovation

The word innovation is used and interpreted in a plethora of ways and applied in many areas. We are not attempting to define the word here, yet a short explanation could be useful to better understand what the team-based project actors are striving to achieve. In the setting presented in this paper, innovations can range from new physical artefacts, i.e., new things, to more intangible products, e.g., new ideas, new processes. The word new can here be interpreted as in beforehand ‘poorly understood’ or ‘unknown’, and as a fact, exceeding what was intended from the beginning [7].

In innovation processes, the desired qualities to manage can be the actors’ capabilities to create visions, new ideas, mutual learning and understanding [8]. The metaphor of a jazz group can be used to describe the support of such a process, “The orchestration of a design group needs to support the group’s imaginative thinking, handling and synthesizing competence and well-being, as well as giving overall managerial support that also addresses the production aspects of the design process” (p.289) [8]. From our perspective, product development processes which aim for innovations have to address these issues by being sensitive to the task at hand, by enabling creativity and by supporting the social processes in the design team.
2 METHODOLOGY

The empirical basis for this study is found within a global team-based product innovation project conducted by students in the final-year course in the Mechanical Engineering MSc degree programme, SIRIUS, at Luleå University of Technology, Sweden. The Swedish students have collaborated with students from the ME310 course, ‘Team Based Design with Corporate Partners, at Stanford University, USA. The study reported on in this paper is based on a perspective of the Swedish student team’s data generation phases and Needfinding efforts.

The students in the SIRIUS course run their project in a setting as close to real world development projects as possible, e.g., close collaboration with affiliated companies, interaction with people in society, and being ‘owners’ of the process and its result. Access to the student project for generation of data has taken place by being coaches for the students. The course runs for about 8 months and the Needfinding activities mainly take place during the first 4-5 months. Data has been continuously generated during these months. A second effort for data generation has been performed in the last month of the project where the students have had the opportunity to reflect on the Needfinding activities in relation to what they have achieved.

Main data generation methods have been observations and interviews, i.e., dialogues. Written documents, e.g., log books and reports, from the students have also provided useful data. The students’ collaborative activities in early phases have been videotaped. Field notes have been taken from the videos to provide additional data to this study. All data is qualitative in its nature.

2.1 The student project

Based on the initial information provided to the students, the project studied here was called Future Elderly Environment (FEE). The students got the information that they were going to develop ‘something’ that would help increase the wellbeing of elderly persons. The theme of wellbeing was initially introduced into the SIRIUS setting as an approach towards increased wellbeing for people with physical limitations and/or people facing other constraints. However, wellbeing as a concept has more to offer than merely remedying problems of specific disability [7]. One basic element is to provide added value for people, enabling them to increase their active participation in society.

The initial information given to the students is intentionally kept as broad and general as possible, providing just enough information to stimulate the Needfinding activities in question. For example, no further directions about the target group were given; the students had to decide for whom they were going to develop the product. Increased wellbeing for elderly persons can be achieved by providing innovative products for, e.g., next generation elderly, elderly themselves or people in the elderly persons’ surroundings. A European Commission-funded project called NeedInn (from needs to innovations) has served as the client for the student project. The innovative product designed by the students has been further developed by one of the students after finishing the course. The product is going to be implemented in a new and high-tech enabled elderly home and is planned to be commercialized.

The FEE project had a close collaboration with students from USA. Four students from Sweden and four students from USA formed the global design team. Due to the fact that the students have participated in organizationally separated courses, the SIRIUS course in Sweden and the ME310 course in USA, the students had to develop prototypes and products respectively. The search for data about needs have been performed in Sweden and in USA by the respective student team. Interpretation of that data has been performed in collaboration, as well as the early design phases. Hence, the products that have been developed are based on the collaboratively identified needs. The geographical and communicative distance has been partly reduced by using videoconferencing technology, shared online workspaces, email etc. The design teams have also visited each other, so the collaboration in early phases was also performed in face-to-face meetings and workshops.

3 PARTICIPATORY PRODUCT INNOVATION

A generic master plan consisting of a timeline and a number of sequences to go through, guides the SIRIUS students in both running the project and the product development activities. The master plan does not point out activities in detail and the purpose is to provide the students with an overview tool to estimate the efforts required for the whole project, as well as a map to keywords that can be useful when searching for relevant literature.
The P²I process is included in the master plan. P²I can be best described as a hybrid of Needfinding [3], [5],[9] and the product development process suggested by Ulrich and Eppinger [10]. The underpinning logic and methodological philosophy for P²I is inspired by an approach to creative product development [9], [11]. The P²I process has an emphasis on the use of qualitative research methods to identify needs and an emphasis on the use of a variety of creative methods, especially to express need statements and to generate idea concepts. Designers’ direct work with identifying user needs is important, since ‘users are not designers’ [7].

An integration of what can be viewed as qualitative Needfinding issues and quantitative product development issues is a challenging task, so P²I is continuously developing. The P²I process provides guidelines rather than entailing a stepwise model, thereby the students are encouraged to enhance and develop the process. At the moment, the whole master plan includes seven overall sequences (1) Planning, (2) Design space exploration, (3) Roadmap, (4) Concept design and prototyping, (5) Detail design and manufacturing, (6) Pre-launch and (7) Product launch. Needfinding activities are a main part of the second sequence. Besides Needfinding, this phase includes scoping of the project, benchmarking of competing products, and a state-of-the-art review of related knowledge or technologies that might be found in other domains. All these activities are performed in an iterative manner. The students are guided through this phase by questions, for example: Who are the actors? How can you find out more about them? Where? What are they doing? Why? What can you learn from other domains? These activities prepare the teams for the next sequence, the roadmap, which has been identified as a boundary or interface mediating between Needfinding and more traditional product development activities [6].

4 A CUSTOMER-CENTRIC VIEW

A customer-centric view begins, logically, at the customer and it begins before the development process gets started [2]. From this strand, product development companies are often criticised for short-circuiting the process in the rush to launch new products to the market. By doing this, it is argued, eight vital steps of the product definition process are ignored [2]. These steps are; (1) develop image diagrams, (2) translate voices into requirements, (3) provide requirements diagrams, (4) develop metrics, (5) design the survey, (6) administer the survey, (7) analyse existing solutions and (8) analyse results of the survey.

Mello [2], advocates a market-driven product definition, and discusses what is commonly referred to as the fuzzy front end in product development. She argues that a product-centric view results in a fuzzy product definition since the views from different functional groups are varying, see left in Figure 2. As an alternative way to minimize fuzziness in product development, a customer-centric view is recommended. This view is, according to Mello, likely to lead to one unified view of the product definition since all functional groups build the product definition on an understanding of the customer, see right in Figure 2.

Visits to the targeted customer segments and customers are planned in the beginning of a market-driven project. Early on planning concerns, for example, identification of lead users [12], specification
of key individuals who will influence, purchase or use the product and selection of key customers [2].
A common image of the customer is developed after visits to customers. The importance of using
different criteria than traditionally when segmenting customers for the purpose of understanding the
customer image is present in the customer-centric view [2].

![Diagram of Product-centric vs. Customer-centric views](image)

Figure 2. Product-centric view vs. Customer-centric view. After [2].

Emphasizing that use is the criterion for identifying customers, it is suggested that companies should
"... determine which of the traditional segments have uniquely different uses of the product. The
difference in the use of the product or service by various groups of customers is the qualifying
question when selecting customers to visit" (p.46) [2]. An advice to keep the input information
manageable is that an increased number of visits to nonusers of the equipment would not reveal any
new concepts, problems, or opportunities [2]. However, Mello also gives the advice to think hard
about which customers to visit. It is far from obvious, even though the companies think that they know
the customer [2]. A distinction between customers and users can be that customers are those who pay
for the product and users are those who actually use the product [13].

5 A NEEDFINDING VIEW
In general, understanding needs is considered important for the design of innovative products [5], [14].
The idea to listen to the ‘voice of the customer’ is not new [2], [15]. Over thirty years ago, Robert
McKim, at the time head of Stanford University’s product design program, discovered that people who
found problems to work on and those who were going to solve them were not necessarily the same. To
get designers closer to end users he introduced Needfinding as an approach [5]. The approach depends
heavily on qualitative research methods and, as a response to a growing understanding of such
methods, Needfinding have been further articulated and extended [5]. Methods which are similar to
Needfinding have been used in, for example, software development [16].
Still, only a few design and development firms seem to fully embrace and apply the approach. One
example is IDEO, a leading design firm in the US [9]. Besides the fact that qualitative methods have
not historically been either well-understood or used, a further explanation for the limited use by
product development firms can be that Needfinding focuses on people’s needs which are often
difficult to articulate and, accordingly, the effort to uncover them might be perceived as too extensive.
Further, a focus on user needs includes ambiguity and contradiction [15].
It is crucial to note that “Solutions come in and out of favor faster than the needs they serve”, and that
a closer focus on needs can “…encourage companies to continue innovating better ways to serve those
needs, independent of current solutions” (p.38) [5]. Basic ideas such as “look for needs, not
solutions” and “look beyond the immediately solvable problem” (p.40) [5] are at the heart of a
Needfinding approach. In practice, this means that the Needfinding team should gather a lot more
information than what seems to be necessary for the initial scope of the project at hand. Furthermore,
the team should keep all possible solutions open for consideration and to avoid prematurely limiting
the design space. Such an approach is a direct opposite of how information is commonly managed in
traditional product development, where the main objective is to narrow down (converge) the
information by reducing ambiguity as early as possible [8], [17]. This kind of controlled process may
hamper new thinking, because it makes the designers act in accordance with a paradigm-preserving style [8].

A Needfinding approach builds on viewing needs as different from requirements. Investigation of user needs is in general indicated as an input to the first steps in representations of integrated product development processes [10][18]. Due to this, these models can be labelled as being user oriented, but this does not necessarily mean that the development is driven by needs. The product development process can be triggered by, for example, the development of a new technology [10], and quantitative and qualitative surveys can be performed by the marketing department to identify a market opportunity [19]. Market research has received some criticisms from product designers [19], who often claim that market research limits design opportunities to the lowest common characteristic of customer taste. Furthermore, product designers often say that customers can not express that “...they want a truly innovative product that they have never ever imagined before” (p.156) [19]. This criticism might indicate some problems with traditional market research, e.g., that it focuses on customer segments and that it merely identifies requirements and ‘wants’, which can be expressed in relation to already existing products. Users can often be more precise in their articulation of their requirements when a solution is in use [20]. Hence, it can be argued that what people have more difficulties to express is a need, yet it is experienced as a problematic situation lacking satisfying solutions [3].

Further critique of the traditional market research is that it usually treats needs as something waiting to be collected. Thus, there is an emphasis on a quantitative approach where the needs should be measured and transformed into characteristics of the emerging product [21]. Such a market research approach searches for and identifies requirements. In this way, needs are likely to remain uncovered. “Needs are obvious after the fact, not before” (p. 39) [5], i.e., only when they are identified and can be expressed as requirements will they also be available for measurement. Due to the difficulty for people to express needs and the unfamiliarity for the design team to identify them – and to truly bring them into the development cycle – a different approach than traditional market surveys is suggested. A wide range of creative ways to identify needs and allow them to drive the development of innovative products is applied by those design firms which base their design and development processes on Needfinding. A focus on diversity rather than on consistency is a basic concept, where unfocused groups rather than focus groups are preferred [9]. The understanding that ‘people are human’ is seen as a source of creativity, not a problem to be solved [9]. Crazy users and rule breakers are seen as invaluable sources for information. For example, an artist, a bodybuilder, a podiatrist and a shoe fetishist were engaged in the design of a sandal [9]. This can be compared to involving lead users [12], whose needs can help indicate the needs of a general user in a future market situation. Lead users try to develop solutions on their own to meet their need and, hence, they can provide useful information to the Needfinding team [12]. The balance between the varieties of people providing data to identify needs is important. Studying only lead users might result in overbuilt product specifications, so general users should also be involved to get an understanding of and cater to mainstream needs [5]. When striving to identify needs, it is important to understand people and the constraints they perceive, not to judge or correct them. Instead, the information generation activities should be seen as exploratory learning lessons in support of product development [2].

5.1 Carrying out Needfinding

The principles of Needfinding are manifested in a four-stage process for studying people. These stages are [5]:

1. **Frame and prepare** – involves decisions about e.g., the scope or coverage of the project, the goal of the study and the definition of the people to be studied (i.e., Needers).
2. **Watch and record** – observing people in their own environment.
3. **Ask and record** – talking with people in their own environment.
4. **Interpret and reframe** – translate the information into need statements. Based on the findings, reframe which people and what to study. Unexpected issues might have been found which must be answered to advance the design.

Quick iterations between the stages are encouraged rather than one long effort. A draft, outlining the identified user needs, is provided after each pass and preliminary design work can begin based on the current understanding [5].
Since what are sought after are needs which are difficult for people to articulate, the use of a variety of techniques applied in real-life situations is important [9]. Observing people gives information about how they act, however it does not provide answers to why they are acting in a certain way; it is also necessary to ask them that important ‘why question’ [9]. Asking a ‘why question’ makes the context and people’s priorities understandable. Asking a ‘what question’ highlights details in the people’s daily activities and goals. It is suggested that it is within the interplay between observations and these questions that people’s needs can be more carefully discerned [6]. Talking to people or asking people these questions is not about interviewing, it is rather about prompting people to tell personal stories about their experiences [9]. This insists on being keenly alive to both text and subtexts [11]. In fact, contradictions may denote unrecognised or unarticulated needs [5].

Having a focus on identifying needs means that a wide range of information about people is of interest, and such information naturally comes in many forms [5]. Thus, the Needfinding team has to pay attention to e.g., facial expression which might express a person’s emotions better than words, and keepsakes in an office area that might reveal information about a person’s relation to their work [5]. A Needfinding approach generates large amounts of various data in short time. All these forms of data have to be recorded for later study and analysis away from the studied site. Additional recording media, for instance video, audio, photos and drawings, is recommended to capture the richness of information in the needer’s natural environment [5]. In this way, representing the results in a tangible form allows for making people’s needs real to those who have not been involved in the Needfinding activities and make the design efforts to meet these needs smoother [5], [9], [11].

The seamless approach between finding needs and performing design activities means that members in a design team should be involved in both studying people’s behaviour and in visualising idea concepts, as well as in visualising those who will ultimately use the solution [9]. This insists on creative methods that empower Needfinders, designers and Needers in a participatory product innovation process. Besides brainstorming, which is frequently used for many kinds of design tasks, different ways to visualise the design ideas are applied [9]. The creation of a creative environment relies on people feeling comfortable and an informal context is essential to make people more open to share ideas and thoughts [5], [11]. In relation to traditional product development processes, the IDEO process – they admit – might seem totally chaotic. Still, there is in fact a well-developed and continuously refined methodology guiding the work, “…it’s just that we interpret that methodology very differently according to the nature of the task at hand” (p.6) [9].

6 NEEDFINDING AS PRACTICED IN THE STUDENT PROJECT

The project was perceived as being very ill-structured; the FEE students said “it is frustrating to have such a fuzzy task”. The task of developing something to increase the wellbeing of elderly persons was discussed with the students, but no detailed direction was given. The students were encouraged to do observations and to talk with elderly people. The decision which those people were and what to talk about was to be made by the students. Firstly, the students started with a brainstorming session to find out what they as a group meant by ‘wellbeing’. They found wellbeing as a combination of physical, mental and social health.

Secondly, the students talked to older relatives, visited several elderly care homes and visited home service personnel. They used shadowing, i.e., followed staff members around for a whole day and observing them doing their work. Further, they used detailed observations, i.e., logging all activities needed to achieve a goal; for example, an elderly person getting out of bed. During these first visits, the students had gathered a lot of information about assistive devices, such as alarms, lift systems for beds or bathtubs, or special furniture as shower chairs and nursing care beds. This product focus was talked about with the students at the end of the project. A student explained this view, “as an engineer, I like to take a thing, a product, look at it, twist and turn it, and then improve it or make it better”.

The students also focused on the buildings, the ground plans for the rooms and so forth. The first building was not built for the purpose of being an elderly home, so the students found a lot of problems in relation to how the house was built. Accordingly, they decided to visit a newly built elderly home and came back rather disappointed concluding that the new home did not have any of the previously identified problems.

At this time, the students were very frustrated and they were even discussing if they were going to stop the Needfinding activities here. They compared their open-ended project with other student projects...
which embarked from a requirement specification and hence, these students were already in concept evaluation phases. It seemed to the FEE students as if they had not made any progress. They wanted to start developing ‘something’, but could not agree on which needs they had identified, if any at all. Furthermore, the students were not comfortable with the lack of a ‘real method’, a method that they could apply in a direct way and just follow the steps. One student said, “It would be nice if there was a method that we could use without changing it”. However, it turned out that the students already had categorized elderly people into four groups. These groups were: those who could take care of themselves, those who needed limited help from partners or relatives, those who needed help from home service and those who lived in elderly homes. The students decided that the people who lived in elderly homes were likely to provide valuable information about needs for increased wellbeing. Based on these efforts the students could decide that they should study people and define what people to be studied. Again, the students were encouraged to do more observations and talking in the elderly home. In this iteration, in a real-life elderly context, the students started to talk with the residents in elderly homes. The students concluded that it was rather difficult to find topics of conversations with the elderly people. “It seems to us as if the elderly talk a lot about the homes that they have left and of course miss a lot. They show photos and talk about it when given a chance”, the students told us. They asked the elderly about their needs and the answer was – we have it really nice here, we don’t need anything. Thereby, the students concluded that the elderly were satisfied and that this drawback in expressing needs made the task of Needfinding difficult. The students decided to place a ‘need box’ at a strategic place in the elderly home so that the residents and the staff could write down their needs, ideas or problems directly. “In this way,” the students said, “they do not need to keep them in mind until our next visit”. However, the ‘need box’ did not meet their expectations; they found only one idea in the box. “What are we going to do? Nothing really happens when we visit the elderly care home! The elderly just sit there in their wheelchairs waiting for… I don’t know what they are waiting for”. The students had talked with the staff about this matter, and they found that the staff had too little time to activate the elderly. Furthermore, the students had heard the staff telling stories, for example after a ‘sing and dance’ session an elderly man continued playing on his accordion during that evening. In the reflection of these visits and dialogues, the students started to focus on activity and stimulation to increase wellbeing for elderly people. They reframed wellbeing to encompass talking and thinking activities, and that each person should be treated as an individual. At first, the student team identified a number of needs and they stated that they would like to “cover as many of these needs as possible and fulfill each need as strongly as possible”. Over time, as they worked with the interpretation of their data, they decided to focus on keywords which were considered as representing identified needs of most importance – activity and stimulation from both a social and individual perspective. However, they still claimed that “hopefully we can include some of the other needs as well”. Based on the keywords, the students started brainstorming sessions to visualize idea concepts, the context, the user and the problems. The students discussed ideas during one local brainstorming session (the US students visited the Swedish team) and during one distributed brainstorming session supported by video conferencing technology. The prototypes that were built were tested and evaluated with groups of elderly people. After the student project was finished, the students appreciated the project as a learning opportunity where they had developed capabilities to run need driven projects. Even though many of the needs actually remained tacit within the student teams, they evidently affected their product development.

7 TOWARDS NEED DRIVEN PRODUCT DEVELOPMENT

Archetypically, in product development, needs are interpreted and put together into requirements specifications by the sales and marketing functions. In this way, designers commonly do not interact directly with potential customers and do not take part in the interpretation of customer needs. Having this mode of operation, it is likely that designers do not have an understanding of the users’ environment and points of view when the design process starts. Despite this, such understanding is emphasized as an initial step in integrated product development processes. In Figure 3, starting from the left side, the marketing function is responsible for performing market research activities to gather the voice of the customer and translate it into needs and/or image statements and further into a requirement specification. The design function, right side in Figure 3, translates requirements into product specification. Handling needs in this way can be described as an
over-the-wall approach to needs. The ‘wall’ prevents designers to gain an understanding of people and their needs. The ‘wall’ might consist of organizational issues, e.g., the company structure can prevent boundary crossing collaboration. Or, the ‘wall’ might consist of cultural issues, such as when designers might prefer to focus on physical objects, or when designers prefer dealing with measurable aspects of both user and product behaviour. As we have noticed in the FEE project, the students felt more comfortable improving on already existing things and they applied a quantitative approach when they would like to focus on as many needs as possible and fulfil them as strongly as possible.

The customer-centric strand criticizes a product-centric view, since the latter view results in diverging perspectives affecting the product definition [2]. In Figure 2 (previous in section 5), the two views are represented. In a product-centric view the product is in the middle and in a customer-centric view the customer is in the middle. This customer focus is proposed to lead to a unified view and give the whole company a customer point of view. However, it can be argued that a unified customer view also might lead to fuzzy product definition since who the customer is is not a straightforward matter. Furthermore, customers might not be those who actually use the product [13]. In the FEE project, the users are elderly people and any people that interact with them on a daily basis, e.g., relatives, visitors, care givers. The customer in this case was the County Council who, it turned out does not have a direct contact with the product. However, this understanding was not available before the Needfinding/design process started.

Dealing with innovations, as in the student project, means that designers do not know the product beforehand, nor can they predict who the user/s and/or the customer/s are. These aspects have to co-evolve iteratively in the design process. Thus, neither a product-centric view, nor a customer-centric view does adequately support that co-evolution.
An interest in people, their activities, their goals and their context, i.e., a focus on needs, seems useful to find opportunities for new products and innovations. A focus on needs to drive the product development process for innovations is suggested in Figure 4. Starting from the left, designers and, for example, marketing people apply a Needfinding approach to frame and prepare the project. By direct interaction in the area of concern, the people to be studied are identified (‘Needers’ in Figure 4). Needfinding activities, i.e., observations, ‘interviews’, are performed in quick iterations. Firstly, needs are identified and translated into need statements which in turn, frame and prepare the project [5]. The potential users and finally, the customers co-evolve in these participative and iterative activities, too. The involvement of designers in these activities makes it possible to visualize idea concepts and users, since potential users become ‘alive’ and understandable in relation to the evolving new concept. Furthermore, a unified view of the product is likely to occur due to a collaborative effort in identifying needs and visualizing idea concepts. The efficiency of such a process is dependent on the designers’ training and experiences in qualitative Needfinding activities, as well as being confident in the flexibility of the process. Designers and engineers can be trained to deal with needs in fuzzy front end activities, where the aim is to keep as much fuzziness as needed for the creative process to support the design of innovative products. Innovation opportunities might be discovered by designers being ‘purposefully fuzzy’, that is, having capabilities to avoid delimiting the design space and exploiting innovation opportunities grounded in people’s needs.

The middle section in Figure 4 represents a product realization process focusing on needs identified by applying Needfinding. On the right, the identified users and customers are involved in testing and evaluation of the product to improve it according to stated requirements. In this way, the product development process is framed by a Needfinding approach and can be seen as need driven.

8 CONCLUDING REMARK

In this paper, practical activities of Needfinding – an intertwined approach to identify needs and to visualize idea concepts in early design – are described and discussed. This is done to gain insights into what are currently perceived as fuzzy front end activities in team-based product innovation. Aiming for innovations, a limitation for applying a customer-centric view is that it is not possible to identify who the customer is at a planning stage before product development starts. Trying to do so, the design team is forced to make vital decisions on the basis of an insufficient understanding of people’s needs. In innovative projects, through the application of a Needfinding approach, Needers – those people who experience a lack of a solution to their problematic situation and thereby, ‘own’ the need – can be identified. Also, customers and/or users can be identified and the solution can be further detailed in compliance with the identified and thoroughly analysed needs. A need driven product development process is likely to support the co-evolvement of these issues in early phases of innovative projects.

9 FURTHER RESEARCH

Our study contributes in general to a customer-centric view, but in particular to a need driven product development process where Needfinding activities make the design team truly committed to needs and give needs high fidelity throughout the whole process. However, in our study we have found that some needs remained tacit within the design team. So, the transition of needs into product development activities still has to be further investigated. For example, how can identified needs (in this case only key words) be transferred to those who did not participate in the Needfinding activities?

From an engineering point of view, a process is preferably systematic. The IDEO process is perceived by them as an organized effort, but as they admit, it seems chaotic [9]. On one hand, being too organized can prevent innovation. On the other hand, being too flexible might increase confusion and disagreement. Further research is suggested concerning how designers apply creativity and deal with ambiguity in formal and systematic processes in their daily work.

REFERENCES
(John Wiley & Sons, New York).


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PAPER B

Needs as a basis for design rationale
NEEDS AS A BASIS FOR DESIGN RATIONALE

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Keywords: Needfinding, product development, information systems

1. Introduction

A basic principle for Needfinding [Faste, 1987; Patnaik & Becker, 1999] is that designers and engineers should interact directly with users to get direct insights into the user domain. Needfinding is not a new phenomena, it is almost forty years ago since the process was adopted at Stanford University’s product design program [Patnaik & Becker, 1999]. As the name, Need-finding, implies, this is an intertwined approach to find needs which are not readily articulated by users. The application of a Needfinding process offers qualitative methods to make those needs visible early on in product development. In fact, the process has become more interesting during recent time, since qualitative methods have gained more acceptance outside the academic realm [ibid.]. The word qualitative indicates that what are sought for are qualities such as people’s experiences, what they perceive or interpret into a situation [Miles & Huberman, 1994; Patton, 2002]. Such data is contextually dependent, i.e., it must be generated in the context in which the phenomena occur. Besides context, people’s activities, behaviours and goals are important to observe and learn from. The objectives, for applying Needfinding, are to make the identification of needs and design a seamless effort, as well as an interest to identify opportunities to innovations. Needs last longer than any solution [Patnaik & Becker, 1999], since they are grounded in people’s activities. The solution and product that might meet such needs change over time. One example is how to store computer data, the products which satisfy the need has changed from, e.g., punch cards, magnetic tape, floppy discs [ibid.] to USB-flash memories.

A guiding methodology in Needfinding is a flexible process, which is adapted to the task at hand [Kelley, 2001]. Such a process is conveyed in a few basic steps and, builds on a ‘philosophy’ which permeates all activities in order to adapt the process according to the project. Therefore, the designer’s ability to rely on such a process depends on familiarity with a number of methods for observations and interviews, as well as an aptitude for socio-technical skills.

Hence, the purpose in this paper is to present and reflect on methods used in a running development project to identify needs in a product development project. This is done to contribute to the advancement of a need driven product development process.

The disposition of this paper is as follows. First, our approach in studying the need identification activities is presented. Second, a theoretical frame for need identification and design is presented, i.e., Needfinding [Patnaik & Becker, 1999]. Third, the practice of finding needs is outlined and discussed.

2. The area of interest and research approach

The study presented here is part of a European Union (EU) funded project called NeedInn (stands for Needs and Innovations) [Larsson & Larsson, 2007]. A main objective for the NeedInn project is to contribute to need oriented product development processes within e-health. Those who benefits from the project are care givers, care takers and solution providers. The motivation for the project is the
recognition of the potential benefits of a need driven process. Though, methods to identify and communicate needs into products development aimed for healthcare were perceived as missing. The NeedInn project has run for 30 months. In general, background and empirical data for the study presented in this paper has been generated during the daily work of need identification activities within the NeedInn project. Observations (e.g., shadowing), participative observations and interviews have been performed. The context for the data generation has been participation in staff meetings, everyday work, scheduled focus groups and workshops. In general, principles for contextual inquiry [Holtzblatt & Jones, 1991], has been applied. In short, these are, context is important, the users are recognized as experts of their work situation and the interviewer/observer should be aware of focusing a combination of assumptions, beliefs and concerns of a particular situation [ibid.].

The form of data generated by participation in the healthcare activities is mainly qualitative, e.g., an interpretation of something in the context where it occurs. Qualitative data are aimed at producing a ‘rich’ and ‘contextual’ understanding of experiences, rather than scientifically verifiable results. The justification for such an approach is that it may provide a rich understanding of rationale in a way that would otherwise be impossible using conventional methods. This is a description of the methodology for a need-based approach; however, the focus on qualitative data is also applicable for the generation of empirical data for this study.

In particular, empirical data for this study has been generated in two workshops and in follow-up interviews with the development company, the designers and the project team leaders.

3. Needfinding

Besides looking for needs, a main principle is to make the identification of needs and design ‘seamless’, meaning that the Needfinder (e.g., a multidisciplinary team of Needfinders) is involved in both studying people and conceptualising new products [Patnaik & Becker, 1999]. Looking beyond the immediately solvable problem is suggested, since the problems which are not currently solvable can be fixed in the future. Therefore, it is useful to make the findings tangible and prescriptive. Further, the findings are better understood when supplemented with drawings, photos, audio recordings and/or video [10]. Behavioural mapping, where the Needfinder spends two or three days within a space and taking photos of people, and camera journals, where users are asked to keep visual diaries of activities are two examples of methods that generates photos of situations in which needs can be identified [Kelley, 2001]. It is recommended to go through many quick passes to study people, rather than one long effort. Doing so, design work is allowed to proceed in parallel with the Needfinding activities [Patnaik & Becker, 1999].

The principles of Needfinding are manifested in a four-stage process for studying people [ibid.]:

1. frame & prepare, involves decisions about, e.g., the scope or coverage of the project, the goal of the study and the definition of the people to be studied,
2. watch & record, include observations and documentation,
3. ask & record, include interviews, or simply asking questions, and documentation,
4. interpret & reframe activities to interpret and analyze data to identify needs, which in turn, reframe the project scope or coverage.

The importance to use a combined effort of observations and interviews is because observing people alone cannot convey everything, asking people adds information. These stages should be reframed and repeated to provide an increasing level of focus and detail [ibid.], such iterations should be series of quick iterations rather than a long effort [Kelley, 2001].

An interest in really understand the user and the constraints the user perceives, the application of a variety of techniques, the presence in a real-life situation and visualisation are basic principles for need-based approaches [ibid.].

4. A practical view
The application area for the NeedInn project is elderly care, thus studies has been performed, for instance, at elderly-care homes, home-care services, physiotherapists, general practitioners and local authorities responsible for those services. One person has been engaged as both a project leader and, initially, as the main Needfinder. After performing shadowing, observations and interviews a number of interesting need areas were found. One of these areas was expressed by the nurses in terms of a perceived problematic situation of sharing everyday information related to the care of the elderly. Therefore, to gain insight into the identified problematic situation, a focus on such information was framed in order to perform an iteration of observations and interviews.

Information about the elderly’s daily situation was written down by hand in a case sheet. This information was mainly concerning the medical state. Information that had to do with the wellbeing of the elderly, but with little medical relevance is in general not documented. Thereby, not easily available. However, this information is of substantial value particularly for the care givers, i.e., nurses, but, also for relatives. Relatives find this information important because it tells them something about the wellbeing of their elderly relative. This information cannot always be provided by the elderly themselves due to, for instance, poor memory or difficulties to communicate. The relatives become dependent on the nurses’ observations and time to tell them something about the elderly person’s day. A staff information meeting is held every day between shifts to exchange information about these issues, e.g., if a caretaker has been unusually worried during the night or if somebody is unusually talkative, thus needs special care additional to medical treatment. These staff meetings last up to one hour, time that the nurses perceive valuable to spend giving care instead. Information from these meetings was sometimes written down; these notes were found as difficult to read.

Coming back after a time off or holidays, the nurses have limited possibilities to catch up information. Further, to provide information for substitutes was found time consuming, but also difficult. This was because the nurses said that they have to rely on their memory. Some written documentation was stored in binders it was, according to the nurses, difficult to find specific information in those binders. Framed by the theme information, this iteration yielded a list of need statements:

- Everything at the same place
- Readily available and easily accessible
- Indications of new information
- Brief up to date information
- Catch-up information

Besides a need statement list, the Needfinding activities yielded identification of key persons to invite into a series of workshops. The goal for the workshops was to make a number of quick iterations to identify and refine needs and to find solutions to the identified problematic situation. In the workshops, the key persons from elderly care were nurses and management.

4.1 Workshop I

In this workshop, the information sharing problem area was in focus. The workshop mode was set to a fantasy phase, inspired by future workshops [Kensing & Madsen, 1991]. The users were encouraged to have ‘if everything is possible …’ in mind. In relation to the need area of information sharing, a documentation system evolved as a solution space. Thus, an issue which was discussed in the workshop was how information was put into and extracted from documentation systems. It was found that technological devices was used, i.e., computers. However, a previously used paper card system was also discussed.

After this workshop, a solution space became apparent and the needs became more visible. It was decided to assign a design team. Two designers were contacted by the project leader, these joined the project. Having two newcomers, it became important to set them up to speed with the insight already generated in the need identification activities. In an informal meeting, the design team discussed these issues, as well as the generated need statement list was discussed. Also, introducing the designers to the user context was utterly vital. Therefore, a second workshop was performed.

4.2 Workshop II
The workshop started by introducing the two designers for the elderly care participants. The designers were assigned the task to present the results from the earlier performed need identification activities. This was done in order to evaluate if the findings were in line with the participants view of the problematic situations. In this way, they could comment and add thoughts which had been triggered since the first workshop.

Thereafter, the second workshop was designed as a future workshop [Kensing & Madsen, 1991]. The basic principle to interact directly with people and/or users is prevalent in future workshops. That is, a future workshop should include people who will get in direct contact with the product that is going to be developed [ibid.].

A future workshop runs in three phases. First, a critique phase, to highlight specific problems about the practice, ‘as-is’. This phase generates a view of things to change. Second, a fantasy phase takes place to imagine a number of ‘to-be’ scenarios. This phase turns the result from the critique phase into positive ideas and generates preferred changes. Third, an implementation phase sorts out what changes that are feasible and realistic [ibid.]. To get the most out of the workshop a clear topic or theme is recommended. The themes were set by the project leader; they were information, documentation and dissemination. The workshop generated rich and deep data about the chosen need area, its context and perceived constraints. The critique phase, rendered in a list of need statements, this time more focused towards a technological solution:

- Not an additional device to carry around.
- Enter information vocally and/or by other input devices.
- Extract the information individually or in groups.
- A portable, mobile, discrete, small, ergonomic device.
- Compatible with clothes (pockets etc).
- High security-level – confidential information.
- An input-information-reminder.
- Snooze functionality for the input-information-reminder.

At this point, several quick iterations had been done. Firstly, iterations were done by the project leader in the initial observation and interview studies. Secondly, new iterations were done within the, so far, conducted workshops. Each iteration makes the design space converge towards possible solutions. The result from this workshop was discussed in the design team and rendered up into an idea for a solution based on verbal input. The decision for verbal input was made because it was in line with how the nurses actually did share information today. The project leader contacted a company specialized on speech technology to join the design team. Again, it became important to interact with potential users in their context. A third workshop was performed. This time the objective for the workshop was to create ideas and concepts for a product, therefore the third workshop can be referred to as a creative session.

**4.3 Workshop III**

The themes for this creative workshop were decided by the design team as verbal information, documentation and audible dissemination. The workshop started with a word association exercise. Such an exercise is fairly comfortable to perform even for people not feeling at ease with creative methods, mainly to set the participants into a creative mode. Association exercises can be done in a number of ways, but in this workshop the participants was provided with post-it notes and pens. Every participant wrote down words which they associated to information sharing, the notes was posted on a whiteboard. This generated a map conveying issues related to the topic. After this, the participants could spend two votes (i.e., colored stickers), on what they perceived was the most important issue. The chosen issue was compiled and clustered into a new topic for a brainstorming session.

The topic for the sessions was – **documentation support**. The participants were reminded of the rules, no judgment, build on the ideas of others, aim for as many ideas as possible and there are no stupid ideas. To support the brainstorming session the participants were encouraged to make sketches and write down the ideas, these were posted on the wall. The participants were told to explain their ideas to
the group when they posted it on the wall. 73 ideas came up, and these were clustered into categories. The categories were functionality, interaction, interface, dissemination, organization and artefacts. The participants were asked to make a quick and dirty screening of the categories, to find issues they thought of as essential and useful. This was discussed in terms of how they fitted into the daily work at the elderly care home. The issues to not have an additional device and that the device should fit into pockets on the work uniforms were emphasized by the participants.

4.4 A Dictaphone device

Based on the identified needs and the activities in the third workshop the concept for a Dictaphone device emerged. The contacted company could provide voice recognition software as a basis. In general, such software is usually installed on a computer or a laptop. At first, this was also the idea. However, the software was integrated into a cell phone based on the need statements ‘not an additional device to carry around’ and ‘fit into pockets’. A cell phone is part of the nurses’ daily work equipment, and had the functionality needed. At the beginning of a shift, the nurse is prompted by the software to log on to the system. This is also an identification tag for who is entering what information, as well as bringing up the relevant information. Relevant information is based on at what department the nurse will work in that shift, but also bringing up relevant information for that nurse. The latter is based on when the nurse was latest logged on. As logged on in the system, both input of new information and checking up stored information is possible. When a nurse want to input information into the system, the cell phone is picked up from the pocket and the nurse can speak directly into the phone. The information is transferred to a central server, and then indexed and stored. The Dictaphone device allows users to make verbal information input, and the software translate the input into written texts, if desired.

5. A need driven process

The task in need identification activities is to make needs visible and possible to communicate within a design team. It is our experience that need statements does not convey the need in terms of the chosen words. For example, ‘Everything at the same place’ might be, when interpreting the words literally, a solution. By putting the statement into a context needs can be discerned; nurses running into all staff rooms in an elderly home looking in binders searching for a particular document, getting more and more stressed and feeling uncomfortable with not spending time providing good care as they are trained and hired to do, ending up scribbling down information on a note. On one hand, to be manageable in a product development process, an expression has to be decided upon. On the other hand, this makes it difficult to communicate the need statements to others. Therefore, participation and interaction in either need interpretation discussions or direct interaction with users is necessary.

In common, need identification activities, as described here, is not used of product development companies, it can be discussed that a lack of understanding for methods generating data about qualities contributes to that. As a designer a weight, a size or a degree of something are important measurements to initialise problem-solving activities. However, need identification is not a problem-solving activity, rather an exploration driven by curiosity and an interest for human activities, as well as their worldviews, goals, efforts and means. An invaluable tool is questions like: Why? What? When? Who? With whom?

Paradoxically, a search for new solutions to existing problematic situations is a part of need identification activities, yet emphasising look for needs, not solutions [Patnaik & Becker, 1999]. The two activities of Needfinding, i.e. identifying needs and finding solutions, became apparent in the need identification activities in this project. One track focuses on the identifying activities and is performed in the potential users’ context, the other track focuses on finding solutions and these activities are performed away from the users’ context, see Figure 1.

Due to a focus on qualitative data, interpretation and categorization occurs along the way when doing observations and interviews. That is, a number of iterations are done during these activities in the user context. Each providing a base for decisions on the next step, as well as providing insights into new potential users and new contexts. Interpretation and categorization is done away from the user context,
i.e., when the generated material is processed and communicated within the design team. This can be done by discuss the material in relation to a context, as in the example above with ‘Everything at the same place’. The work with the generated material makes the findings clear; see Figure 1, the Finding box upper right corner.

Figure 1. An overview of the duality in Needfinding.

There is a zigzagged shaded line in the middle of Figure 1; this is representing an interface between these two kinds of activities. The Assessing box in the middle represent that need statements and need areas has to be grounded in the user context, but also communicated in a design situation away from the user context.

The principle to make the identification activities and design ‘seamless’ [Patnaik & Becker, 1999], makes it difficult to draw an exact boundary between what is done in the user context and away from it. Still, solutions have to be suppressed and not exposed in the user context until a number of iterations have been done.

Of course, there is a client for product development projects. The NeedInn project also had a client having a particular interest, i.e., e-health, which frames the need identification activities towards information and communication based products. Though, if the aim is new products, it is important to not introduce a solution or trying to solve the problematic situation until it is fully understood. If so, no difficult-to-articulate needs can be found, rather requirements which can be expressed in relation to the suggested solution. For example, in this project the speech technology company was engaged when a need area had been decided on after workshop II. In this case and due to limitations in time, one company was engaged, but it could have been possible to engage several companies which could have suggested different solutions on the same problem. In turn, such joint effort might lead to truly innovative products.

It is important to frame and reframe [Patnaik & Becker, 1999] the need identification activities until a satisfying focus for the development tasks can be decided on. In this project, these frame and reframe activities was done after each workshop. Feedback to the users and into the user context is important to keep needs in focus. After each iteration, the needs and solutions become more and more focused.
towards a product. Thus, it can be argued that it might also be a horizontal interface in Figure 1, below the Assessing box in the middle. It is also our experience that a traditional approach to product development becomes a primary process in the latter part of a project. In order to reach a need driven product development process ‘needs’ still has to be prevalent in the process. For example, trade-offs have to be based on what has been found in the need identification activities and potential users should be given opportunities to evaluate the product, e.g., in similarities to a participative design approach. Access to key persons, i.e., those who are thought of as directly affected by the potential product, is an issue which is important. Further, it is important that the person/s being observed or interviewed really feels like they are providing valuable input. The interviewer must have an honest interest in what the users are doing and being truly interested to learn something from them. The Needfinding team should not provide a solution before been engaged with the users and have gained an understanding about their situation. When you, as a skilled problem-solver, think that you have the right solution on another person’s problematic situation, it is easy to say; “this is not a problem, you just… “, and suggest a solution. Doing so spoils further identification of needs. From this point of view, it might be possible to argue that a Needfinder is a role which facilitates people, e.g., social scientists, marketing people, designers and engineers, to engage in need identification activities based on their core competencies. A need identifying facilitative role can coordinate competencies in a multidisciplinary team towards identifying and communicating needs, and not to propose solutions. This role seems to be separated from the role of a project leader, since one main task for the Needfinder is to direct communication in the team to focus on needs areas and needs statements. Traditionally, in product development ambiguity has to be minimized as early as possible. This is not the case when performing need identification activities; instead there is an intrinsic value in diversity. The objective is to increase the design space and open up for innovation opportunities. Thus, it can be argued that a need-based approach is particularly useful for innovative or new product development. But, it is also useful for improvement of existing products, since it provide insight into what improvements that are required by the users and, probing for needs gives a rationale for those requirements.

The involvement of designers and other staff from product development companies makes it possible to visualize idea concepts and needs, since the potential users become ‘alive’ and understandable in a need-based approach. Furthermore, a unified view of what to develop is likely to occur due to a collaborative effort in identifying needs and visualizing idea concepts. In design a shared view and understanding of what to develop is important. A need-based approach provides such a shared view, since all ideas, solutions, concepts etc are connected to needs. This shared view is built by interaction with potential users, thus the potential for the product to be accepted and wanted before launch might increase. In turn, reach the market faster.

6. Concluding remark

In this paper, practical activities of need identification activities - an intertwined approach to identifying needs and to visualizing idea concepts – are the focus. These have been described based on an e-health project, where a Dictaphone device has been developed. This is done to contribute to a need driven product development process. The presented methods are strongly depending on a familiarity with managing qualitative data. A need-based approach can, due to practically dealing with identifying needs and finding solutions, provide designers with insights into such methods. In the case presented in this paper, the product development process was driven by user needs, showing possibilities for implementation of a need-based approach into product development. One benefit that has been identified is that probing into needs provide a rational for requirements, i.e., those statements that users express. Another benefit of the study is indication of the role of a Needfinder as important to facilitate the communication of needs within the design team.

Need identification activities make the design team truly committed to needs and give needs high fidelity throughout the whole process. However, in our study we have experienced that need statements are difficult to express. Thus, studies on how to compile need statements into same level of abstraction has started. Further research concerning the use of creative methods in workshops, to encourage users to participate in need identification activities seems interesting.


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References


Kelley, T. *The art of innovation. Lessons in creativity from IDEO, America’s leading design firm*. (2001), Currency and Doubleday, USA.


Patton, M. Q. *Qualitative research & Evaluation methods*, 3rd edition. (2002), Sage Publications, USA.

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Making 'Santa Claus Wishes’ traceable – radiology nurses as mediators in healthcare innovation
Making “Santa Claus wishes” traceable - radiology nurses as mediators in healthcare innovation

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Abstract

In this paper we present a study of two radiology nurses who have had a key position in two different development projects. Three important aspects of our findings are highlighted: First, requirement documents are common and central in these development projects and serve as a basis for decision-making. Second, radiology nurses have the responsibility to create and write these requirement documents. This includes mediating and negotiating with stakeholders and balancing between practical, organizational, technical and political issues. Third, in the projects radiology nurses serve as mediators, project leaders, change leaders, user representatives and designers. This paper highlights the active work of radiology nurses and their mediating role. It also addresses a challenge for the design community on how to support and learn from these processes.

KEYWORDS: requirements, mediator, traceability, healthcare, radiology, design, needfinding, innovation

Introduction

Identifying needs and establishing requirements is fundamental in design and development of new technologies (Preece et al, 2002 pp. 13; Maguire, 2001). Knowledge about how this is done today is fragmented, and often more based on ideal models than on real life experiences. A deeper understanding about how requirements are “made” and formulated is much needed for the future.

In this paper we are referring to experiences from two case studies of the digitalisation of radiology. The case studies focus two radiology nurses, who had a key position in two different
design and development projects. We focus on three important aspects in these projects. First, requirement documents are common and central in these development projects. Second, requirement documents were created and written by radiology nurses with a responsibility of mapping and mediating needs and wants. Third, radiology nurses play an important and active role in these projects and serve as mediators, project leaders, change leaders, user representatives, needfinders and designers.

A requirement document in this paper is referred to as a digital document, used in dialogue with stakeholders (Krippendorff, 1998) to explain what the radiology department requires. Requirements can be both needs and wants, described in different levels of understanding and they can be both explicit and tacit. The requirement document is also a basis for decision-making in development projects that include some kind of digital system.

Making requirement documents is a complex and time-consuming activity. They are often the end result of many hours of work spent on collecting data and information, understanding, mapping, interpreting, validating and adjusting needs and wants. This work is also adjusted and updated according to current or upcoming conditions e.g. technical, practical, organizational, political and cultural circumstances. This process involves validating, negotiating and deciding which requirement to keep and to understand why. If this “negotiating activity” is not sufficiently explicit, such work might be lost in translation or even invisible. That makes the traceability unwieldy and the cause and effect for each requirement less apparent, something that is crucial to consider when decisions are being made. Requirements are often described on a very general level and thereby stakeholders can interpret them very differently. This can be problematic. The radiology nurse needs the skill of making requirements clear and traceable for stakeholders so that decisions are made and validated based on facts rather than assumptions. Traceable here means explaining the requirements in terms of what they represent, why they are needed, for which purpose, and if they relate to other requirements that must be taken into account.

The Swedish Radiology Setting

During the last decade radiology has changed from using analogue pictures (Film-Screen radiography) towards using digital imaging and patient systems such as RIS (Radiology Information System) and PACS (Picture and Archive System). This has been a challenging journey for people working within this field, especially considering their change in workflow and increased use of Information- and communication technology (ICT) (Helgeson & Toft, 2010; Duyck et al, 2008). Besides being a high technology area, using several products and systems in the front end of development, radiology in Sweden has a back office function towards other departments/clinics such as orthopaedics, surgery or primary healthcare units etc. These customers are through referrals ordering different kinds of radiological surveys/investigations where the radiological department work as a service provider with the patient associated somewhere else. In addition to the high use of technology, professionals working at the radiology department tend to be involved in different development projects more or less all the time.
Being a radiology nurse or a radiologist demands skills in using specific technical equipment that provides a wide range of diagnostic imaging services (modalities); CT scanning, MRI scanning, Radio isotope scanning, Ultrasound scanning, X ray etc. It is common for radiologists and radiology nurses to work closely together in the same department since radiology nurses produce images while radiologists review, investigate and interpret them. Besides radiology specialists, there are technicians, either employed at the radiology or medical technical department, who support the diagnostic imaging equipment and physicists who make sure that the radiation level is correct. A high use of ICT-products and an on-going development in the front-end of healthcare affects the workflow and every-day-practice of radiology. Every time an ICT-product is updated, implemented or replaced some kind of redesign of the practical work is being made to match with the already existing use of ICT, thus ensuring a high quality of care and a healthy work environment. This redesign is highly user-oriented and connected to participation, communication and interaction among people, products, services and systems (Helgeson & Toft, 2010).

Methodology

Our work is part of a research and development project that gave access to the radiology setting. The research in this paper is built upon observations (Blomberg et al. 1993) of the every-day-practice of radiology and semi-structured interviews (Preece et al 2002 pp. 394) to get an insight of different roles and design aspects in the development and implement process of two types of software systems. Case studies have been chosen as the approach because the method offers a way to focus on a single phenomenon within a real life context (Yin, 1999). We have made two case studies at different radiology departments at two hospitals in Sweden. Interviews have been made with three radiology nurses, one radiologist and two medical technical engineers. We also had access to project information, e.g. requirement documents.

There were similarities and differences between the two cases and the way the systems where planned and implemented. Instead of making a comparison and elaborate on the success factor for each of the cases we deliberately focus on highlighting the important and active work that the radiology nurses’ performed. The case studies are described for the understanding of context and data, and then analysed and discussed.

Case study 1

At this department the development project was about implementing a new RIS and at the same time upgrading the existing PACS. Since everybody involved knew that both systems were going to be integrated at some levels, one goal was to have one supplier for both systems instead of two separate ones. This was a way to prepare for upcoming problems like having one supplier blaming another supplier for lack in interoperability and to gain an easier communication and
support. The project leader picked out for this particular project was a radiology nurse who had worked with radiology for 20 years and who had previous experience of digitalization projects at another department in another town. The role was to capture and describe what they as customers and users wanted and to communicate this to the supplier via their project leader.

Before implementing the new RIS it had to be matched to a Swedish radiology setting, which included translating the text from English to Swedish. The radiology nurse spent one summer working full-time translating and testing the system with different common scenarios to see if it could support the needs of the department. In consultation with the staff and one technical expert at the department, the radiology nurse used previous experience and knowledge about the existing workflow to evaluate the system. The test result was then written down and became a first version of a requirement document. Writing this kind of document was a new work activity wherefore the radiology nurse turned to the regional healthcare organization for help and used their earlier work ‘framework for healthcare and informatics’ as a starting point. The requirement document was used in negotiating with stakeholders and included what they needed, why they needed it, independencies and comments on the status for implementation. Along with the stakeholders’ input and on-going work this document increased remarkably and resulted in many versions, one for each update. After a while the radiology nurse and the technical expert had to break it down and summarize the critical points. As the radiology nurse explained;

“We asked ourselves: What had to be fulfilled? What would be good to fulfil? What was ‘Santa Claus wishes’?” ['Santa Claus wish’ was the suppliers’/developers’ label on requirements they didn’t regard as realistic]

Based on their skill and experience in radiology, organization, technology, economy, politics, procurement and so on, the radiology nurse and technical expert made a list of prioritized requirements. Afterwards they gave the list to the management for feedback and revision and then further to the supplier. It is important to understand that this downsizing activity is not something that was done at a blink of an eye. Quite the opposite, the radiology nurse and the technical expert spent many hours discussing, negotiating and considering every aspect of each requirement. They were trying to trace the cause and effect and independences before validating, prioritizing and mediating them. During this process the radiology nurse and technical expert aimed at having a holistic worldview and kept the patient in mind while negotiating with stakeholders. The radiology nurse explained these properties as follows. “I understand what everyone does and can relate that to the big picture, someone needs to understand this, since everything is related. It is the referral and the patients’ way trough the system that matters.”

Involving users

After downsizing the requirement document the supplier continued developing the system and during the implementation phase the radiology nurse put documents on each working station for the users to write down problems and comments. Every day several A4-papers filled with notes were collected. It was the radiology nurse’s role to make sense out of these notes and to
communicate the problems to the supplier for revision and updates of the system. At the department, the radiology nurse held daily morning meetings with the staff/users to inform them about the project status. As everybody could not attend, the radiology nurse wrote and handed out meeting protocols as well.

Outcome for case study 1

In the end the project failed, meaning that the system was not used and another one was implemented. This happened due to a lack in communication regarding the fact that the system was never built to fit the Swedish setting. In Sweden, the radiology department is a service, a back-office function, and this differs from other countries. A patient in Sweden is more attached to a clinic than to a specific doctor and that changes the information flow of the system. The supplier used their existing system made for one country/setting and thought that the translation into a Swedish setting would be more of a linguistic nature rather than a cultural one. It was only when the radiology nurse had mediated the radiology department’s practical, organizational and cultural preferences via the requirement document and in dialogue with the supplier that this was understood to be a problem. According to the radiology nurse, this should have been taken into account quite early in the project, already when the mismatch between needs and solutions became clear. “They let us believe that we could get what we wanted…they should have told us that this is how the work flow of the system is built and you can’t get what you want.”

Understanding if a system is adequate for a certain setting demands knowledge about this setting, knowledge that the radiology nurse had learned and comprehended over time by working at the radiology department and in close collaboration with colleagues and people from other departments/clinics, IT, management, procurement etc. This is why the radiology nurse’s skill was so important to take into account, but perhaps much earlier to prevent problems.

Case study 2

This case study focused on a development project where the goal was to implement a new PACS and a total digitalisation of the department, including becoming a paperless working place. The project leader was a radiology nurse with 30 years experience of working in different roles at the radiology department. The radiology nurse had also earlier worked as an application specialist for a supplier and had previous experience of digitalisation of a small-scale PACS. Given the circumstances, management wanted a decision support document before deciding to actually implement PACS. In order to understand how a digitalisation would affect the upcoming work, the radiology nurse started out by describing the existing workflow. Together with a physicist, the radiology nurse made a need analysis as a part of the decision support document on what a digitalisation would mean in practice, including a cost analysis regarding staff, technology investment, new planning on existing facilities and so on. Based on the radiology nurse’s and physician’s own knowledge and experience, they planned for which qualitative and quantitative
data to collect from others and then used the collected data as a basis for the need analysis. The decision support document included pros and cons. The radiology nurse and physicist where prepared for negotiating and arguing why a digitalisation was beneficial, but as management never doubted that the department would benefit from a digitalisation it was decided that an implementation project for PACS would start right away. Looking back at the work they did the radiology nurse explain it like this “It was a heck of a job to do it (meaning the decision support document) but it is fun to see, while looking back, that we actually came pretty close in the end.”

After management had given them a clear go they started the PACS-project where many different professionals were involved. Besides experts in radiology there where people from the IT department and procurement, medical technical engineers, physicists, and experts from the supplier. In this development project, a requirement document was also used. It was the radiology nurse’s responsibility to compile the document even if it was done in close collaboration with other stakeholders like the internal project team (project leader, one physicist, two operation managers, one from each city, two from the IT department, one procurement expert and a few times also one orthopedic). Every project part wrote their own requirements and then the radiology nurse put them together. Besides representing the users in the project team, the radiology nurse was responsible for producing requirements regarding usability and workflow. This was done based on the radiology nurse’s own experience and knowledge and in dialogue with colleagues/upcoming users at the department (radiology nurses, radiologist, technical experts etc.).

Documenting workflows was one way to understand the way people at the department worked at that present time and to describe how they were supposed to work after a digitalisation. The radiology nurses had previous experience of a small-scale PACS and skill to understand both of these scenarios. That is why management gave the radiology nurse the assignment to make flowcharts even without any skill in creating them.

“They told me to make a flowchart of both an analogue and a digital radiology department and I thought to my self: flowchart? What is that? They told me that there were software products for doing that and I just said: -ok, where can I find one of these? I sat down and learned while using it and realized that it was very fun and useful. Today I tell others what we did and have lectures on how to digitize a radiology department.”

Involving users

To understand what a digitalisation would be like in practice, the radiology nurse had several meetings, both informal and formal, with the users. The radiology nurse organized afternoon meetings and split the users into small groups to discuss and work with scenarios on how this new workflow would be. To give them an understanding of what the digitalization really meant, the radiology nurse had prepared questions for the groups to discuss things like: How do you deal with this information? What is the most important thing in this situation? How do you do now? The goal was to give them an understanding of what the digitalisation really meant and to feel participant and
involved, something highly prioritized by the radiology nurse; “We made a lot of things to make the staff feel involved, since that is very important when you start such a major project.”

Outcome for case study 2

This project ended successfully, meaning that the system was implemented without any major problems. The radiology nurse has given lectures and shared her project experience with other departments to give suggestions and tips on what to think about before entering the digital world of radiology and what it means to go through a development project.

Discussion

In the early 1980s there was a shift in system design going from supporting individual tasks to focusing on collaboration and interaction among people and artefacts (Blomberg et al., 2003). This was the take-off for research areas using an ethnographical approach to design. Since then researchers have argued that “making work visible” (Suchman, 1995) or studying human behaviour from a holistic point of view is crucial when aiming for a deep understanding of what people actually do and not just say they do or how they behave instead of ought to behave (Blomberg et al., 2003). Others talk about the workarounds people do when they use radiology systems, claiming that involving users and understanding these workarounds will eliminate some of the obstacles and increase efficiency (Bramson & Bramson, 2005). Previous work has shown that the ethnographical approach explained above is a part of needfinding (Patnaik & Becker, 1999). Needfinding is an important part of the design thinking approach (Brown, 2008) in encompassing the definition of a problem or opportunity through observation (Seidel et al. 2012). A basic principle for needfinding is to interact directly with users to get an insight into the users’ domain and to understand their needs (Patniak & Becker, 2004). The task of a “needfinder” (Bergstrom et al, 2006; Ericson et al, 2007) is therefore to study a real-life practice and by using an ethnographical approach be able to answer questions like who? is doing what?, where?, when? and why?, in order to represent this practice and mediate it to different stakeholders. To be able to understand the meaning of each requirement, the radiology nurses used an ethnographical approach to be able to answer the same questions as needfinders do, having the same holistic point of view. In this sense the radiology nurses could be seen as needfinders too.

There is a transformation of the healthcare sector towards using more ICT-products, being more efficient and accessible for individuals. ICT-products used in healthcare today have increased in number compared to ten years ago but also in the amount of users and interconnection. This will change the way we design and develop supportive products. It will most certainly demand for a holistic point of view, understanding the context and on-going interactions. In other words, there are opportunities of understanding the practice and arena in which you intend to change or support with ICT. But maybe it is time to update the way it is done and by whom, according to current conditions in real life settings.
A Swedish study on the use of ICT in healthcare shows that less than a third of the healthcare staff is satisfied with their user participation in the development process and many, according to the study, are suffering from stress and tension caused by the malfunctioning of ICT systems (UserAward, 2010). The same study suggests more research on how to improve processes around requirement management, procurement, education, implementation and so on. The study also argues for the need for user representatives and patients to play a more active role in healthcare development (UserAward, 2010). All of these suggestions are of high relevance of course, but how can these improvements be accomplished?

The different roles of radiology nurses’

Our study shows that healthcare professionals like radiology nurses play a very important and active role in mediating an understanding of their practice as a basis for innovation. Besides their profession they serve as mediators, project leaders, user representatives, needfinders and designers (crafting, making, visualizing, and imagining the future). They are responsible for visualizing and making their and their colleagues work visible and they act in all of these roles while crafting the future in terms of shaping new systems.

Different stakeholders (users, management, developers, IT department, procurement etc.) involved in radiology development projects contribute with their specific knowledge and worldview to support the implementation to be useful and efficient. But they become sequentially relevant and irrelevant (Krippendorff, 1998) depending on which role they have in the project. Therefore the radiology nurse has to take on the role of a mediator to understand and relate each stakeholder’s input to the big picture. This responsibility puts the radiology nurse in a challenged position since the design work is done in collaboration with stakeholders that are not necessary pushing in the same direction (Krippendorff, 1998). On the other hand, such a responsibility can make radiology nurses feel empowered by the opportunity to actually affect the design and outcome of the system.

Given the circumstances of moving towards a digital change, the radiology nurses could be seen as change leaders as well, helping people in the organisation “… understand how the new systems can strengthen or reinforce the core values of the organization” (Bramson & Bramson, 2005). One example of this is brought up in Case Study 2 when the radiology nurse prepared questions for afternoon meetings to make users/colleagues start thinking about what a digitalization would mean in practice. The users had to discuss these questions in small groups and then report back to the whole group for mutual benefit. The purpose with this was to find out scenarios on how their future work would be carried out and to make the users feel involved. It was an opportunity to discuss challenges and benefits and to let everyone be heard.
Without any specific training in development processes or design, the radiology nurses where entrusted to make a requirement document, a fundamental part of the development process. The requirement documents were made and compiled by the radiology nurse, either as an input to the procurement process or the development process. The radiology nurses used their own understanding in complement with all the other users’ input to explain how they worked, what they needed and how they wanted to work with ICT. Such an experienced knowledge cannot be neglected when designing and implementing ICT-products because this understanding of the big picture is needed. One radiology nurse (Case study 2) highlighted the importance of having someone that understands what everyone does, relating that knowledge to the big picture. In healthcare today, the use of a single ICT-product is most likely connected to other products. This makes a holistic approach preferred over a ‘drill hole approach’ when it comes to the development of products, to ensure interoperability. Hence, it is important to have someone that can understand the holistic view and its relevance to the design and development process. Having a holistic view in healthcare development includes not only experience and skill about the specific healthcare domain like radiology, it also demands knowing how the organisation works practically and politically. Besides having the respect of the colleagues and management, both radiology nurses had several years of experience (in case study 1 over 20 years and case study 2 over 30 years) working with radiology. They knew how to “…’balance between organizational and political issues” (Kensing & Blomberg, 1998) and to negotiate with stakeholders by understanding how the radiology, and healthcare organisation in general, works. This is more than being a user representative so what exactly does such a concept really mean in healthcare practice? If government wants user representatives to be more involved in development and change maybe it is time to learn the true meaning of that concept by actually studying and understanding what is going on out there, in real life settings of today. That could give the healthcare domain input on how to make use of existing initiatives, strengthening the different roles that people have within the organisation. At the same time the design community could match such initiatives and roles in healthcare with the designers’ special knowledge to support innovation and design processes.

Negotiation and traceability

In both case studies the radiology nurses had to make the requirements understandable for other stakeholders in order to mediate them. This included explaining what they needed and wanted but also why a requirement was listed in the document and possible dependencies among them. The radiology nurses did a lot of work trying to make sense of what was required by, e.g., making flowcharts (case study 2), writing comment and independencies in the requirement document (case study 1) etc. Even so, the most important part was how they as mediators asked questions, talked and explained using spoken language. They used their ability to communicate back and forth in dialogue with other stakeholders at formal and informal meetings. In this sense, as mediators, the nurses became the only party actually seeing all the pieces of the puzzle. Something important to notice, though, is that the puzzle was seen from their point of view, which can be problematic. Suchman writes about representations and highlights the risks of using them improperly, i.e., not
being aware of the negative consequences they can have. Representations like flowcharts, requirement documents etc. can serve interests and become the absolute truth without questioning their purpose or for whose interest they are made. Using representations to “make work visible” is difficult because “…work has a tendency to disappear at a distance, such that the further removed we are from the work of others, the more simplified, often stereotyped, our view of their work becomes” (Suchman, 1995). This does not mean that all representations are useless and ineffective, rather that when using them a reflective view is needed to understand what they represent and why they are made. In Case study 1, the requirement document became too complex, resulting in the need to downsize the list of requirements and compare them.

The supplier labelled some of the requirements Santa Claus wishes. Others were referred to as has to be fulfilled or would be good to fulfil. The interesting thing about these different “status of requirement” is actually why they are labelled like this and who is best suited to put labels on the requirements? Can a supplier call a requirement a Santa Claus wish? The answer is simple. Yes, they can, because in their world some of the requirements seemed to be wishes with a low chance of being fulfilled. The problem occurs when there is a mismatch between the supplier’s definition and other stakeholders’ view. Without understanding the meaning and value of the different status of requirements, it is not possible to choose which one to keep or not. That is why every requirement must be traceable, i.e., explained in terms of what they represent, why they are needed, for which purpose, and if they relate to other requirements that must be considered. The party best suited for this task must be the one having the overall picture. In our case study this was the radiology nurse.
Conclusions

In this paper we have addressed three issues central for further research and improvement for healthcare development in Sweden: First: how are requirement documents actually produced and used in development processes? Second: who are the actors in the requirement management process? Third: how is this process relevant for design and innovation?

The case studies show that radiology nurses play an important role in healthcare innovation. First of all they are responsible for creating and writing requirement documents. This includes mediating and negotiating with other stakeholders and balancing between practical, organizational, technical and political issues that has to be taken into account. Second, radiology nurses shift in and out of different roles such as mediators, project leaders, user representatives, needfinders and designers.

Healthcare is a domain with a lot of potential for innovation. The design discipline can contribute to that process in different ways. As designers we are trained in understanding the practice and context in which we intend to change and we also have the skill of suggesting possible solutions. We are used to having a mediating role, working closely together with users and developers in understanding, visualising and imagining the future. The important work of radiology nurses explained in this paper shows how healthcare professionals are a part of what could be classified as designers “territory”. Without any specific training in design or development processes, the radiology nurses were entrusted to identify needs and establish requirements, which is fundamental in design and development of new technologies.

The challenge we want to address is how the design community can find a way to match the role that radiology nurses had in the projects, a role essential to design. Is it time to update the way design work is done and by whom according to current conditions. A way to start that process would be to pay more attention and learn from the crucial role that radiology nurses or other healthcare professionals have as change leaders and needfinders in healthcare innovation.

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References


UsersAward. (2010). *Vård-IT-kartan,* Sweden

PAPER D

Tailoring the Software Product Management Framework for Use in a Healthcare Organization: Case Study
Tailoring the Software Product Management Framework for Use in a Healthcare Organization: Case Study

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Abstract. Many reference models were developed for software process improvement. Each model, however, is an idealized prescription that is applicable in a limited set of situation only. This paper has investigated how an existing reference model can be tailored to a domain it has not been designed for initially. The tailoring approach is based on translating the reference model to the new domain and on inductive interviews for evaluating the translated model. The approach has been applied for assessing and improving strategic requirements engineering practice in a healthcare organization with a framework for software product management.

Keywords: reference model tailoring, inductive process improvement.

1 Introduction

A plethora of reference models have been developed for improving processes and capabilities. Models such as the CMMI [1] and ITIL [2] prescribe broad sets of best practices and have been successfully used for all-over-the board process improvement in software organizations. Lightweight models such as the software product management (SPM) framework [3] and the improvement framework for lightweight assessment and improvement planning ifLAP [4] focus on specialized processes and roles and were successfully used in practice for focused and cost-efficient process improvements.

Any model, however, abstracts and represents only a fraction of the phenomena that can be observed in reality, usually those that were perceived relevant for the creation of the specific model [5]. As a consequence, reference models and the processes and capabilities they encourage represent idealized guidelines for selected domains. Many situations are inconsistent with the assumptions behind these ideals, however. For example, the focus of CMMI on software development, rather than software use for service provision gave rise to the creation ITIL. Similarly, the strategic requirements engineering activities needed by product managers for planning software products gave rise to the SPM framework because CMMI was not specific enough to support these concerns.

Process improvement situations that are insufficiently supported by existing frameworks encourage researchers and experts to create new reference models. This
increases the number of standards that need to be known, selected, and applied in practice. Reference model tailoring represents an alternative to the creation of new models. Tailoring involves the interpretation and translation of an existing framework to a new context, which has been insufficiently supported previously. The resulting increased applicability of the existing frameworks limits the growth of the number of frameworks and improves the understanding of their validity.

This paper describes a case of tailoring an existing reference model to a new domain. It describes a simple two-step approach for translating the reference model and for evaluating the translation. As a result, existing process improvement knowledge can be transferred instead of being reinvented. The results contribute to a consolidation of software process improvement frameworks and enable the use of new domains to validate process knowledge.

The remainder of the paper is structured as follows. Section 2 describes related work. Section 3 describes the research methodology. Section 4 describes the translation results and section 5 the evaluation results of the reference model tailoring approach. Section 6 discusses the results. Section 7 concludes.

2 Related Work

Process knowledge is applied to so many different situations that no single model is able to capture all variability. Software process tailoring has been coined as a term to describe the adaptation of “off-the-shelf” software processes to meet the needs of a specific organization [6]. To enable such tailoring, situational factors have found their way into process improvement frameworks to account for an organization’s specific process improvement ambitions and for domain specialties [7, 8]. Companies can choose their desired level of maturity and omit practices and capabilities that they perceive excessive [1].

Variability exists also within an organization. Projects and organizational units are required to tailor idealized processes to make them practicable, efficient, and effective [9, 10]. Tailoring strategies include dropping, downsizing, adding, expanding, and refinement actions applied on resources, communication, decision-making, documentation, knowledge, and technology. Analysis of the gap between the planned process model and the process enactment allows steering and managing process tailoring and improvement [11]. Enactment of tailored processes results in real-world experimentation with results that enable learning in the organization [12].

For situations, where no process knowledge is available, inductive process improvement approaches have been proposed [13]. In a bottom-up fashion, critical issues are identified and solutions sought for addressing these issues [14]. When based on appropriate sampling of projects, roles, and practitioners the organization’s knowledge can be externalized and effective improvement results obtained [4]. The results of inductive improvements capture process knowledge that can be made available to the software industry, for example by building new or updated frameworks.

Many situations with no process knowledge available are still so similar to domains with existing reference models so that inductive creation of a new reference
model is ineffective. The organizational learning process would require too much effort and the results would be applicable to the concerned organization only. In these situations, more effective is the tailoring of an existing reference model and transfer the process knowledge it captures. Such tailoring provides the additional opportunity of understanding how domains relate to each other and of extending the validation of existing process knowledge.

3 Research Method

Our work aimed at understanding how to transfer an existing reference model from a known assessment domain to a new such domain while being confident that the weak points of the assessed processes are found and the most valuable changes identified. The here presented case study [15] was part of an improvement initiative in a Swedish health-care organization that uses IT solutions and embedded systems such as medical devices that it procured in a regulated market [16]. The effort aimed at improving strategic requirements engineering in the organization.

Due to the similarities of software product management [17] with the strategic requirements engineering needs in the healthcare organization, we selected the SPM framework as a basis for process assessment and improvement. In a two-step process, we tailored the reference model to the healthcare domain and evaluated the tailored version with inductive questions that we integrated into the practitioner interviews. The interviews were analyzed with content analysis [18] to identify correspondences and misalignments of the assessment framework. The results are two-fold. On a method engineering level, they show how to translate and evaluate an existing assessment framework into a new, initially unforeseen domain. On a method application level, they show how to assess strategic requirements engineering of a healthcare organization with the software product management framework.

To evaluate the fitness of the tailored SPM framework for strategic requirements engineering in a healthcare organization (SRE@HC) we posed the following initial research question. RQ1: What are the correspondences between the SPM framework and SRE@HC? The identified correspondences were used to build the SRE@HC framework that we evaluated with the following research question. RQ2: What is the congruence of the SRE@HC framework with the SRE@HC domain?

The research was performed in collaboration with one of the county councils in Sweden. It served a population of 150’000 people with one hospital and multiple primary care centers. The hospital was divided according to medical specialties and services, including orthopedics, pediatrics, radiology, and operating room departments. The county council was supported by an organization that included IT, procurement, and estate departments. The support organization ensures compliance with regulations such as WTO GPA. On top of the administration, a political organization took overall responsibility for healthcare delivery. Fig. 2 (right-hand side) gives an overview of the county council and its constituents. The county council is representative for other public-sector healthcare organizations, except that it does not include medical research departments that can be found at university hospitals.
The research was performed as a two-step process. Step 1 answered RQ1 by tailoring the SPM framework into the SRE@HC framework. Step 2 answered RQ2 by evaluating the application of the SRE@HC framework in the healthcare organization. Fig. 1 gives an overview.

**Fig. 1.** Research process (grey: previous work, black: step 1, white: step 2)

Step 1: RQ1 was answered by first identifying correspondences between the SPM framework and strategic requirements engineering in the healthcare organization and then validating the resulting assessment instrument with an expert responsible for strategic requirements engineering in our partner organization. The requirements engineering and healthcare experience of the authors enabled the first step. Correspondences were identified for organizational roles, activities, and artifacts. As a result of this mapping, a tailored questionnaire for SRE@HC assessment was created, which was reviewed internally in the research team as an offline evaluation that did not involve any outside experts [19]. The expert from the county council performed a practitioner evaluation by reviewing the questionnaire.

Step 2: RQ2 was answered by evaluating the SRE@HC instrument in real process improvement. 14 interviews were performed that lasted approximately one hour each. Questions about compliance with SRE@HC practices were used to identify the maturity of the organization from the perspectives of the interviewees. Questions about the rationales for compliance and non-compliance with SRE@HC practices and open-ended questions about total improvement potential were used to collect evidence about congruence of the SRE@HC framework with the SRE@HC domain. This evidence was analyzed by directed content analysis to identify agreements, disagreements, and omissions of the SRE@HC framework with respect to the SRE@HC domain.

Flexible research is confronted with the following threats to validity: reactivity, respondent bias, researcher bias, reliability, and generalizability [20].

*Reactivity* refers to the way in which the researcher’s presence alters the behavior of the subjects involved in the research. One of the researchers had established trusted relationships with many of the interviewed practitioners in the healthcare organization during multiple years that preceded this research. The trusting relationship and the
inside-out knowledge of the organization reduced the likelihood of receiving biased information. The researchers without personal relationship assured neutrality of the research.

Respondent bias refers to the risks of obtaining answers that respondents judge are those the researchers want and of having information withheld that can be used against the respondents. This threat was the most critical threat in the presented research as the respondent’s organizational units and activities were assessed. Risk-limiting was that all respondents perceived strategic requirements engineering to be a key area to improve and that they benefitted from the improvements launched on the basis of the obtained results. In addition, the results were triangulated between the individually interviewed subjects and member checking used with the responsible for strategic requirements engineering at the organization.

Researcher bias refers to the preconceptions and assumptions the researchers into a study. We used observer triangulation and an audit trail to address this threat to validity. Each interview was performed by two researchers. Also the analysis of the interview results was performed jointly. A record of the data collection and data analysis activities was kept during the study.

Reliability refers to how carefully the research was performed and how honestly the results were presented. Reliability was achieved by following the above-described research design, and by verifying the results with member checking. In addition, a chain of evidence was maintained.

Generalizability refers to how far the obtained results are applicable and valid both within the studied setting and beyond. For internal generalizability, we used a combination of purposive and stratified sampling. Interview partners were selected to cover the organizational units and roles needed for the assessment as well as possible. The responsible for strategic requirements engineering at the partner organization acted as a gate-keeper in the interview partner selection. All selected interview partners participated in the study. Concerning external generalizability, we used convenience sampling in the selection of the partnering county council. This decision reduced the reactivity threats of the study, but implied that the results are only generalizable to those parts of a healthcare organization that exclude research hospitals.

4 Step 1: Translation of the SPM Framework

The scope and structure of the SPM reference model are well described by its design decisions and creation process [3, 21, 22]. Product management was thought to interact with external stakeholders such as customers and supplying partners and with internal stakeholders such as a company board and various company functions. Professional software product management was interpreted as a matter of well-organized information collection, analysis, and decision-making about to the development and release of a portfolio, products, releases, and requirements for the market.

Strategic requirements engineering in the studied healthcare organization was strikingly similar. The hospital and primary care centers interacted with patients as customers and the support organization as a supplying partner. The support organization
did the same by considering the hospital and primary care centers as customers and by facilitating procurements from external suppliers. Decisions were made about the organization’s portfolio, about services to be developed and assets to be procured, about projects to be performed for evolving services and assets, and about needs for investments.

Despite the similarities, many differences between software product management and strategic requirements engineering in the healthcare organization existed. They concerned the organization of supplies and services, the assignment of activities to roles, the approach to decision-making, and the concepts and terms used to refer to the entities that are managed. In comparison to a software product company, the healthcare organization was not only embedded in an external supply chain, but had in addition an internal supply between the healthcare core units (a hospital and primary care centers) and the support units (IT, medical technologies, and procurement among others). Fig. 2 gives an overview of the two types of organizations. To serve patients, each service delivering unit managed its own portfolio of services. The service units delivered equipment to the healthcare units. The units had shared decision-making for investments that were needed for maintaining and enhancing the service and equipment portfolios.

In the healthcare organization the SPM product management role was split and distributed over multiple roles. The medical director was responsible for the portfolio of services offered to patients. He delegated this responsibility to heads of department and heads of ward for each specialty in the hospital, such as orthopedics, and to the heads of the primary care centers. Each such head was then also responsible for managing the lifecycle of the equipment required to deliver healthcare services. Project leadership, for example for business process improvement projects, did not exist on the healthcare side and were delegated to the support units. Needs for investment were collected and specified by deputy managers.

The support organization was responsible for the assets needed to perform the healthcare services. The head of IT was responsible for the software solutions, and the head of medical technologies for equipment such as operations robots and radiology labs. For managing the portfolio and the investments they collaborated closely with the chief financial officers. Responsible for specific assets and investments for improving or replacing them were the IT architect, the head of support services for

![Fig. 2. Structures of a software product organization (left) and of a healthcare organization (right). The hospital and primary care centers represent the healthcare core business.](image-url)
healthcare equipment, and the head of procurements. Project managers performed procurement and system integration projects and managed the requirements.

The organizational differences implied that the SPM roles needed to be translated into the healthcare context. The translations affected the wording used in the SRE@HC assessment questionnaires and the roles that were interviewed. Table 1 gives an overview of these translations that accounted for the differences observed above. 4 of total 13 roles could be transferred without adaptation.

<table>
<thead>
<tr>
<th>SPM</th>
<th>Healthcare</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market</td>
<td>Population</td>
<td>HC core units</td>
</tr>
<tr>
<td>Customer</td>
<td>Patient</td>
<td>HC core unit</td>
</tr>
<tr>
<td>Prospect</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Partner</td>
<td>Other health care organizations</td>
<td>Supplier</td>
</tr>
<tr>
<td>Partner network</td>
<td>Association of county councils</td>
<td>Domain specific groups of interests</td>
</tr>
<tr>
<td>Competitor</td>
<td>Alternative</td>
<td>-</td>
</tr>
<tr>
<td>Company board</td>
<td>Investment council</td>
<td>Investment council</td>
</tr>
<tr>
<td>Development</td>
<td>Healthcare services and support units</td>
<td>Suppliers</td>
</tr>
<tr>
<td>Market research party</td>
<td>Regulator</td>
<td>Regulator</td>
</tr>
</tbody>
</table>

The differences between the software product, healthcare, and support domains implied also that SPM concepts needed to be translated. The translations again affected the wording necessary to make the SRE@HC assessment questionnaires understood by the interviewees. Table 2 gives an overview. 12 of total 23 concepts could be transferred without adaptation.

<table>
<thead>
<tr>
<th>SPM</th>
<th>Healthcare</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product line</td>
<td>Assets of same supplier</td>
<td>Assets of same supplier</td>
</tr>
<tr>
<td>Product</td>
<td>Service (type of operation, treatment, etc.)</td>
<td>Asset, Equipment, Solution, Investment</td>
</tr>
<tr>
<td>Component</td>
<td>Asset, Equipment, Solution, Investment</td>
<td>Parts</td>
</tr>
<tr>
<td>Roadmap</td>
<td>Plan</td>
<td>Plan</td>
</tr>
<tr>
<td>Release</td>
<td>Project results (new service)</td>
<td>Project results</td>
</tr>
<tr>
<td>Release definition</td>
<td>Specification</td>
<td>Specification</td>
</tr>
<tr>
<td>Requirements</td>
<td>Needs (pre-project), requirements</td>
<td>Needs (pre-project), requirements</td>
</tr>
<tr>
<td>Partnering &amp; contracting</td>
<td>Provision of access to services</td>
<td>Provision of access to assets</td>
</tr>
<tr>
<td>SLA</td>
<td>Quality guarantees</td>
<td>SLA</td>
</tr>
<tr>
<td>Pricing model</td>
<td>Pricing model (only dentistry)</td>
<td>-</td>
</tr>
<tr>
<td>Revenue</td>
<td>Revenue (only dentistry), Re-investment</td>
<td>Investment</td>
</tr>
<tr>
<td>Engineering capacity</td>
<td>Budget</td>
<td>Budget</td>
</tr>
</tbody>
</table>
The translated SRE@HC framework for assessing a healthcare organization was structured, packaged, and used alike the software product management framework.

5 Step 2: Evaluation of the SRE@HC Framework

Fig. 3 shows the maturity profile of the county council that was assessed with the translated framework. Each block represents a focus area with capabilities that are ordered from left to right according to increasing maturity. The portfolio focus areas were population/HC core unit analysis, lifecycle management, and access provision from left to right. The service and asset focus areas were intelligence, service/asset planning, and equipment/component planning. The project focus areas were requirements prioritization, specification, specification validation, change management, project result validation, and launch. The need focus areas were need gathering, requirements identification, and requirements organizing.

<table>
<thead>
<tr>
<th>Healthcare</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portfolio</td>
<td>Medical Director</td>
</tr>
<tr>
<td></td>
<td>Head of Hospital Dept.</td>
</tr>
<tr>
<td></td>
<td>Head of Prim. Care Center</td>
</tr>
<tr>
<td>Service / Asset</td>
<td>Head of Ward</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Project</td>
<td>-</td>
</tr>
<tr>
<td>Requirements</td>
<td>Deputy Head of Ward</td>
</tr>
</tbody>
</table>

Fig. 3. SRE@HC maturity profile of the county council (green/light colored: capability implemented, red/dark colored: capability not implemented).

The assessment of the capabilities was based on the translated roles and concepts. The capabilities suggested by the translated reference model were understandable for the interviewees, with the following exceptions.

Portfolio: The interviewees stated that they are in a controlled market that does not allow competition to the county council within the county. They acknowledged, however, that private organizations started to provide primary care and that county councils compete across the counties. All units except parts of dentistry could not specify pricing for their services. Their compensation was determined by a re-investment formula. The healthcare organization tried to achieve synergies across services and assets, but not with product lines. Instead they were interested of using product families from the same supplier. The first two exceptions were due to regulations of the healthcare sector. The third exception was due to the use instead of development of assets.
Service / Asset: The respondents stated that the make or buy decision was always a buy decision. The healthcare service units obtained assets from the support units, the support units procured them from external suppliers. The delegation to the service units was the key rationale for the organizational split of service and service units. The external procurement was due to political regulations.

Project: The healthcare service units performed only operations and delegated the projects to the support units. Revenue consideration was again not as important because of the re-investment funding approach. Instead, cost savings were important. This exception was due to the culture of the organization.

Requirements: All capabilities were understandable.

The answers to the inductive questions about improvement potential partially overlapped with the reference model. Fig. 4 gives an overview of the elicited challenges together with causes and consequences.

Fig. 4. Improvement potential based on induction: challenges, causes, and consequences

Congruent were the following findings. The organization had not defined any business analyst role. The observed lack of this role is congruent with the reference model that expects stakeholder needs to be collected and transformed into well-communicated and managed requirements. Organizational units were decoupled from decision-making. Such observed lack of integration integration is congruent with the reference model that expects stakeholder consultation. The organization requested transparency of decision-making. Again such transparency was also foreseen in the reference model, as part of requirement lifecycle management, prioritization methodology, and communication of plans.

The reference model was missing several improvements that were perceived critical by the interviewees. The interviewees requested a decision-making process that defines how the many parties should collaborate. The SPM activities that were assumed to be coordinated by a single product manager had to be translated into a concerted collaboration of managers for strategic requirements engineering and investment decision-making. Also, the interviewees requested impact evaluation of the investment decisions and the consequent project results. The reference model only
requested functional validation and certification. Finally, the organization looked for ways of improving prioritization of investment needs. The reference model foresees such prioritization only for services and assets, but not in sufficient depth for the whole portfolio. Such portfolio decisions would have been important for matching budget with investment needs.

A problem area that was completely excluded by the reference model was the difficulty of regulated procurements. The reference model did not suggest any practice for how requirements should be specified for such procurement and for how to reduce lead time.

Some of the expected capabilities of the reference model were not adequate. The reference model had too high expectations on the handling of intellectual property. None of the interviewees perceived such a practice to be critical. The reference model recommended collaboration with supplying partners. Such collaboration is prohibited by procurement regulations for fairness reasons.

The assessment based on the SRE@HC framework and the inductive improvement potential questions was effective. The healthcare organization perceived the assessment results to be credible and initiated improvement actions. Positions for business analysts were created and a first position already publicly announced. Organization-wide process definition was launched to improve collaboration across organizational units for investment decision-making. A tooling project was launched for tracking needs and requirements, for increasing transparency of decision-making, and for identifying bottlenecks that lead to long procurement lead times.

6 Discussion

The presented case has shown that it is possible to transfer existing reference models to a domain that was not foreseen by the authors of the original model initially. The tailoring is a kind of situational adaptation [8] for transferring knowledge from one domain to another: here from software product management to strategic requirements engineering in healthcare. Understanding of how to transfer reference models extends the ability of process improvement professionals to take advantage of existing knowledge. It discourages the reinvention of yet another reference model each time a new process improvement problem is encountered and encourages consolidation of existing models instead.

The case showed that the tailoring can be performed with two simple steps: translation and evaluation of the reference model. Translation was needed to adapt the reference model to the changed organizational structure, and the roles and concepts of the new domain. Expertise in the target domains, here requirements engineering and healthcare, enabled such translation. Comparison of framework-based assessment results with inductive questions about improvement potential enabled the evaluation of the translated framework. Capability requirements that were congruent with capability needs confirmed adequacy of the reference model. Concepts that are difficult to
understand, unnecessary capability requirements, and missed improvement needs indicated needs for further tailoring of the translated reference model.

The case represents a single transfer of a reference model into a new domain. Replication of such work is needed to better understand how existing results can be effectively diffused, how evaluation results can be integrated into original models, and when the benefits outweigh the cost in comparison to invention of a new reference model.

7 Summary and Conclusions

Many process improvement domains benefit from knowledge embedded in reference models that were designed for other domains. The paper has presented a two-step process for tailoring an existing reference model to such a new domain. The process is based on translating organizational structure, roles, and concepts and on inductive validation of the prescriptions that the reference model contains.

The process has been applied for transferring best practice from software product management to strategic requirements engineering in a healthcare organization. Application of the process in the case study showed feasibility and effectiveness of the tailoring. The evaluation results showed that important process assessment needs were congruent with the structure and scope of the initial model and that the missed improvement issues could be captured with lightweight inductive questioning.

The results are a rich, empirically grounded basis for improving strategic requirements engineering also in other organizations and for transferring the knowledge captured in the software product management reference model to even other domains. Such work should be the focus of future research.

References