University of Bergen

Master Thesis

A Self-Reporting Tool to Reduce the Occurrence of Postoperative Adverse Events After Total Hip Arthroplasty

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Abstract

This thesis presents a research that has designed and evaluated a high-fidelity smartphone prototype, called SafeTHA. SafeTHA has been designed for patients to reduce the occurrence of postoperative adverse events after total hip arthroplasty (THA). A User-Centered Design approach was utilized to facilitate an optimal user experience and to emphasize the end-user. The prototype has two main functionalities. Firstly, it enables patients to self-report their current state through answering five simple questions from evidence-based practices regarding pain, anxiety, mobility, progress, and quality of recovery. Secondly, it informs the user about several aspects of rehabilitation such as pain, known risk factors, wound management, and recommended activity level.

The use of mobile technology could enable timely self-reporting and collection of subjective patient data out of a hospital setting. The low-, and mid-fidelity prototypes were assessed by experts of Interaction Design, Medical Informatics, Biomedical Engineering, and healthcare professionals with respect to interaction flow, information content, and self-reporting functionalities. They found it to be practical, intuitive, sufficient and simple for users. The high-fidelity prototype was evaluated by medical experts and usability experts through the rigorous methods, System Usability Scale (SUS) and Heuristic Evaluation (HE).

The results indicate that patient self-reporting could help recognize safety issues, adverse events, and empower patients postoperatively. Additional testing in a clinical setting is needed to fully demonstrate its usefulness.

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Chapter 1

Introduction

The occurrence of adverse events creates a lot of unwanted costs and distress for society. In Norway, from 2011 to 2015, 16 838 compensation claims were filed related to this matter. 5308 people received reimbursement, which lead to 3,4 billion NOK in compensation costs. In addition to these costs comes patient suffering and absence from work as well as diminished life quality. The leading field regarding adverse events in Norway was Orthopaedics with 37% complaints nationwide (Ferguson & NTB, 2016).

Currently, there are no known mobile applications that can help us prevent this problem concerning the field of Orthopaedics. Therefore, a self-reporting mobile application for patients that underwent total hip arthroplasty has been designed. The main motivation behind this tool is to improve patient safety and well-being, lower the likelihood of adverse events, and reduce costs for society. Furthermore, the tool also gives the patient information relating to the rehabilitation process. Patient empowerment is an important advantage since the average number of hospital discharges have gone up, and therefore shortening days spent in the hospital for the patient (Eurostat, 2015). The tool is a segment of a future planned safety reporting platform which involves learning and decision-support (Krumsvik & Babic, 2017).

1.1 User Groups

The primary user group for this application is patients. They will report their state throughout a postoperative period of 30 days with the help of SafeTHA. The reporting emphasizes patient's well-being by capturing data such as pain level, anxiety, mobility, progress, and quality of recovery.

The second group are physicians, however they will not use the application itself. They will assess the data that is being reported from the patients. After the patient has filled in data on a given day, a report will be generated and sent to the physician ready for further assessment of the patients' self-reported data.

1.2 Research Questions

This research will attempt to answer the following questions:

RQ1: Is it possible to design a self-reporting tool that can support and empower patients after total hip arthroplasty?

RQ2: Can the safety risks after total hip arthroplasty be reduced through patient involvement according to health professionals?

RQ3: Can the User-Centered Design approach and Human-Computer Interaction principles be utilized to design tools that are used in a healthcare context?

1.3 Outline

The following is an outline of the thesis.

Chapter 2: Literature Review presents the literature and related work relevant to the research.

Chapter 3: Methods and Methodologies introduces the research framework, *design science*, data gathering methods, development methodologies, prototyping, evaluation methods, and research ethics.

Chapter 4: Requirements explains the different requirements of SafeTHA application.

Chapter 5: Prototype Development presents the design iterations that were carried out to create the artefact.

Chapter 6: Evaluation encapsulates the results from the summative evaluation.

Chapter 7: Discussion examines the different methods and methodologies, prototype, as well as answering the research questions.

Chapter 8: Conclusion and Future Work summarizes the research findings and gives propositions for the further development.

Chapter 2

Literature Review

This chapter will present theoretical topics that were relevant for the research: total hip arthroplasty, adverse events, patient safety reporting systems, patient empowerment, and Human-Computer Interaction. A set of tools that enable self-reporting will be mentioned, as well.

2.1 Total Hip Arthroplasty

Total Hip Arthroplasty (THA), or total hip replacement, is one of the most successful orthopaedic procedures that are carried out presently. THA can relieve pain, restore mobility, and improve quality of life for patients with hip pain due to different conditions. The first hip prosthesis was designed by the British orthopaedic surgeon, Sir John Charnley in the mid to late 1960s (Erens, Thornhill, & Katz, 2016). Figure 2.1 shows an x-ray of a patient that has underwent THA.

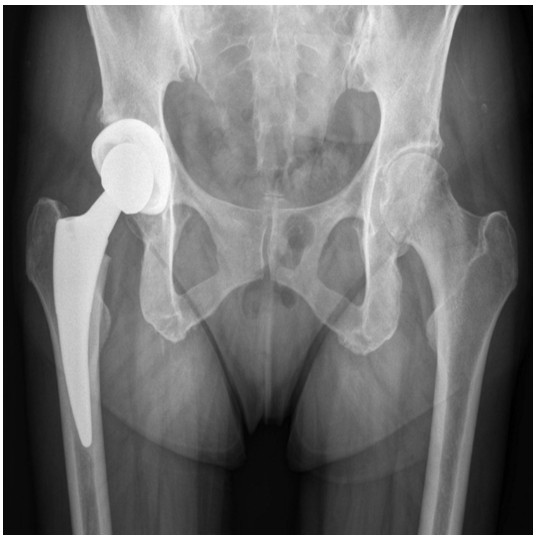

Figure 2.1: Patient that has underwent THA (Gustke, 2012, p. 50).

The normal hip operates as a "ball-and-socket" joint. The femoral head (ball) conveys with the acetabulum (socket), enabling a flowing range of motion in multiple planes. Any condition that affects either of the aforementioned can lead to deterioration of the joint. This can lead to abnormality, pain, and loss of function. Osteoarthritis is the most common condition that affects the hip in this way (Erens et al., 2016).

THA is a surgery where synthetic materials supersede diseased articular surfaces, thereby relieving pain and improving joint kinematics and function (Erens et al., 2016). Figure 2.2 illustrates the different components of a hip prosthesis.

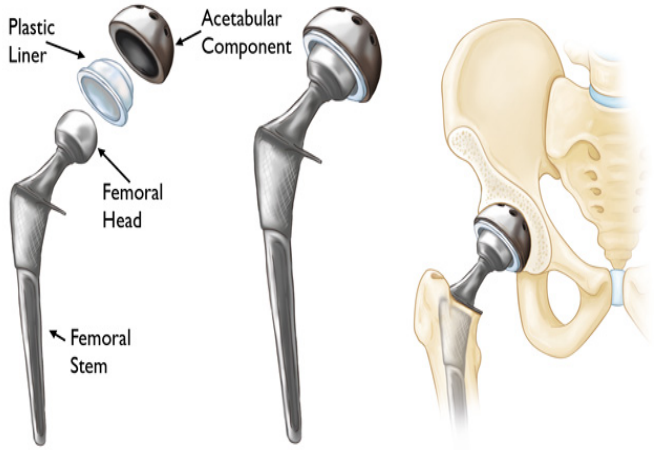

Figure 2.2: Hip prosthesis (Foran, 2015, para. 20).

THA has been performed with success at all ages, from teenagers with juvenile arthritis to elderly patients with degenerative arthritis (Foran, 2015). Moreover,

the age distribution of patients aged 45 and over receiving THA in recent years, have changed significantly. It is increasing for younger age groups and decreasing for older age groups. Furthermore, the number of THA is expected to increase in the coming decades (Wolford, Palso, & Bercovitz, 2015).

2.1.1 Postoperative Complications

Complications after THA include:

- Infection
- Dislocation
- Osteolysis and wear
- Asceptic loosening
- Periprosthetic fracture
- Implant failure or fracture
- Leg length discrepancy
- Heterotopic ossification
- Thromboembolic disease
- Sequelae from metal-on-metal wear debris

Other complications that can occur with any major surgery, such as those associated to anaesthesia, blood loss, or transfusion reactions may also develop postoperatively (Erens et al., 2016).

2.1.2 Total Hip Arthroplasty in Norway

In 2015, there were in total 9794 hip replacement surgeries in Norway. 85.8% were primary operations, 0.2% re-operations without prosthesis removal or replacement, and 14% revisions. In addition, there were 136 primary hemiprosthesis not caused by hip fractures (NRL, 2016).

According to the Norwegian Arthroplasty Register, at least 95% of all operations are reported to the registry. The Norwegian Arthroplasty Register was established in 1987 by the Department of Orthopaedic Surgery in Bergen (NRL, 2016).

2.2 Adverse Events

> "Adverse event: An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable" (WHO World Alliance for Patient Safety, 2005, p. 8).

The WHO strongly recommends that both health-care organizations or individuals report these types of incidents. If a given event occurs, there is an opportunity to generalize the problem, and therefore the possibility for generalizable solutions can be used in the future (WHO World Alliance for Patient Safety, 2005). The post-operative mortality rate after total hip arthroplasty, with estimates citing a 30-day rate, is less than 1% (Erens et al., 2016).

2.2.1 Medical Devices

Currently, there are some databases that are publicly accessible and offer information about e.g. orthopaedic implants. These play a vital role in adverse event prevention.

MAUDE (Manufacturer and User Facility Device Experience) is a database that houses medical device reports submitted to the FDA in USA (Food and Drug Administration) by mandatory reporters. These are manufacturers, importers, and device user facilities, as well as voluntary reporters such as healthcare, professionals, patients, and consumers (FDA, 2016, para. 12).

Each year, the FDA receives over 100 000 medical device reports of suspected device-associated deaths, serious injuries and defects. The FDA uses medical device reports to monitor product performance, identify potential device-related safety issues, and to be a factor in benefit-risk assessments of these products (FDA, 2016).

In the UK, safety reporting for clinical investigations of medical devices should be reported to the MHRA (Medicines and Healthcare products Regulatory Agency): "All serious adverse events, whether initially considered to be device related or not, involving a device under clinical investigation coming within the scope of the Medical Devices Directive and undergoing clinical investigation" (NHS, 2016, para. 13).

The Norwegian Directorate of Health is the regulatory agency for medical de-

vices in Norway. If errors, damages, adverse events, and failure related to medical devices occur, together with corrections, changes to labelling or instructions this shall be reported to the Directorate. Norwegian producers of medical devices and Norwegian responsible representatives shall submit medical devices in the register (Helsedirektoratet, 2017).

2.2.2 Orthopaedics and Adverse Events in Norway

There is a need for an application with emphasis on adverse events in orthopaedics. A report concerning the matter from 2012 substantiates this claim, as orthopaedics topped the statistics (Gotteberg, Pedersen, & Pettersen, 2013). The reported problems were mainly about inexperienced physicians that treated fractures for outpatients. The report by Gotteberg et al. (2013) also claimed that the communication between doctors in training and physicians were inadequate, since many patients did not experience proper safety and quality of service. Correct expertise, as well as early diagnostics can prevent unnecessary adverse events.

In 2012 a woman fractured her wrist, and after a consultation with healthcare she felt that something was wrong, but no one listened to her. This resulted with her not returning to her original profession, due to permanent wrist complications (Gotteberg et al., 2013). Such cases show that serious issues needs to be addressed within healthcare; informing health personnel as well as patients should be done when appropriate.

Postoperative care is very important in regards to orthopaedic surgery. A patient that was treated for a leg fracture, underwent surgery with no complications. However, when the patient had his check-up three months post surgery, x-rays revealed that the leg was not healing properly due to an infection. The infection lead to the patient being permanently disabled by 30% and also dependant on crutches (Hjort, 2011). Furthermore, Hjort (2000) states that this is a rather common and difficult problem: Orthopaedic surgery on bones and joints get easily infected, especially when using extraneous materials like prostheses and screws. To prevent adverse events, information needs to be accessible for all parties involved, especially the patients.

2.2.3 Victims

Holistically, there are four *victims* that are affected by adverse events, according to (Hjort, 2011):

- Patients: the first victim, and the consequences can affect both body and mind. Bodily implications may vary, for instance from a light wound infection, to more catastrophic repercussions like invalidity or death. The psychological consequences differ as well. From light disappointment to lifelong bitterness and despair.
- Physicians: the second victim. They are used to succeed and are often unprepared when they experience an adverse event. In some cases the physician rejects all criticism, but it is likely more common to react with guilt and despair. Sometimes the situation might worsen because of lacking support from colleagues and superiors.
- Relatives: the third victim. They often share the same psychological reactions as the patient. Many experience that their questions remain unanswered. For example, a male that lost his wife during anaesthesia said: "I don't want money. I want a peace of mind".
- Healthcare: the fourth victim. Adverse events drains scarce resources, create frustration and weakens the cohesion. The most serious consequence might be lost trust from the society, largely because of the media reports.

2.2.4 Norwegian Law

§3-3. Duty of notification to the Norwegian Directorate for Health (Lovdata, 2016):

According to Norwegian Law the purpose of the duty of notification is to improve patient safety. These notifications shall be used to clarify the causes of adverse events, and to prevent equivalent cases from happening again.

Health institutions that are included in this law, shall send a notification to the Norwegian Directorate for Health without being hindered by confidentiality if there is significant patient injury due to provision of health services, or if a patient injuries another patient. Events that could have lead to serious patient injury should also be reported. The notifications shall not contain any identifiable personal data.

The Norwegian Directorate for Health shall manage the notifications to build up and convey the knowledge of health personnel, healthcare, users, responsible authorities, and manufacturers regarding actions that may be initiated to improve patient safety.

The Norwegian Directorate for Health shall ensure that information about individuals can not be attributed to the person concerned.

On suspicion of serious system failure, the Norwegian Directorate for Health shall notify the Norwegian Board of Health.

2.3 Patient Safety Reporting Systems

Patient safety reporting systems are systems that identify risks to patients and can be used to improve patient safety. Such systems may uncover what has happened if an incident occurs, and may assist in preventing it in the future. An incident is an event that could or did lead to patient injury. Other high-risk industries, such as aviation have successfully used reporting systems to improve safety (Pronovost et al., 2006).

These systems are important in changing the way of dealing with adverse events. Patient safety reporting systems can encourage a stronger focus on eliminating flaws in practice processes and highlight the demand for the whole practice team to share responsibility for patient safety (Trier, Valderas, Wensing, Martin, & Egebart, 2015).

According to Basch (2013), patient reporting is more reliable than clinician assessment of adverse events. If two different clinicians evaluate the same patient, they often disagree with each other's analysis. Numerous studies have shown that patient reporting is feasible and most patients are willing to self-report their experiences with treatment. Furthermore, recent research conducted by Berrewaerts, Delbecque, Orban, and Desseilles (2016) confirms the value of patient reporting in the context of adverse drug reactions. Their findings suggest that the patient's role has gained acceptance in identifying and describing such reactions.

In the US, patient safety has become more financially important to the healthcare industry as some insurance companies have stopped financing for the treatment of complications that occur to inpatients. Therefore, hospitals are trying to decrease the rate of adverse events and potential harm to hospitalized patients (Elkin, Johnson, Callahan, & Classen, 2016).

Additionally, to improve patient safety and reduce the complication rate, organizations will have to learn not only from their own experiences but also from other organizations which requires a national dataset (Elkin et al., 2016).

2.4 Patient Empowerment

Educating patients in a healthcare context is of great value, especially with the tendency towards shorter hospital stays in industrial countries (Eurostat, 2015). As a consequence of this trend, it is of importance that new and innovative ideas concerning patient education are encouraged with regard to timing, content, and methods, as today's patients have to take greater responsibility in their process of rehabilitation (Johansson, Salanterä, & Katajisto, 2007).

Moreover, Fricker, Thummler, and Gavras (2015) suggest that patients, when encouraged to take active responsibility in the self-management of their health with support from digital health technologies, should be placed at the centre of the empowering process.

Furthermore, in Johansson et al. (2007) study on orthopaedic patients, they claim that the most important needs and expectations are in the areas of biophysiological and functional issues. These include complications, medications, postoperative, and recovery related issues. In general, patients are viewed as empowered when they have acquired knowledge that meets their needs, assumptions, or preferences which leads to them making good use of this knowledge. Patients that adopt an active role in the learning process will gain confidence and certainty about their knowledge, and may therefore be deemed empowered (Johansson et al., 2007).

Research conducted by Johansson, Hupli, and Salanterä (2002) regarding patients' learning needs after hip arthroplasty, suggest the most important needs after hospital discharge, summarized in Table 2.1:

Table 2.1: Learning needs after hospital discharge (Johansson et al., 2002, p. 637)

After discharge (n =144) (mean = 3.97-4.25)
What physical activities I cannot do, such as lifting (mean = 4.25)
How to prevent a complication from occurring (mean = 4.20)
What complications might occur from my illness (mean = 4.19)
How to recognize a complication (mean = 4.37)
How to care for my feet properly (mean = 3.97)

Shared decision making between patients and health personnel and self management are mutually supportive approaches, and should therefore be given similar importance and implemented consistently. Technologies of patient engagement, such as health information materials, decision aids, and self management action plans are most effective when they work as an addition to interactions between patients and health personnel (Coulter & Ellins, 2007).

Moreover, as stated by Brennan and Safran (2003, p. 301):

> "Patient empowerment is a philosophy of health care that proceeds from the perspective that optimal outcomes of healthcare interventions are achieved when patients become active participants in the healthcare process."

2.5 Human-Computer Interaction

Human-computer interaction (HCI) focuses mainly on the design, evaluation, and implementation of interactive computing systems intended for human use, but also the study of major occurrences surrounding them (Preece, Rogers, & Sharp, 2015).

As a discipline, HCI emerged in the early 1980s. It was originally a speciality area in computer science covered in cognitive science and human factors engineering. Since its introduction in the 80s, it has grown rapidly and constant for three decades, and has also engaged professionals from many other fields and incorporated diverse concepts and approaches (Carroll, 2013).

Presently, HCI covers several disciplines which includes human factors and ergonomics, information systems, cognitive science, information science, organizational psychology, industrial engineering, and computer engineering (Grudin, 2005).

2.5.1 Human-Computer Interaction and Healthcare

Using HCI as an approach to improve healthcare services is of great importance. The most common approaches to improve adverse events have usually been to focus on industrial design and human factors, instead of HCI. According to Acharya, Thimbleby, and Oladimeji (2010), the field could be saving lives.

However, the impact of HCI in the healthcare industry is not as high as it should be, and therefore it is quite hard to be influential. The electronic patient record

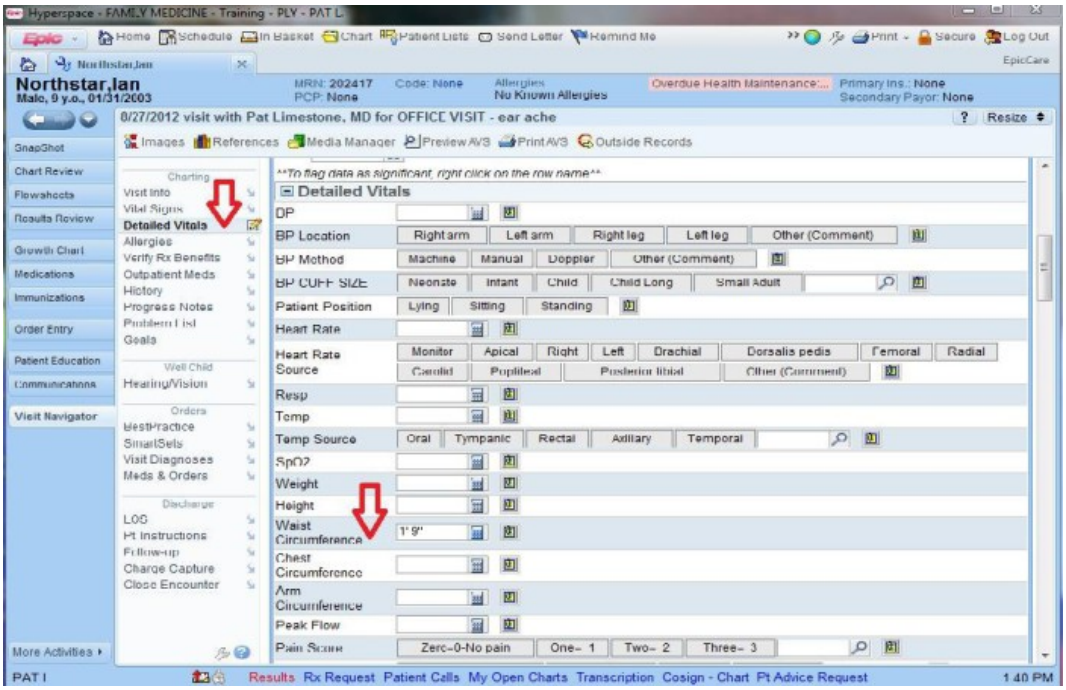

Figure 2.3: Patient electronic record (SitePoint, 2017, para. 22).

shown in Figure 2.3 is a good example: A system with poor design, which is excused because it is highly complex (Acharya et al., 2010).

Adverse events are seldom explored from any perspectives other than clinical implications. How a patient is treated after an overdose is a clinical matter, but the HCI and latent conditions leading to the incident itself are in general ignored. The field has to be given more attention in healthcare and serve as a contributor, or else it will continue to be problematic (Acharya et al., 2010). This claim is also substantiated in Fruhling and Wilson (2007, p. 137): "Human-computer interaction research can provide valuable guidance to improve the usability of healthcare IT". The success of these applications are dependant on the ability of people to use them effectively and efficiently.

Additionally, by involving patients in their own healthcare has important ramifications concerning the design of user interfaces. Designing a successful user interface constitutes one of the most vital challenges in the area of health care informatics (Patel & Kushniruk, 1998).

2.5.2 mHealth

According to Istepanian, Laxminarayan, and Pattichis (2007, p. 3), mHealth can be defined as "emerging mobile communications and network technologies for health-

care". This concept is a subset of e-health systems, and represents an evolution of it. From telemedicine platforms to mobile solutions.

In recent years, the use of mobile phones as platforms for delivery of health interventions has become quite popular among researchers. This type of research has targeted a broad scope of health conditions and has been derived from health sciences, but also disciplines in computer science such as Human-Computer Interaction (Klasnja & Pratt, 2013).

The use of mobile applications also allow physicians to closely monitor patients that have chronic heart failure, and help with detecting early signs of arrhythmia or ischemia that can indicate a forthcoming heart attack. Furthermore, patients can use mobile phone applications combined with sensing and measurement devices to keep track of their physical activities, as well as monitoring of physiological markers that are relevant to their health status (Klasnja & Pratt, 2013).

Using mobile applications to benefit healthcare increases the accessibility of health information. Intervention content can be delivered to individuals without troubling them. For example, by using push notifications, an intervention can be sent to an individual's phone with reminders, health information, motivational messages, and other types of helpful content (Klasnja & Pratt, 2013). These types of interventions can make it easier for users to take care of their health more consistently, and therefore more effectively.

From the patient perspective there is a demand for more specialized tools that would enable easier self-monitoring. Recent research conducted by Kim, Wineinger, and Steinhubl (2016) support this statement as they achieved excellent results in using mHealth technology to improve health in hypertensive participants.

2.6 Related Work

This section will present a selection of tools that illustrate the different possibilities related to self-reporting. Such tools were chosen based on function, implementation, and different HCI platform solutions. Ranging from pictures to represent emotional states to complex systems making use of physiological data.

2.6.1 MAHI

Mobile Access to Health Information (MAHI), is a health monitoring application for newly diagnosed individuals with diabetes. Its purpose is to encourage reflective thinking skills through social interaction with diabetes educators, as displayed in Figure 2.4. The application includes a blood glucose meter, a java-enabled cellphone, and a bluetooth adapter (Mamykina, Mynatt, Davidson, & Greenblatt, 2008).

Figure 2.4: MAHI website (Mamykina et al., 2008, p. 479).

MAHI helps patients to capture rich media which indicates past actions and blood sugar levels. After using MAHI, patients experienced an overall improvement in quality of life. Many users went from no meal pattern, exercise, and no blood glucose monitoring to a proper diet, frequent exercising, and measuring their blood sugar at least twice a day (Mamykina et al., 2008).

2.6.2 MOBITEL

The MOBIle TELemonitoring in Heart Failure Patients Study (MOBITEL) was made to evaluate the effect home-based telemonitoring using Internet and mobile phone technology on the result of heart failure patients after an occurrence of acute decompensation (Scherr et al., 2009).

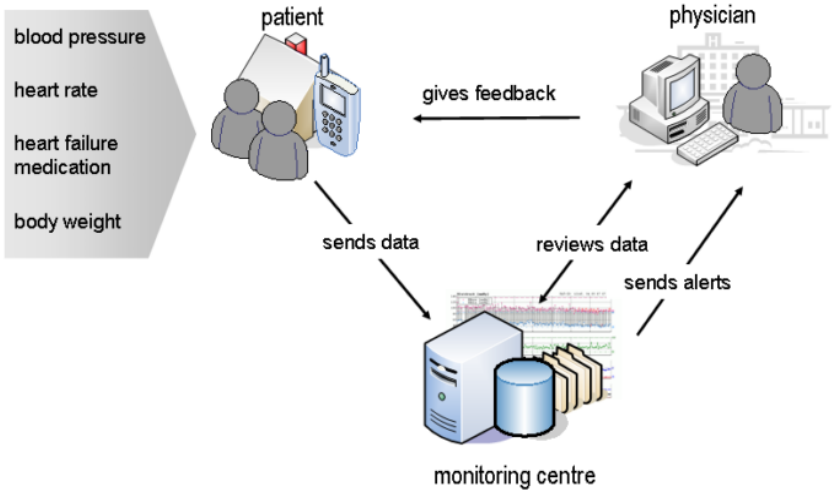

Figure 2.5: Schematic depiction of the equipment and data collection process used in MOBITEL (Scherr et al., 2009, p. 3).

As seen in Figure 2.5, patients were asked to measure vital physiological data such as blood pressure, heart rate, medication, and body weight. The data was measured on a daily basis at a fixed time. Thereafter, the monitor centre assessed the data. Additionally, if values went outside individually adjustable borders, the physicians were alerted via e-mail (Scherr et al., 2009). The results of this study indicate that MOBITEL helps to reduce both occurrence and duration of heart failure hospitalizations.

2.6.3 PAM

PAM, the Photographic Affect Meter, is a mobile application used to assess emotion in humans over time. It has multiple usages in regard to affective states e.g. concerning dietary choices, exercise behaviour, lapses in substance abuse, or traumatic events (Pollak, Adams, & Gay, 2011). Users are able to self-report their mood through a variety of pictures which represents their current state, depicted in Figure 2.6.

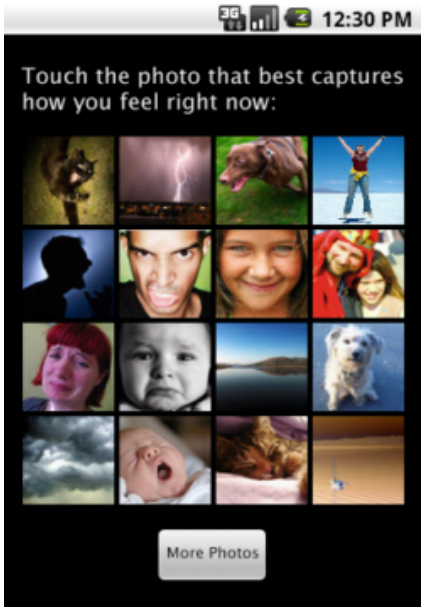

Figure 2.6: PAM on an android mobile device (Pollak et al., 2011, p. 727).

According to Pollak et al. (2011), PAM is feasible as a solution to measure state affect regularly and in situ due to its strong correlation with PANAS PA, which is one of the most widely accepted measures of affect.

2.6.4 Managing Chemoterapy-Associated Side-Effects

Weaver et al. (2007) carried out research on how to efficiently monitor adverse effects of chemotherapy, and provide guidance on toxicity management. Firstly, patients were given a Motorola V600 with preloaded software. Thereafter, patients assessed common adverse effects such as vomiting, nausea, mucositis, and diarrhoea, as illustrated in Figure 2.7. If moderate or severe symptoms surfaced, a nurse was alerted by the computer. Lastly, the nurse then contacted the patient to further assess the situation.

Figure 2.7: Mobile symptom diary (Weaver et al., 2007, p. 1888).

Using mobile technology to monitor patients' symptoms worked satisfactorily. Their well-being increased due to their side-effects being closely monitored, as well as enabling them to participate in their own care management (Weaver et al., 2007).

Chapter 3

Methods and Methodologies

This chapter will present the framework, methods, and methodologies used in this research that concerns data gathering, prototype development, and evaluation.

3.1 Design Science

Design Science research is a set of synthetic and analytical techniques and perspectives for conducting research in Information Systems. It involves the establishment of new knowledge through design of novel or avant-garde artefacts and analysis of the use and/or effectiveness of such artefacts along with reflection and abstraction. Thus, improving and understanding behaviour of aspects of Information Systems. Artefacts include, but are not limited to: algorithms, human/computer interfaces, and system design methodologies or languages (Vaishnavi & Kuechler, 2004).

According to March & Smith (1995) in Oates (2006) there are four types of IT artefacts:

- Constructs: these relate to the concepts or vocabularies that are being used in a specific IT-related domain. This can involve the notions of entities, objects or data flows.
- Models: combinations of constructs that represent a set of circumstances and are used to aid problem understanding and solution development. Example of models can be data flow diagrams, use case scenarios or a storyboard.
- Methods: provides guidance on the models to be produced and process stages that are followed to resolve problems with the help of IT. They include formal, mathematical algorithms, commercialized and published methods.

- Instantiations: a working system which demonstrate that constructs, models, methods, ideas, genres or theories can be applied in a computer-based system.

Hevner, March, Park, and Ram (2004) address seven guidelines for design science research to help assist researchers, reviewers, editors, and readers to understand how to do design science research efficiently. Each of the seven guidelines should be included in the design science research to be complete. However, determining when, where, and how to apply them in a research project is solely up to the people involved in the process.

The next section will elaborate on these guidelines, as well as explain how they were relevant to the research.

3.1.1 Design as an Artifact

The first guideline in design science research is that the artefact must be created as an instantiation, construct, model or method. Artefacts are seen as co-equal and mutually dependent with people or the organizational and social contexts in which they are used, in regard to business needs. Furthermore, artefacts that are contrived with the help of design-science research are seldom complete information systems that are used in practice (Hevner et al., 2004).

SafeTHA is a high-fidelity prototype created in Axure that is fully functional in terms of fulfilling the requirements in Section 4.1. It is regarded as an instantiation with reference to Oates (2006) definition of IT artefacts. Moreover, the prototype was paramount to answer the research questions presented in Section 1.2.

3.1.2 Problem Relevance

The second guideline is to gather knowledge and understanding that empowers development and implementation of technology-based solutions to business problems that are of great importance and still unsolved. To achieve this there has to be constructed an innovative artefact that solves the current problem in a new way compared to previous work (Hevner et al., 2004).

Currently, there are no well-known artefacts available to reduce the occurrence of adverse events after total hip arthroplasty. There are self-reporting artefacts mentioned in Section 2.6, however such artefacts have other areas of use.

3.1.3 Design Evaluation

The third guideline highlights the importance of evaluating the design artefact. Utility, quality, and efficacy must be meticulously demonstrated with the help of well-performed evaluation methods. The evaluation is a critical element of the research process (Hevner et al., 2004). Additionally, Hevner et al. (2004) state that when evaluating an IT artefact it is required to have appropriate metrics as well as gathering and analysis of suitable data. The design artefact can be seen as complete and effective when it meets the expectations concerning requirements and constraints of the problem that was meant to be solved.

The evaluation methods used in this project are well-established in HCI literature, explained in Section 3.5. Experts in the field of Orthopaedics, Biomaterials, Physiotherapy, and Human-Computer Interaction have stated their opinion about SafeTHA through several design iterations. Furthermore, both patients and students have been involved in assessing and usability testing the application.

3.1.4 Research Contributions

The fourth guideline states that to have an effective design science research, there has to be provided clear contributions in the areas of the design artefact, design construction knowledge, and/or design evaluation knowledge. There are three types of research contributions: the design artefact, foundations and methodologies. At least one has to be present in a research project (Hevner et al., 2004).

SafeTHA has contributed mainly to the areas of the design artefact by attempting to reduce the occurrence of adverse events after total hip arthroplasty. By encouraging the patient to actively participate in self-reporting creates significant amounts of data. This data can be further analysed by clinicians, health care management, and used in an educational context.

3.1.5 Research Rigor

The fifth guideline in Hevner et.al's framework, rigorously address how the research is conducted. Design science research demands that rigorous methods prioritize both the construction and evaluation of the artefact that is designed (Hevner et al., 2004).

Personal Kanban was employed to assist in constructing the artefact, explained in Section 3.3.1. It was particularly useful in regards to fulfilling the functional requirements described in Section 4.1.1 because one acquires a clear overview of the work flow. In prototype development User-Centered Design (UCD) was of great importance due to its focus on users, understanding the holistic user experience, and working iteratively. Lastly, to evaluate the usability of SafeTHA rigorous methods such as Heuristic Evaluation (HE) and System Usability Scale (SUS) described in Section 3.5.2 and 3.5.3 were used.

3.1.6 Design as a Search Process

The sixth guideline highlights the importance of design as being a search process to discover an effective solution to a given problem. As stated by Simon (1996) in Hevner et al. (2004, p. 88)'s article: "Problem solving can be viewed as utilizing available means to reach desired ends while satisfying laws existing in the environment". To be able to design efficiently, it is required to have sufficient knowledge of the application domain (e.g. requirements and constraints), as well as the solution domain, for example technical and organizational (Hevner et al., 2004).

In accordance with the principles of UCD described in Section 3.4.2, one works for continuous development through designing iteratively. This accentuates the *search process*. Additionally, the approach demands sufficient knowledge of the domain and users in order to achieve a valuable artefact.

3.1.7 Communication of Research

The final guideline emphasizes that design-science research must be presented to two types of audiences: technology-oriented and management-oriented audiences. By correctly presenting it to technology-oriented audiences, there has to be adequate detail to enable the described artefact to be constructed and used inside a pertinent organizational context. Regarding the latter, there is a need for sufficient detail to determine if the organizational resources should commit to constructing and using the artefact inside their given organizational context (Hevner et al., 2004).

The thesis has been written in sufficient detail to satisfy both technology-oriented and management-oriented audience. Furthermore, a full paper has been presented at the *Informatics for Health* conference (2017). An abstract has been accepted to the *European Medical and Biological Engineering* conference (2017). Lastly, a full paper

will be presented at the *International Conference on Informatics, Management and Technology in Healthcare* (2017).

3.1.8 Summary

All of the described guidelines have been followed and completed in this research.

3.2 Data Gathering

This section will explain the different methods for gathering data that were used in this project. Table 3.1 sums up the different techniques. There is a variety of data that needs to be captured and measured and therefore several methods have been utilized. These will be discussed in the next section.

Table 3.1: Data gathering techniques (Preece et al., 2015, p. 270)

Technique	**Good for**	**Kind of data**	**Advantages**	**Disadvantages**
Interviews	Exploring issues	Some quantitative, but mostly qualitative	Interviewer can guide interviewee if necessary. Encourages contact between developers and users	Time-consuming, artificial environment may intimidate interviewee
Focus groups	Collecting multiple viewpoints	Some quantitative, but mostly qualitative	Highlights areas of consensus and conflict. Encourages contact between developers and users	Possibility of dominant characters
Questionnaires	Answering specific questions	Quantitative and qualitative	Can reach many people with low resource	The design is crucial. Response rates may be low. Unless carefully designed, the responses may not provide suitable data
Direct observation in the field	Understanding context of user activity	Mostly qualitative	Observing gives insights that other techniques don't	Very time-consuming. Huge amounts of data are produced
Direct observation in a controlled environment	Capturing the detail of what individuals do	Quantitative and qualitative	Can focus on the details of a task without interruption	Results may have limited use in the normal environment because the conditions were artificial
Indirect observation	Observing users without disturbing their activity; data captured automatically	Quantitative (logging) and qualitative (diary)	User doesn't get distracted by the data gathering; automatic recording means that it can extend over long periods of time	A large amount of quantitative data needs tool support to analyze (logging); participants' memories may exaggerate (diary)

3.2.1 Qualitative Data

3.2.1.1 Interview

Interviews were chosen as a qualitative data gathering method both to gather requirements, discuss the concept and the prototypes throughout the design iterations since it is a good way to explore issues (Preece et al., 2015). This enables the

interviewer to capture knowledge from professionals and patients which may not be clearly stated in the literature, such as postoperative patient information retrieval. Two types of interviews were used: *Semi-structured* and *unstructured* as they are the most suitable for gathering in-depth information (Oates, 2006).

In a semi-structured interview one has a list of questions or themes that will be covered, but the order of the questions can change depending on the flow of the interview. Additionally, there is a possibility to ask new questions throughout the interview if the interviewee highlights e.g. issues that the interviewer had not prepared for (Oates, 2006). This type of data gathering was used to elicit knowledge, evaluate the concept, as well as the different designs.

An unstructured interview is more of a conversation where the researcher has less control. Usually the interviewer starts up the interview by introducing a topic and then let the interviewees talk freely, preferably without interruption (Oates, 2006). This form was used when discussing proof of concept and eliciting feedback on the clinical practices and research.

3.2.2 Quantitative Data

3.2.2.1 Questionnaire

Questionnaires were chosen as the primary quantitative data gathering method. A questionnaire is a pre-defined collection of items assembled in a pre-determined order. Participants are asked to respond to the items, and as a result providing the researcher with data that can be analysed and interpreted (Oates, 2006).

Heuristic Evaluation and System Usability Scale, elaborated in Section 3.5.2 and 3.5.3 are the two questionnaires used in this research. As these questionnaires have been validated, one can disregard the risk of responses not providing suitable data as stated in Table 3.1.

3.2.2.2 Direct Observation

Direct observation in a controlled environment (see Table 3.1) was utilized to gather data that could aid in assessing the usability of SafeTHA. The observation resulted in both qualitative and quantitative data. Objective data such as the number of tasks successfully completed, errors committed by the user during tasks, and time spent per completed task are important factors towards measuring usability.

3.2.3 Data Validity

Validity refers to the data measured by the data gathering method - if it measures what it is intended to measure. This covers both the method itself and how it is implemented (Preece et al., 2015). Validity is further categorized as *external* and *internal*.

An experiment with good *external* validity yields results that are not unique to a given set of circumstances, but are generalizable (Oates, 2006). The main risk to external validity comes from non-representativeness. This includes over-reliance on special types of participants, too few participants, non-representative participants, and non-representative test cases (Oates, 2006, p. 133).

Internal validity explores if the research was well designed and if it collected the correct type of data from the right sources. To achieve good validity, the data should lead to the research's claimed findings (Oates, 2006).

The research's data validity will be discussed in Chapter 7.

3.2.4 Methodological Triangulation

Methodological triangulation refers to using more than one kind of method to investigate a phenomenon. There are two types of methodological triangulation: *across method* and *within method*. The former was used in this research, as it involves a combination of quantitative and qualitative data gathering techniques (Bekhet & Zauszniewski, 2012).

The approach has been proven to be helpful in providing conformation of findings, more comprehensive data, increased data validity, and improved understanding of the investigated phenomenon (Bekhet & Zauszniewski, 2012).

3.3 SafeTHA Development Methodology

This section will present the method that was used to develop SafeTHA and aid work flow through several design iterations.

3.3.1 Personal Kanban

Kanban was chosen to manage the project in terms of work flow management. Recent findings by Law and Larusdottir (2015) suggest that when emphasizing on HCI and user experience, Kanban is a better fit compared to the most common practice, Scrum.

Personal Kanban is a variant of Kanban, intended for individuals instead of teams. It has two crucial elements: to visualize work flow and limit work-in-progress (WIP) (Benson & Barry, 2011). Simply put, to visualize the work flow means that work has to be split into pieces, writing each item on a card and put on a designated Kanban board depicted in Figure 3.1. It is important to use named columns to illustrate the position of each item in the work flow. Regarding the latter, limit work in progress limits the number of items that may be in progress at each work flow state (Kniberg & Skarin, 2010).

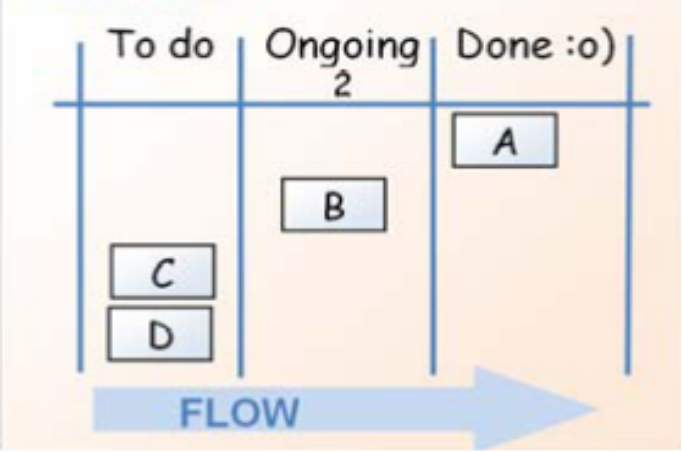

Figure 3.1: Example: Kanban board (Kniberg & Skarin, 2010, p. 15).

The web-based project management tool, Trello, discussed in Section 5.1.5 was used to visualize the work flow and limit work-in-progress.

3.4 Prototype

In this section the different techniques and approaches used to develop the various prototypes will be presented.

A prototype is one manifestation of design that enables stakeholders to interact with it and examine its suitability. It is limited in terms of being a complete product,

because a prototype will commonly emphasize one set of characteristics and de-emphasize others (Preece et al., 2015). A prototype can be a simple paper drawing illustrating a concept, or a fully functional software implementation.

3.4.1 Prototype Fidelity

Prototypes have different fidelities, these are summarized in Table 3.2.

Table 3.2: Different levels of prototype fidelity (Engelberg & Seffah, 2002, p. 204)

Fidelity	Appearance	Optimal uses	Advantages	Limitations
Low	Rough sketch; highly schematic and approximate. Little or no interactive functionality	Early design: conceptualizing and envisioning the application	Low cost: useful communication vehicle; proof of concept	Limited usefulness after requirements established; limitations in usability testing
Mid	Fairly detailed and complete but objects are presented in schematic or approximate form. Provides simulated interactive functionality and full navigation	Designing and evaluating most interactive aspects, including navigation, functionality, content, layout, and terminology	Much lower cost and time as compared to high fidelity; detail is sufficient for usability testing; serves as a reference for the functional specification	Does not fully communicate the look and feel of the final product; some limitations as a specification document
High	Lifelike simulation of the final product; refined graphic design. Highly functional, but the back end might be simulated rather than real	Marketing tool; training tool; simulation of advanced or highly interactive techniques	High degree of functionality; fully interactive; defines look and feel of final product; serves as a living specification	Expensive to develop; time consuming to build

All three levels of fidelities were relevant in this project, hence the emphasis is on HCI. Furthermore, the prototypes of SafeTHA had to be continuously evaluated throughout the design process to make sure appropriate elements were implemented due to the absence of similar applications. Low-fidelity prototypes were developed in design iteration 1 and 2, mid-fidelity prototypes in design iteration 3 and 4, and a high-fidelity prototype in design iteration 5. The variety of prototypes allowed proper time and resource allocation throughout the research process.

3.4.2 User-Centered Design

User-centered design (UCD) is a design approach which emphasizes designing for and involving end users in application development. The approach results in more usable and satisfying systems, increases software effectiveness, efficiency, and learnability which are common usability goals explained in Section 3.4.5 (Fricker et al., 2015).

UCD practice focuses on four fundamental principles that were followed throughout the research process (Fricker et al., 2015):

1. Focus on real end users.

2. Validate requirements and designs.

3. Design, prototype and develop iteratively.

4. Understand and design for the holistic user experience.

Fricker et al. (2015) recommends using a UCD approach in the medical domain, because UCD enables and actively encourages understanding into user needs and requirements. It increases the probability of a high-quality user experience as well as saving money during the development process.

Furthermore, a systematic literature review carried out by Witteman et al. (2015) discussed the importance of UCD and the development of patient decision aids. Their findings indicate that the framework is highly suitable in healthcare to develop tools for decision-making, patient education and self-management, applications for communication with healthcare teams, and patient portals for electronic medical records (Witteman et al., 2015).

UCD was utilized in this research as the user groups are very specific and SafeTHA is directed towards patient safety. Continuous feedback through every design iteration was necessary in order to achieve an optimal end-product. Although other approaches were considered, UCD is scientifically proven, and as mentioned previously, it is an approach that is recommended to use when designing for healthcare.

3.4.3 User Experience

User Experience (UX) refers to all aspects of an individuals' interaction with a product, application, or system (Nielsen & Norman, 1998). One can not design a user experience, instead one can design for the user experience (Preece et al., 2015). Focusing on delivering a good UX when developing an interactive product is critical. If the application is not engaging, people will either not use it or search for alternatives (Fricker et al., 2015).

Designing for the UX was of great importance, because the intention of SafeTHA is to support the user throughout the rehabilitation process. The user should not feel forced to use the application. It should improve patient safety and well-being leading to the user wanting to use it.

3.4.4 Design Principles

According to Preece et al. (2015), design principles are used by designers to assist their thinking when designing for the user experience. These are generalizable abstractions that are supposed to align designers towards contemplating about different facets of their designs.

Furthermore, design principles are procured from a mix of theory-based knowledge, experience, and common sense. They are usually written in a prescriptive manner, giving advice to designers on what to provide and what to avoid concerning the interface (Preece et al., 2015).

Each of the following design principles were emphasized in order to achieve a great user experience. Avoiding user error was particularly important because the self-reporting data had to be correct and easy to fill in. How the design principles relate to SafeTHA will be discussed in Section 5.2.5.2.

3.4.4.1 Visibility

Visibility refers mainly to visualization of different functions for a system or a product. More specifically, a system can have multiple kinds of indicators that inform the user about different options one has in a given situation. Therefore, more visible functions increase the likelihood of the user knowing what to do next. In a car, for instance, the controls that enables the user to perform different operations are obvious, such as indicators, headlights, horn, and hazard warning lights that informs the user what can be done (Preece et al., 2015).

Functions with low visibility are hard to find as well as understanding how to use them, e.g. devices that use sensor technology such as faucets, elevators and lights. People can experience problems with figuring out how to activate or deactivate them, which can lead to a frustrating user experience (Preece et al., 2015).

3.4.4.2 Feedback

This principle relates to the concept of visibility. Appropriate feedback requires sending back information to the user about what action has been done and what has been completed, which allows the user to continue with the activity. There are several types of feedback available for HCI: audio, tactile, verbal, visual, and

combinations of these (Preece et al., 2015). Feedback can be illustrated by using the remote control to switch channels on your TV and change the volume.

3.4.4.3 Constraints

Constraints refer to controlling different ways of restricting the kinds of user interaction that can take place at a given time. A very common constraint, related to graphical user interfaces, is to deactivate certain menu options by shading them grey. This restricts the user only to actions that are permitted at a given stage in the activity (Preece et al., 2015).

3.4.4.4 Consistency

Consistency pertains to designing interfaces that have homogeneous operations and use similar elements for achieving similar tasks. An interface that follow rules such as using the same operation to select all files, is seen as consistent. Inconsistent interfaces on the other hand, allow exceptions to a rule. This can be exemplified by having the possibility to highlight graphical objects by using the right mouse button, whereas all other operations use the left mouse button. Consistent interfaces are therefore easier to learn, since they follow the same universal rule. Inconsistent interfaces make the user prone to do mistakes (Preece et al., 2015).

3.4.4.5 Affordance

Affordance is a term used to refer to an attribute of an object that enables individuals to know how to use it. Afford, in this context, means at a simple level to "give a clue". A perceptually obvious affordance in a physical object can for instance be a door handle, something which requires pulling, or a mouse button that affords pushing (Preece et al., 2015).

3.4.5 Usability

The term "usability" refers to making sure that interactive products are easy to learn, effective to use, and can be seen as enjoyable from the user's point of view. It requires optimizing the interactions people have with interactive products to empower them to carry out their tasks at work, school, and in their everyday

lives (Preece et al., 2015). To be more specific, usability can be broken down into six subgoals.

- **Effectiveness** is a very extensive goal, due to the fact that it refers to how good a product is to fulfil what it is supposed to do (Preece et al., 2015). For example, a speaker not functioning properly would have a rather low effectiveness.
- **Efficiency** refers to the way a product supports the user in accomplishing tasks (Preece et al., 2015).
- **Safety** takes into account to protect the user from dangerous conditions and undesirable situations (Preece et al., 2015).
- **Utility** involves the product's functionality. It should provide the right kind of functionality, enabling users to do what they need or want to do (Preece et al., 2015).
- **Learnability** refers to how easy it is for a user to learn how to use the system as intended. Most people don't like spending numerous hours doing tutorials, and will rather get started straight away and become competent carrying out tasks (Preece et al., 2015).
- **Memorability** Memorability takes into consideration how easy a product is to remember and use, once it is mastered. This is very important for interactive products that are used infrequently (Preece et al., 2015).

These goals were applied to develop SafeTHA. They will be discussed in Chapter 7.

3.5 Evaluation

This section will introduce the different evaluation methods that were used to comprehensively evaluate the prototype, according to the design science guideline explained in Section 3.1.3. The different methods involve several user groups such as students, experts in healthcare, and experts in HCI.

3.5.1 Individual Expert Review

An individual expert review requires one single practitioner who is asked to give an opinion on the usability of a user interface. To improve the results of this method,

it is recommended to do informal interviews and testing. The expert should be very experienced in terms of usability, design principles, and have some domain experience (Wilson, 2013).

According to Wilson (2013), there are several types of expertise one can refer to in HCI:

- **HCI and usability**. Experience with a variety of HCI methods and hands-on usability evaluation experience.
- **Product genre**. Experience with the type of product or service that will be evaluated.
- **Specific product**. Previous or current work with the version of the product.
- **Domain**. Understanding of the concepts, terminology, and work practices used in the domain.
- **User and environment**. Familiarity with users and the range of environments enclosed.
- **Business**. Clear perception of the business goals the product is trying to fulfil.

Generally, the more expertise one has in the aforementioned categories, the more problems and issues will be identified in the individual expert review (Wilson, 2013).

The primary advantages of an individual expert review is that there is no need for a usability lab, recruiter, participants, or extensive funding. Moreover, it is a custom procedure for evaluation that maps the UX and business goals. However, there are disadvantages to the method, such as false positives which can lead to spending time to fix things that are not broken. In addition to that, there is also a likelihood of missing some major and minor problems (Wilson, 2013).

This evaluation method was used in design iteration three with a Professor of Interaction Design and an Associate Professor of Medical Informatics. The choice of using it several times was due to its efficiency in uncovering issues or suggesting improvements.

3.5.2 Heuristic Evaluation

Heuristic evaluation is a usability analysis method where a number of participants are presented with an interface design and asked to evaluate it. The evaluation has

several advantages: it is cheap, intuitive, does not require any prior planning, and is easy to motivate people to do. Moreover, it can be used both early and late in the development process (Nielsen & Molich, 1990).

According to Nielsen and Molich (1990), it is recommended to have three to five evaluators to maximise its potential (see Figure 3.2). Furthermore, they recommend that additional resources are used on alternative evaluation methods.

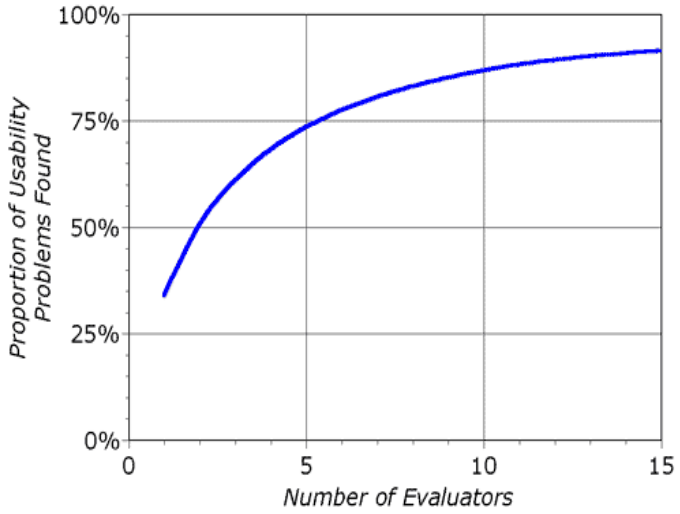

Figure 3.2: Usability inspection - number of evaluators (Nielsen, 1995b, para. 19)

There are 10 general principles or *heuristics* one should follow when evaluating (Nielsen, 1995a, para. 2-11):

1. **Visibility of system status**. The system should always provide users with information about what is going on, through appropriate feedback within a reasonable time-frame.
2. **Match between system and the real world**. The system should speak the language of the user, rather than using system-oriented terms. Information should appear in a natural and logical order.
3. **User control and freedom**. The system should support undo and redo functions, since users often choose system functions by mistake.
4. **Consistency and standards**. Users should not have to question the meaning of words, situations, or actions mean the same thing.
5. **Error prevention**. Either good error messages or diligent design that prevent problems from occurring.

6. **Recognition rather than recall**. Lessen the user's memory load by making objects, actions, and options visible.
7. **Flexibility and efficiency of use**. Accelerators, which the novice user will not see, may speed up the interaction for an expert user, therefore the system can cater to both inexperienced and experienced users.
8. **Aesthetic and minimalist design**. Rarely needed or irrelevant information should not be present in dialogues.
9. **Help users recognize, diagnose, and recover from errors**. Error messages should be expressed in plain language and no codes, giving the user a firm indication to what the problem is and suggest a solution.
10. **Help and documentation**. Using a system without the need for documentation is often the "best" way. However, sometimes it may be necessary to provide help and documentation focusing on the users' tasks.

3.5.3 System Usability Scale

The System Usability Scale (SUS) is a simplistic ten-item scale, conveying a global view of subjective usability assessments (Brooke, Jordan, Thomas, Weerdmeester, & McClelland, 1996). It is a *likert* scale, which means that a statement is made and the respondent indicates the degree of agreement on a 5 or 7 point scale. The statements cover a collection of system usability aspects, such as the necessity for support, training, and complexity (Brooke et al., 1996).

As previously stated, each item is rated: Strongly disagree, disagree, neutral, agree, and strongly agree, which translates into a 1-5 scoring system. Items 1, 3, 5, 7, and 9 has a score contribution of scale position minus 1, whereas items 2, 4, 6, 8, and 10 the contribution is 5 minus the scale positions. Thenceforth, multiply the sum of the items scores by 2.5 to obtain the total value of system usability (Brooke et al., 1996). The ten items are listed below (Brooke et al., 1996, p. 192).

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.

5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

3.6 Research Ethics

As a researcher, one should treat everyone involved in the research, whether directly or indirectly, reasonably and with honesty - that is what makes an ethical researcher (Oates, 2006). The participants in this project have the right to not participate, right to withdraw, right to give informed consent, right to anonymity, and right to confidentiality.

Furthermore, the research has complied with the World Medical Association's (WMA) Declaration of Helsinki. According to WMA, it is "a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data" (WMA, 2013, para. 1).

The project has been approved by the Data Protection Official for Research, Norwegian Centre for Research Data. Project number 50140.

Chapter 4

Requirements

This chapter will present the requirements of SafeTHA, as User-Centered Design, discussed in Section 3.4.2, encourages understanding of the user needs and requirements. User characteristics will be demonstrated as personas.

4.1 Establishing Requirements

> "A requirement is a statement about an intended product that specifies what it should do or how it should perform. One of the aims of the requirements activity is to make the requirements as specific, unambiguous, and clear as possible" (Preece et al., 2015, p. 353).

Initial requirements were chosen after a literature study, discussion with experts and a former patient. Requirements have been modified during development, which will be discussed in the following chapter.

4.1.1 Functional Requirements

A functional requirement describes the specifications of the product's functionality, what it should do (Preece et al., 2015). These are the functional requirements that were chosen for SafeTHA:

1. The application shall inform the patient about what type of activities that can be performed.
2. The application must elaborate on pain and time aspects for the patient.

3. The application must inform the patient about risk factors connected to age, sex, height, body weight, and tobacco use and how to reduce them.
4. The application will provide guidelines for scar and wound management.
5. Users must be able to report pain levels using the Visual Analogue Scale (VAS).
6. The application must enable the users to report their quality of recovery (QoR).
7. Users must be able to assess their mobility.
8. Users must be able to report their anxiety levels.
9. The application must enable the users to take a picture of the procedure site for 30 days following the surgery.
10. The application must inform the user regarding the average length of the rehabilitation process.
11. The application must provide the user with sufficient information concerning pre- and post-operation.
12. A self-reporting summary will be sent to a physician in PDF format via e-mail every time a user has completed it.
13. There must be a possibility to edit the data entry if the input is incorrect.

The risk factors were based on Prokopetz et al. (2012) systematic review. These include: age, sex, height, body weight, and tobacco use.

The decision of taking pictures of the surgical area for 30 days following surgery, is because the majority of postoperative complications develop during this time span. Furthermore, during this 30 day period, many of the unforeseen visits to the emergency department, and re-admissions to the hospital ensue (Bruce, Russell, Mollison, & Krukowski, 2001).

Self-reporting pain will be done with the help of a Visual analogue scale (VAS). The VAS is widely used to measure different types of subjective experiences, including pain. When using a VAS to assess pain, the participant is asked to mark a 100 mm long horizontal line. It can be labelled “no pain” in one end and “unbearable pain” in the other end, which can be seen in Figure 4.1. The main advantages of a VAS is that it is quickly completed, generates ratio data, is easy to score, has a high sensitivity to change, and a good construct validity (Briggs & Closs, 1999).

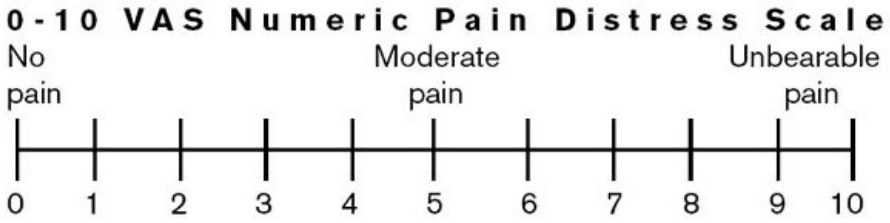

Figure 4.1: Visual analogue scale (TrialDataSolutions, 2017, para. 2).

The quality of recovery score (QoR score) is measured through a questionnaire containing 9 items. These items are based on research conducted by Myles et al. (1999). Additionally, the QoR score has good convergent validity with the VAS (Myles et al., 1999).

Assessment of patient mobility is based on Semple, Sharpe, Murnaghan, Theodoropoulos, and Metcalfe (2015) and takes into consideration questions such as: *How* difficult is it to stand on your leg, walk, and go up and down stairs? These can be rated from 1 (not at all difficult) to 5 (extremely difficult).

Additionally, measuring patient anxiety levels is important because longer hospital stays have been reported for patients that are anxious postoperative, which also impacts the quality of patient recovery (Mossey, Mutran, Knott, & Craik, 1989). Therefore, measuring the patient's anxiety level might contribute to a more precise and successful self-monitoring.

Functional requirements that are not corroborated in the literature have been thoroughly discussed with the healthcare professionals in Section and 5.2.1.1 and 5.2.1.2.

4.1.2 Non-Functional Requirements

According to Preece et al. (2015) non-functional requirements describe the constraints of the system and its development. Such requirements are listed below.

1. The application must be designed for the mobile operating system *Android*.
2. The application must be easy to use for a wide range of people, including non-technical users.
3. The application must do what users expect it to do.

4.1.3 Persona

A persona is a rich description of the typical users of the application. It is used under development to aid designers in designing for the intended user group and is a central part of UCD. To create a persona one needs the user goals, skills, attitudes, tasks, and environment (Preece et al., 2015). Two personas were created based on the information from Section 2.1 combined with the discussion from Section 5.2.1.1. The personas are represented in Figure 4.2 and Figure 4.3, respectively.

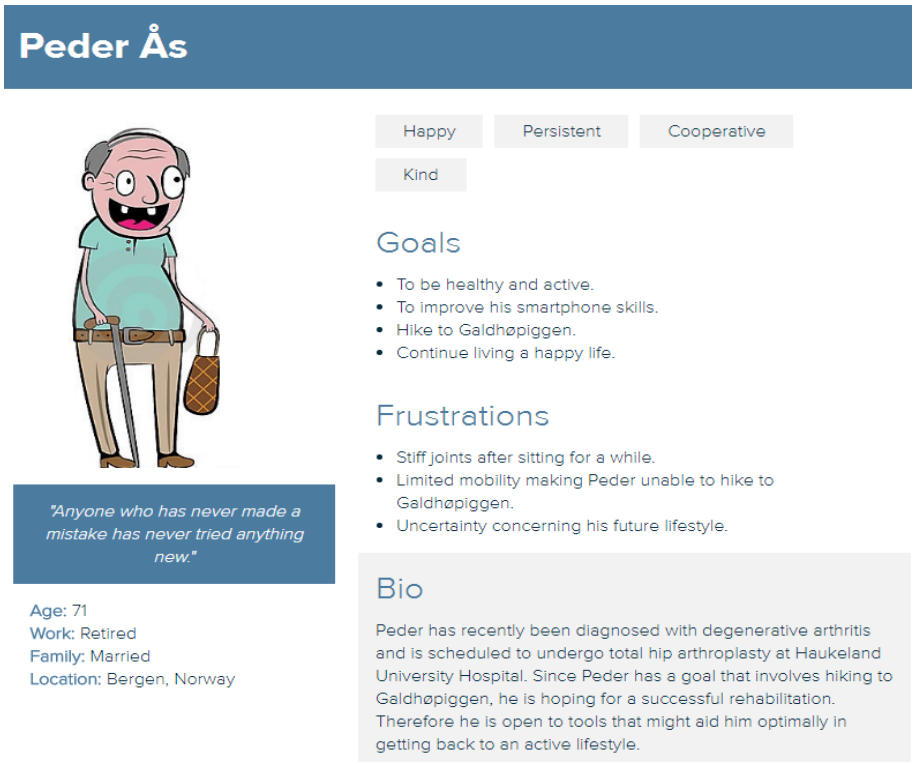

Figure 4.2: Persona Peder Ås.

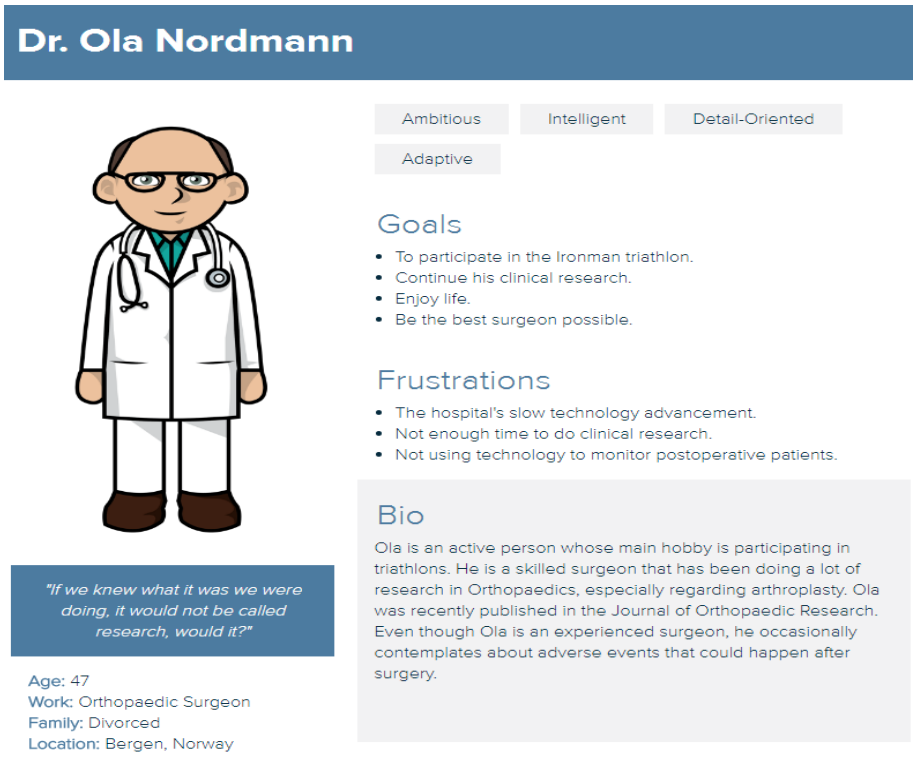

Figure 4.3: Persona Dr. Ola Nordmann.

Chapter 5

Prototype Development

The following chapter will present the tools used in the prototype development and go in-depth about the design iterations that were conducted throughout the research process.

5.1 Tools

This section will present the different applications that were utilized in the prototype development.

5.1.1 Draw.io

Draw.io is a web based diagramming tool developed by JGraph that integrates with Google Drive, OneDrive, and Dropbox. It enables a user to create diagrams such as flowcharts, UML, entity relation, network diagrams, mockups, and more (JGraph, 2017).

5.1.2 Balsamiq

Balsamiq Mockups 3 is an application developed by Balsamiq Studios. Its purpose is to create graphical user interface mockups and website wireframes. It enables the designer to arrange pre-made widgets with the help of a "what you see is what you get" editor. The tool is offered as a desktop version as well as a plug-in for Google Drive, Confluence, and JIRA (Balsamiq, 2017).

5.1.3 Axure

Axure RP 8 is a wireframing, prototyping, documentation and specification software tool for web and desktop applications developed by Axure Software Solutions. Axure enables UX designers to analyse problems, design solutions and create interactive prototypes. It generates HTML web sites and Microsoft Word documents as output. The application is used by 87% of the Fortune 100 companies (Axure, 2017).

5.1.4 Adobe Photoshop

Adobe Photoshop is a photo editing and manipulation program created by Adobe Systems. In addition to being a raster graphics editor, it has limited abilities to edit or render text, vector graphics, 3D graphics, and video. Regarding raster graphics editing, Photoshop has become the industry standard (Adobe, 2017).

5.1.5 Trello

Trello is a tool for web-based project management, developed in 2011 by Fog Creek Software. The tool has several uses, such as real estate management, software project management, and law office case management. Trello uses the Kanban model for managing projects (Trello, 2017).

5.2 Iterations

There is a total of five design iterations. The aim of each design iteration is displayed in Table 5.1.

Table 5.1: Design iterations.

Iteration	Aim
1	Concept evaluation.
2	Create a low-fidelity prototype. Evaluation of the prototype and requirements from medical experts.
3	Create a mid-fidelity prototype. Expert review from HCI experts.
4	Continue with the mid-fidelity prototype. Evaluation from a medical expert regarding the content.
5	Create a high-fidelity prototype. Perform usability testing and inspection.

5.2.1 Design Iteration One

Design iteration one consisted of carrying out a literature review and proof of concept discussion. As a result, a proposed platform solution was assembled. The platform is divided into two modules; one for medical staff that emphasizes e-learning through knowledge representation in forms of statistics, treatment options, and detailed, actual adverse event reports. Secondly, the patient module gives patients a choice of recommendation, for two main situations: "*about your diagnosis*", and "*what if you get a problem*", as advice and guidance during the postoperative rehabilitation. Both modules focus on total arthroplasty regarding the knee and hip areas. It is designed for mobile devices, enabling context-independent learning.

5.2.1.1 Proof of Concept

To assess the feasibility of the proposed platform, a discussion was initiated with two experts in biomedical engineering and a chief surgeon in Orthopaedics at the Haukeland University Hospital in Bergen, Norway. Evaluation data was collected by note taking. The expectations one has from proof of concept is evidence that demonstrates the feasibility of a business model or idea (InvestorWords, 2017).

5.2.1.2 Interview with former patient

A semi-structured interview was conducted in Ørsta, Norway with a female, 51 years of age, that underwent THA in 2014 and is currently working as a nurse. Interview data was obtained by recording and taking notes. The purpose of the interview was to acquire the patients' opinion regarding the patient module.

The interview consisted of the following questions:

1. What do you think are the key factors in terms of rehabilitation after surgery?
2. How valuable is pre- and postoperative information regarding surgery to you?
3. How much information was given to you pre and post-admission? Did you receive any information on how to recognize adverse events?
4. What do you think about the idea of self-reporting with the help of a mobile application?
5. What are your thoughts about the patient module in terms of feasibility?

5.2.1.3 Sketch

Sketching is a low-fidelity prototype technique which often relies on hand-drawn sketches with pen and paper. It is a quick and efficient way to demonstrate e.g. an idea (Preece et al., 2015).

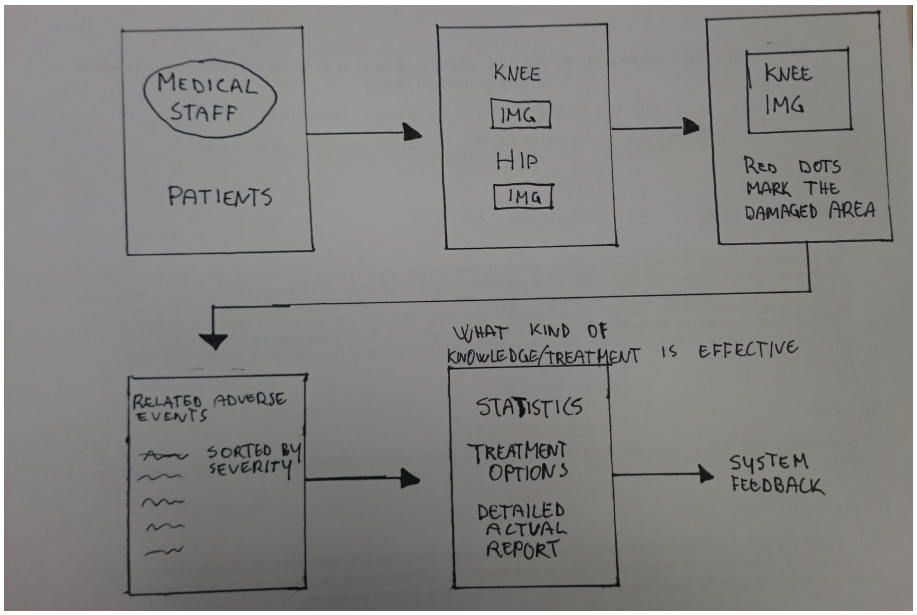

Figure 5.1: SafeTHA sketch.

Figure 5.1 illustrates the planned elements of the application after the literature review and proof of concept. It displays what happens if "Medical Staff" is chosen. Subsequently, the user is presented with an anatomical illustration of the knee and hip. After pressing the knee illustration a larger picture appears, highlighting specific damaged areas marked by click-able red dots. When a dot is selected, a list appears with the adverse events that are related to the selected area, in this example sorted by severity. Afterwards, the user is given three options in regards to which treatment or knowledge that is effective to treat the injury. A menu offered to choose from either *statistics, treatment options* or a *detailed actual report* of prior events. Lastly, the application gives feedback to the user upon request.

Subsequently, a more detailed sketch was created in Axure RP to exemplify what occurs in the case of selecting the knee, as shown in Figure 5.2.

5.2.1.4 Platform Architecture

The architecture of the platform was designed with the aforementioned tools in Section 5.1.4 and Section 5.1.1.

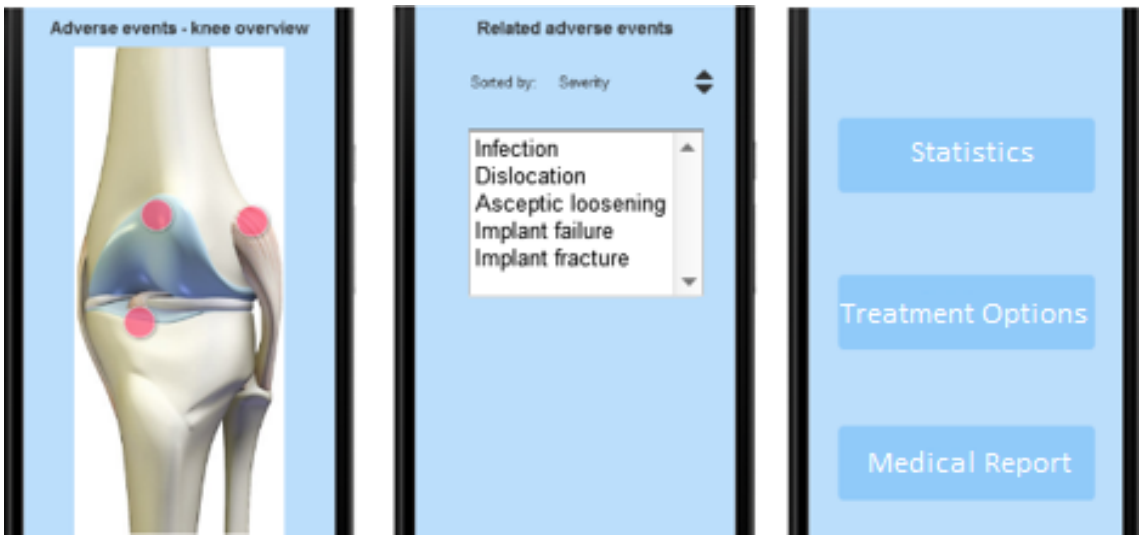

Figure 5.2: The knee and its related adverse events. More information could be obtained about statistics, treatment options, and an actual detailed medical report.

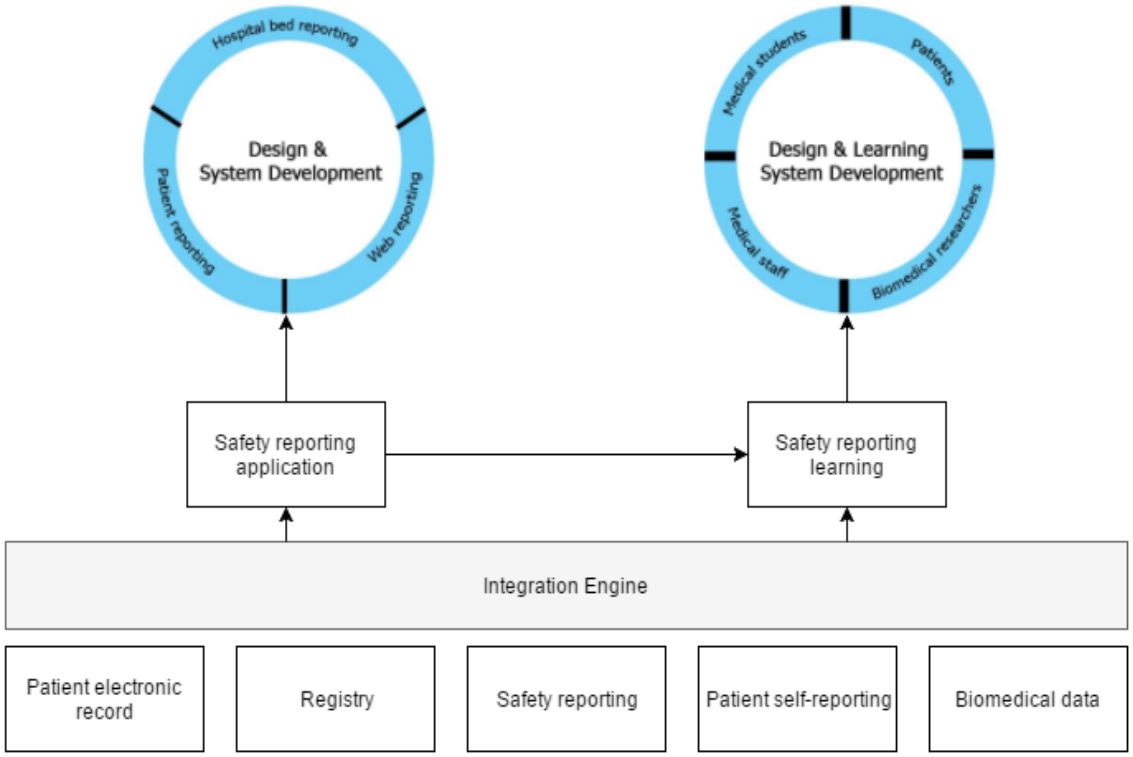

Figure 5.3: Patient safety - platform architecture.

The architectural foundation depicted in Figure 5.3 is based on various databases such as patient electronic records, registry, safety reporting data with the results of information retrieval, patient self-reporting data, and biomedical databases maintained by the Biomedical Laboratory at the Haukeland University Hospital. HL7

standards created by Health Level Seven International will be used to exchange, integrate, share, and retrieve data (HL7, 2016). This research emphasizes the *Safety reporting learning* module, whilst the other segments were created in collaboration with Åserød and Babic (2017).

Furthermore, the learning side of the architecture attempts to make applications for several user groups interested in learning about patient safety. Those are physicians, medical students, biomedical engineers, and patients.

5.2.1.5 Evaluation

Feedback on the proof of concept was unreservedly positive. The senior surgeon commented on its potential to educate different types of patients and was very positive towards learning and using data for both students and patients. A profiling of the patient population, that would be enabled by the platform, could be utilized to address patients' specific needs. One of the experts in the field of biomedical engineering considered the platform to be a very good concept, and definitely a feasible one. He viewed it as a great use of existing new technologies, such as Big Data and Internet of Things.

Furthermore, he suggested that it can be viewed as a tool for decision support making, and not solely as a learning platform. He provided suggestions on the design structure for further development. In particular, the design should give a possibility to add a rotatable model of the knee to the Figure 5.2, and to enable selection of areas if the patient had multiple injuries. Additionally, it could be reasonable to combine statistics and treatment options since each treatment would have a statistic associated with it. "Detailed medical report" would be better presented as "Case studies" with a list of cases to match the patient, adverse events, and treatment options. Lastly, he suggested to add a screen for patient details with basic options to cover the major risk factors such as age, sex, height, and weight.

The patient suggested that the key factors regarding rehabilitation could be movement restrictions, recommended activity level, pain and time aspects, medication regime as prescribed, the ability to choose which type of procedure or surgery, possible complications, and average length of the rehabilitation process. Moreover, the module could be able to make patients follow the guidelines for rehabilitation because it would be a freely available mobile application. The patient stated that pre and post-information concerning surgery was of great importance since it can create safety for the patient in the given situation. Good information can make the reha-

bilitation process easier both physically and mentally. The patient proclaimed that the application would be "a great relief" in terms of self-monitoring and information and definitely feasible.

The patients' experience was with the Lovisenberg Diaconal Hospital in Oslo, Norway. Information that she received there was mostly given orally. Written information was sent out pre-admission and informed about the surgery, prosthesis type, sedation, intensive care observation, and that the patient should try to mobilize the first day post-surgery. She thought there was too limited information regarding how to recognize adverse events, pain and time aspects, and scar management. Additionally, the patient mentioned that receiving information orally was inefficient because one might suffer from amnesia post-surgery for several hours due to medications related to the procedure.

5.2.1.6 Research Modifications

The findings from this design iteration indicate a general positivity towards both the learning and patient module. However, to be able to demonstrate the concept in sufficient detail, further research scope in this project emphasizes the patient module.

5.2.2 Design Iteration Two

In the second design iteration a low-fidelity prototype of the patient module was created in Balsamiq, together with an essential use case and thereafter discussed with an expert in biomedical engineering at the Haukeland University Hospital in Bergen. Consequently, the requirements were altered. Additionally, a physiotherapist assessed the questions in the prototype regarding mobility.

5.2.2.1 Essential Use Case

An essential use case is an organized narrative that consists of three parts: a name that conveys the user intention, a list containing the users' actions, and the system responsibility when a user has completed an action (Preece et al., 2015). The use case shown in the table below was created prior to the visual representation of SafeTHA in order to describe the interaction between the patient and the application.

Table 5.2: Patient safety reporting - essential use case.

patientSafetyReporting	
USER INTENTION	SYSTEM RESPONSIBILITY
enter pain level	save pain level
assess quality of recovery	save quality of recovery statement
assess mobility	save mobility statement
complete self reporting	register reporting and send a PDF with the report to the physician

5.2.2.2 Wireframes

Wireframes are a collection of documents that substantiate an application's structure, content, and controls. Wireframes can be constructed at different levels of abstraction, showing a part of the product or a complete overview (Preece et al., 2015).

Several wireframes were created with Balsamiq. Screen 4, 5, and 6 are portrayed in Figure 5.4.

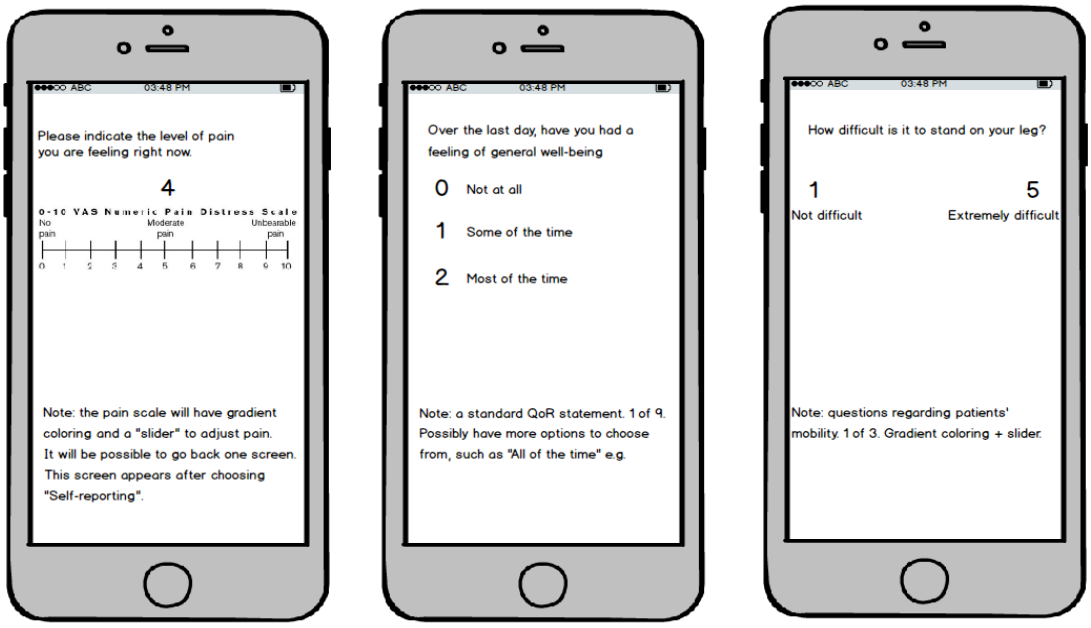

Figure 5.4: SafeTHA wireframes.

The first screen shows the Visual Analogue Scale discussed in Section 4.1.1 and

how it would be presented to the patient. Thereafter, a quality of recovery statement with three different alternatives. Lastly, a question about the patients' mobility graded from 1 (not difficult) to 5 (extremely difficult) which can be useful in tracking progression.

5.2.2.3 Evaluation

The expert in biomedical engineering thought the patient module looked excellent, logical and very well researched in terms of requirements and content. He really liked the idea of feedback based on risk factors, and encouraging the patient to reduce them. He stated that it is very difficult for people to change their habits, but regular interaction with an application can be very effective at forming habits. The expert liked the idea of getting feedback from the surgical area, claiming it is very novel and potentially really useful approach.

Furthermore, he suggested that the patient should not fill in everything every day, but rather spread the data that needs to be filled in over several days. Afterwards one can provide the patient with some useful information, such as guidance in the rehabilitation process each day or two as a reward after filling in the necessary data.

The requirements are mostly measured using qualitative scoring systems. The expert therefore mentioned the possibility of including quantitative measurements taken from the smart phone, e.g. track patient mobility by counting steps or collect physiological data.

The physiotherapist thought the module looked promising and very interesting. He suggested to add the following questions: "Do you have any problems getting in and out of bed?" and "Do you have any problems getting in and out of your car?" as they could be of relevance to the rehabilitation process.

5.2.3 Design Iteration Three

In the third design iteration a mid-fidelity prototype was developed in Axure RP. The prototype was designed for the mobile operating system Android by following Material Design guidelines and contains all the main elements derived from the aforementioned design iterations. An individual expert review, previously mentioned in Section 3.5.1, was carried out separately by a Professor of Interaction Design, and an Associate Professor of Medical Informatics at Linköping University, Sweden.

5.2.3.1 Material Design

Material Design is a design language developed by Google. It combines classical principles of successful design together with innovation and technology. The goal of Material Design is to develop a system of design that allows for a unified user experience across Google's platforms and devices (Google, 2017). This design language was selected because it is recommended when designing for Android.

5.2.3.2 Design Color, Font, and Logo

The colors used for designing SafeTHA are in accordance with guidelines from the Ministry of Health and Care Services (Regjeringen, 2014). The choice of using these guidelines were taken because the application is intended for Norwegians in the first place.

Furthermore, the font used in SafeTHA is *Roboto*. Although Regjeringen (2014) suggest using *Scala Sans*, Roboto was chosen in line with Material Design guidelines. SafeTHA's logo was made in Adobe Photoshop and illustrates a hip prosthesis.

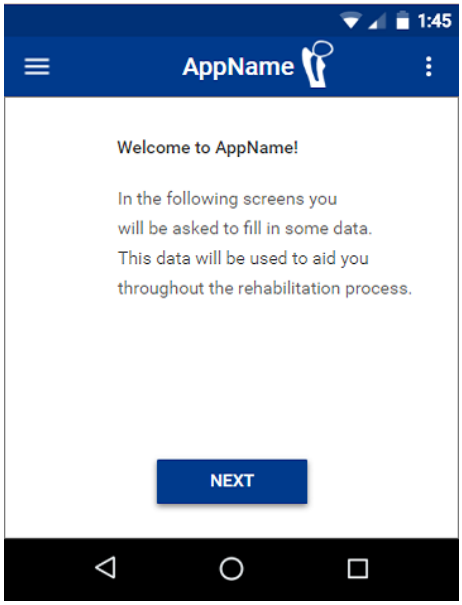

Figure 5.5: Home screen (screenshot).

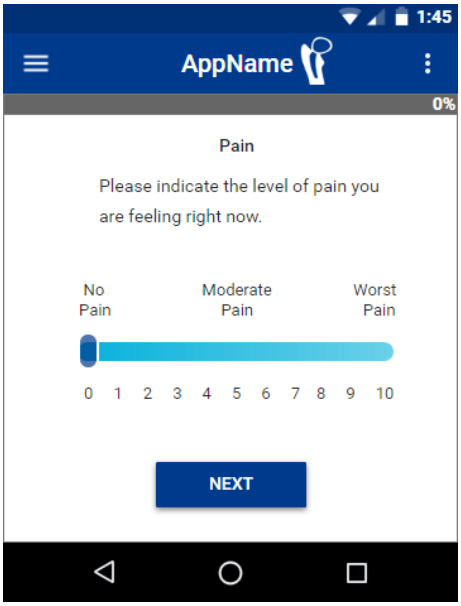

Figure 5.6: Self-reporting pain (screenshot).

The design is illustrated in Figure 5.5 and Figure 5.6. The first screen shows what type of information the user is presented with when the application is launched. The latter presents the screen where patients can report their pain level.

5.2.3.3 Evaluation

As mentioned previously in this section, two evaluations were carried out to assess the usability of SafeTHA. Both experts tried out the prototype followed by a discussion.

The first expert's initial thoughts were that SafeTHA is quite suitable for a mobile platform, aimed at a general user population, and a task that seems fairly straightforward. However, he suggested that the interaction flow has to be changed in terms of what is important to the patient, in order to streamline the self-reporting process and lower the thresholds.

The first time a patient starts the application, one should be taken directly to self-reporting. In addition to that, estimating pain, mobility, and anxiety could be combined into one screen. The second screen could contain quality of recovery assessment and image taking.

After completing the two significant screens, the patient would be asked to provide the personal data. This would happen only once. Moreover, the patient data may be stored in e.g. a profile that is accessible through the application menu and possible to edit if necessary.

The expert stated that the general information could be tucked away deeper in the interaction flow, possibly also accessible only through the application menu. He thought that the feature was not going to be very popular or frequently used.

In addition, he proclaimed that the overall design goal for SafeTHA could be to make self-reporting as quick and effortless as possible. Therefore he recommended to make the image feature optional. If the application requires an image to submit the data, the M.D. might get a lot of irrelevant pictures, a significantly smaller data set or both.

Lastly, the expert suggested a possibility to enable communication with the M.D. in the application. For instance, if one experiences severe pain after a few pain-free days, feedback from the M.D would be of great value.

The second expert proposed that the application could have more of an identity by using e.g. a well-known hospital logo, in addition to the logo symbolizing a hip prosthesis. He mentioned that one can use persuasive technology, such as having pictures of patients in SafeTHA to gain trust with the users.

He suggested to inform the user about the self-reporting progress by notifying

which step they are on instead of percentage progress. Furthermore, after a user has filled in the necessary data for several days, one could create a graph to visualize the user statistics.

Besides the aforementioned matters, the second expert had the same opinions as the first one in regards to simplifying the self-reporting, feedback from the M.D., and user profile.

Finally, he recommended using yes/no questions such as "have you fallen today?" and possibly create a secondary design intended for the older generation.

5.2.3.4 Refined Functional Requirements

The functional requirement from Section 4.1.1: "The application must enable the users to take a picture of the procedure site for 30 days following surgery" was removed as the first expert advised against it. The risk factors mentioned in the same section have been altered to simplify the reporting process. Instead of the patient entering information and acquiring a customized list of risk factors, they are included in the general information as "known risk factors" without the patient having to fill in anything. Furthermore, the requirement: "A self-reporting summary shall be sent to a physician in PDF format via e-mail every time a user has completed it." was removed as Axure RP does not support this feature. It will, however, be included in a future version.

5.2.4 Design Iteration Four

In the fourth design iteration, a second mid-fidelity prototype was created in Axure RP based on the feedback from the previous evaluation, with the main focus being on the interaction flow as depicted in Figure 5.7. The self-reporting progress was changed from percentage to steps. Additionally, the language was changed to Norwegian. The prototype's content was then evaluated by a physician employed at the Volda Hospital in a semi-structured interview to assess the self-reporting questions and statements in SafeTHA together with the general information. Although the idea of taking a picture of the surgical area requirement was removed from the prototype, the physician was asked about it to get a second opinion.

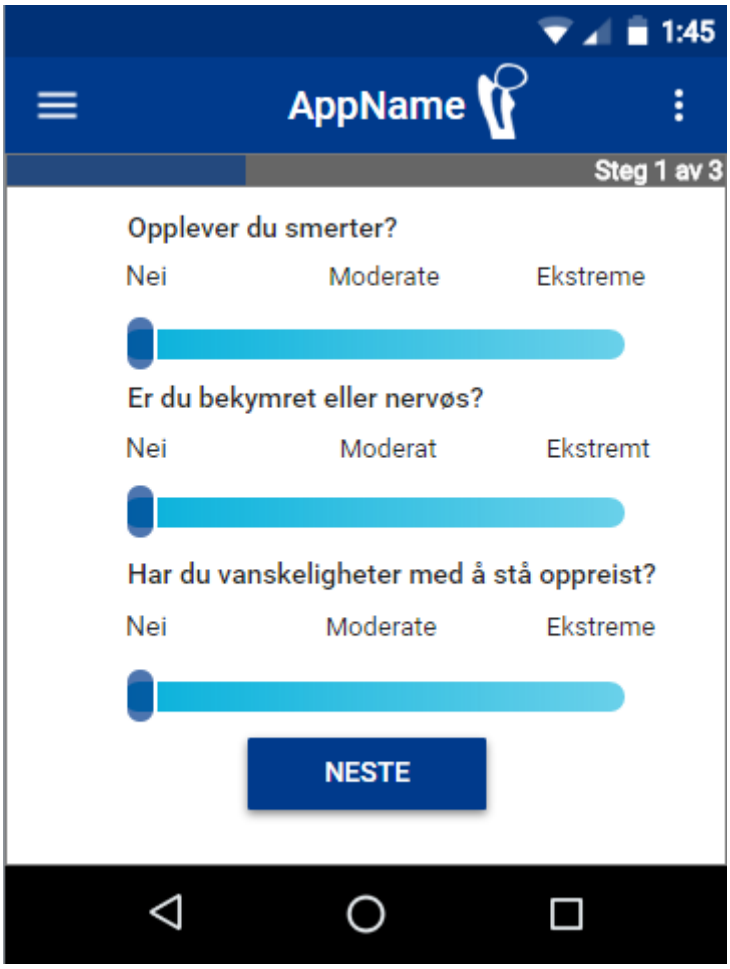

Figure 5.7: Self-reporting pain, anxiety, and mobility (screenshot).

5.2.4.1 Interview with Physician

The semi-structured interview with the physician was conducted by using Skype. Data was acquired by recording and taking notes. Firstly, the physician was presented with the current prototype together with an oral explanation of how it works. Then the content was discussed in regards to reporting frequency, quality of recovery, mobility, anxiety, picture of the surgical area, and pain. Lastly, the physician commented on the general information such as recommended activity level, risk factors, scar management, and pain aspects.

5.2.4.2 Evaluation

In terms of self-reporting, the physician highlighted the significance of data quality. If a patient is asked about *nervousness* or *anxiety* in a standardized interview, the patient often asks what is meant by that. The patient would sometimes ask if it

is in general, in regards to the recovery etc. Therefore, the physician recommended to add a help text with what anxiety actually is in the self-reporting context.

He emphasized that *pain* is a very subjective emotion and hard to measure. An explanation to the pain measurement would be important to acquire quality data. The *mobility* statement was sufficient for capturing good data.

The *quality of recovery* statement slider starts with a negative placement compared to pain, anxiety, and mobility. Thus, he recommended to make it consistent with the previous statements. One can quickly forget to read the statement properly and provide wrong data.

The physician stated that having a *picture of the surgical area* could be very valuable and relevant to assess. However, the patients should not do that themselves. The primary care doctor takes care of bandaging one week post surgery and also examines the wound. If the patient had taken a photo of the wound, the risk of contamination leading to infection increases. Furthermore, he meant that one would be met by a lot of opposition from healthcare as it could lead to adverse events. The idea itself is good, but the practicalities hinder it. Taking a picture of the skin around the bandages could be valuable.

In regards to *reporting frequency*, the physician recommended daily reporting the first week, followed by two times per week the second week, and one time per week in the remaining ones. He expressed that it is important to have a high reporting frequency the first week, as a lot of issues might surface in that period. Additionally, he recommended to start the self-reporting the day after surgery, because if one does not have pain data from day 1 and the patient reports moderate pain on day 10 without any data from day 1, the reporting is not valuable. Differences in reported pain levels can enable the detection of unforeseen events.

The physician stated that the general information was adequate and it covers what the patients are concerned with. He highlighted the importance of high quality information, but how much information that is given to patients vary from hospital to hospital, and it is therefore valuable to have freely available and accessible in an application.

As for recommended *activity levels*, he commented that the hip prosthesis can handle full body load. Therefore, he agreed that the information about mobilizing as quickly as possible was the most important. Restrictions such as avoiding sitting in deep chairs, practising new techniques to put socks on, and not sitting with a hip angle of above 90 degrees should be included. He emphasized that the most

important *risk factor* was smoking because it slows down the healing process. He added that patients are given blood thinning medication, as it decreases the risk of thrombosis which was not mentioned in the prototype. Additionally, he specified that reduced activity level is also a risk factor regarding thrombosis.

In regards to *scar management*, the physician mentioned that most patients are concerned with the cosmetic part of the recovery. He explained that at the Volda Hospital the incisions are sutured intra-cutaneous with self-dissolving material that does not need to be removed. This could be added as extra information. Furthermore, it could also be of importance to mention that one should think of a scar as something translucent, because it is connective tissue with properties similar to skin.

In the matter of *pain aspect*, it could be relevant to inform about how to use pain killers. The patients should not experience a lot of discomfort after hospital discharge.

Lastly, the physician suggested to add an extra question in the self-reporting: "Are you satisfied with your progress?". A patient can be pain-free and not anxious, but discontent with the rehabilitation progress. It would not be necessary with any further questions because the existing ones cover many important aspects. In addition to that, he claimed that one does not need e.g. several quality of recovery statements, as the one in the prototype was sufficient. The physician stated that one should not have too many questions as the threshold must be low, making the self-reporting effortless. This was also emphasized in the evaluation in design iteration three. Moreover, this type of self-reporting could uncover how good healthcare institutions are in providing services, not just limited to the surgical domain.

5.2.5 Design Iteration Five

In the fifth and final design iteration, a high-fidelity prototype was developed in Axure RP. This involved alterations to the content, design, as well as implementation of functions. Consequently, the prototype was evaluated through the System Usability Scale and Heuristic Evaluation. This will be discussed in the next chapter.

5.2.5.1 Application Content

Several changes were made to the content of SafeTHA based on the evaluation from Section 5.2.4.2. Firstly, the quality of recovery statement has been changed

to comply with the other statements in terms of starting point. Secondly, an additional question has been included: "Are you happy with your progress?". Thirdly, a help text has been added to the statements concerning anxiety and pain in order to explain what is meant in the self-reporting context, as these could be ambiguous. Lastly, additional information regarding the surgical area was added in the prototype. Most of the information was gathered from Rasmussen and Skorgen (2016) leaflet from the Lovisenberg Diaconal Hospital, however some key points were added as a result of the interview with the physician in Section 5.2.4.1. The *risk factors* were also modified: gender, age, and sex were removed. Reduced activity level and sitting positions that should be avoided were added, as recommended by the physician.

5.2.5.2 Complying with the Design Principles

The design principles mentioned in Section 3.4.4 were followed to develop the high-fidelity prototype and design for the user experience.

The first principle,*visibility*, was achieved by having buttons that clearly stated in Norwegian what the next action would be. Additionally, the Android sliding sidebar menu was removed as it had no functionality and to avoid confusing the user. This was especially important because of the potential diverse user groups, because some could be smart-phone novices.

Feedback, the second principle, was followed by informing the user throughout the self-reporting process, with the help of verbal feedback as well as visualizing what step they are on. The slider in the self-reporting screens move accordingly to the users' interaction.

The third principle, *constraints*, was applied by implementing modal dialogs to the self-reporting screens and personal information screen. The self-reporting screen modal dialog asks the user if every data entry is correct. The latter informs the user that the birth number must be 11 digits, and the telephone number must be 8 digits. This is further limited by only allowing numerical input. These constraints lower the likelihood of user error.

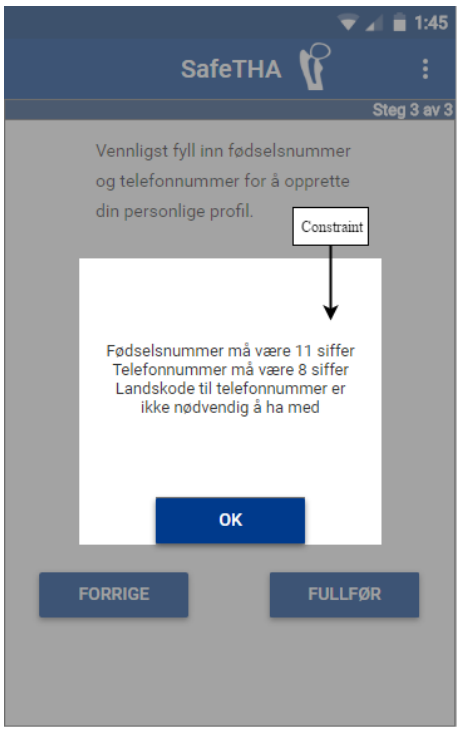

Figure 5.8: Constraint - modal dialog.

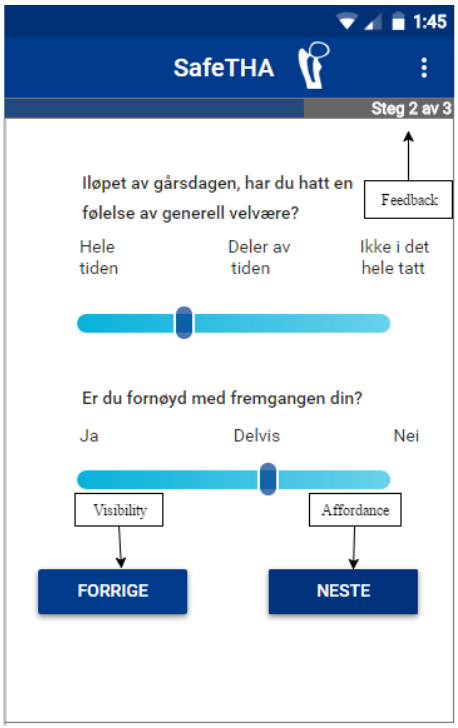

Figure 5.9: Visibility, affordance, and feedback.

The fourth principle, *consistency*, was accomplished by having a consistent design in every screen. Colors, logo, button size, and icons remained the same regardless of which stage the user was located at.

Affordance, the fifth and final principle, was attained by implementing solutions that are well-known to the users, such as the slider used in the self-reporting and the "more options" button. In addition, the buttons lift and fill with color when focused or pressed, indicating an interaction. This is in line with Material Design guidelines presented in Section 5.2.3.

Figure 5.8 and 5.9 illustrate an example of the discussed principles. Consistency was secured by using the same design and layout.

Chapter 6

Evaluation

This chapter presents the results from the usability inspection method, *Heuristic Evaluation* (HE), as well as the system usability testing method, *System Usability Scale* (SUS), discussed in Section 3.5.2 and 3.5.3.

6.1 Participants

Two different groups participated in the final evaluation of SafeTHA: five students of Information Science and three health professionals were recruited due to their expertise. According to Tullis and Albert (2008), the participants should be representatives matching the target audience. However, it is possible to settle for participants that are close approximations of the target users, as long as one is aware of the data limitations.

6.1.1 Usability Experts

All are Information Science students that have attended courses in Interaction Design, Human-Computer Interaction or both, and therefore considered usability experts. They participated in SUS and HE. An overview of the student evaluators can be viewed in Table 6.1.

Table 6.1: Usability experts - overview.

Participant	Age	Gender	Academic level
#1	26	F	Master
#2	23	M	Bachelor
#3	26	M	Master
#4	22	F	Bachelor
#5	24	M	Master

6.1.2 Medical Experts

Healthcare professionals are experts in the medical domain. This group participated in the SUS. Table 6.2 summarizes the medical experts.

Table 6.2: Medical experts - overview.

Participant	Age	Gender	Profession
#6	28	F	Medical Student (6th year)
#7	28	M	Hospital Intern
#8	37	M	Medical Officer

6.2 System Usability Testing

The system usability testing was performed on the Android device Sony Xperia Z2. As for participant representation, *P1* equals participant one, and so forth.

6.2.1 Tasks

The participants were presented with the following tasks to get familiar with the application:

1. Complete the self-reporting process.
2. Fill in a random birth and telephone number.
3. Navigate to *recommended activity level*.
4. Navigate to *risk factors*.
5. Find information *about* the application.

The participants did not receive any instructions beforehand on how to complete the tasks.

6.2.2 Observation

While conducting the usability testing, observation was used as a technique for gathering data as discussed in Section 3.2.2.2. This produced qualitative and quantitative data. The latter will be discussed in the following section. The results of the observation will be presented together with the task results in Section 6.2.4.

6.2.3 Performance Metrics

Performance metrics are some of the most valuable tools for usability professionals. The metrics rely on user behaviour as well as tasks (Tullis & Albert, 2008). This evaluation measured two types of metrics: *Task success*, measuring how effective the users were in completing the tasks, and *time-on-task*, measuring the time spent on completing each task. The former is divided in success with our without assistance.

6.2.4 Task Results

The task results are presented in terms of both qualitative and quantitative data.

6.2.4.1 Usability Experts

Time-on-task, was measured in seconds as illustrated in Figure 6.1, 6.2, 6.3, 6.4, and 6.5.

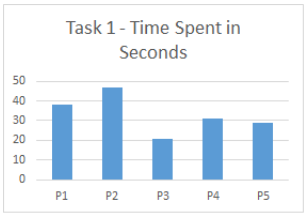

Figure 6.1: Task 1 - time spent (usability experts).

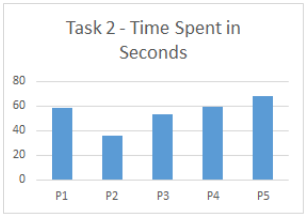

Figure 6.2: Task 2 - time spent (usability experts).

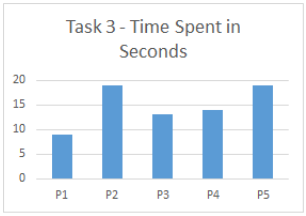

Figure 6.3: Task 3 - time spent (usability experts).

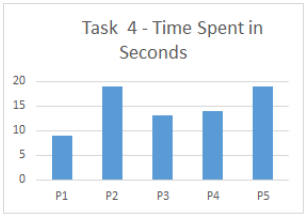

Figure 6.4: Task 4 - time spent (usability experts).

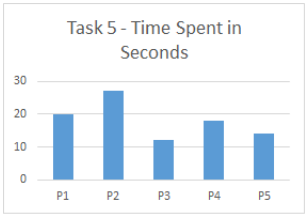

Figure 6.5: Task 5 - time spent (usability experts).

As for task one, shown in Figure 6.1, there are some variations in time spent. *P3*, *P4*, and *P5*'s times were quite similar, whereas *P1* and *P2* spent a bit more time. The time differences could be explained by the fact that all of the participants except *P3* performed several adjustments to the statements where one could use the slider.

In regards to task two, depicted in Figure 6.2 the results were fairly similar between *P1*, *P3*, *P4*, and *P5*, while *P2* completed it quicker. *P1*, *P4*, and *P5* required assistance, as it was hard for them to put in the data correctly. This could be related to them not being familiar with the test device mentioned in Section 6.2. In addition, there are some performance limitations in Axure as the input field was limited to numerical input only, which made the interaction slower as compared to a native application. Observation showed that the participants who needed assistance tried gestures such as double tapping since the prototype responded slower than they are used to.

Task three and four, displayed in Figure 6.3 and Figure 6.4, respectively, had relatively identical results, as none of the participants spent more than 20 seconds to complete either of the tasks. The time differences in these tasks could be explained by the fact that some participants spent time reading the content in the application.

As illustrated in Figure 6.5, the results show that task five was completed in 20 seconds, or less, by all of the participants except for *P2*. The results vary because

P1, *P2*, and *P4* continued to read the information from the previous task, while *P3* and *P5* did not.

Task success, was measured by giving a score of 1 if the participant completed the task without assistance. In addition, if guidance was necessary, that would result in a score of 0.5. None of the usability experts failed any tasks.

Figure 6.6: Overview - task success (usability experts).

As displayed in Figure 6.6, the usability experts *P1*, *P4*, and *P5* experienced difficulties with task number two and required assistance. The cause of that problem was related to the test device, as they seemed to be unfamiliar with it.

6.2.4.2 Medical Experts

The results from the *time-on-task* is presented in Figure 6.7, 6.8, 6.9, 6.10, and 6.11.

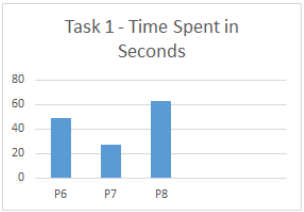

Figure 6.7: Task 1 - time spent (medical experts).

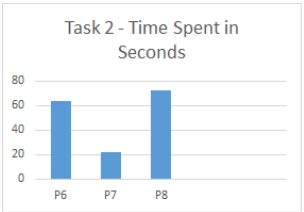

Figure 6.8: Task 2 - time spent (medical experts).

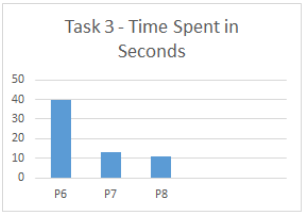

Figure 6.9: Task 3 - time spent (medical experts).

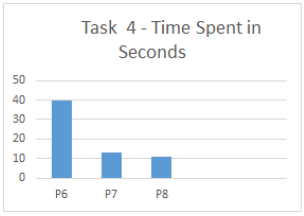

Figure 6.10: Task 4 - time spent (medical experts).

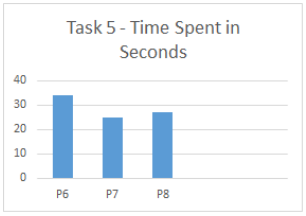

Figure 6.11: Task 5 - time spent (medical experts).

In task one, illustrated in Figure 6.7, there are some time differences, as e.g. *P8* spent more time adjusting the slider in the self-reporting screens. None of the participants experienced any issues in task one.

As for task two, displayed in Figure 6.8 there is a large gap between the participants. *P7* filled in the data rather quickly, whereas *P6* was having a conversation with the researcher while doing the task, leading to a slower completion. *P8* had issues entering the data and needed assistance.

Task three and four, depicted in Figure 6.9 and 6.10 was quickly completed by *P7* and *P8*. *P6*, however, read a lot of the information in both tasks, and therefore had a slower time of completion.

The time spent on task five, visualized in Figure 6.11 was relatively equal among the participants, as all of them went back to the general information screen before finding the information about the application.

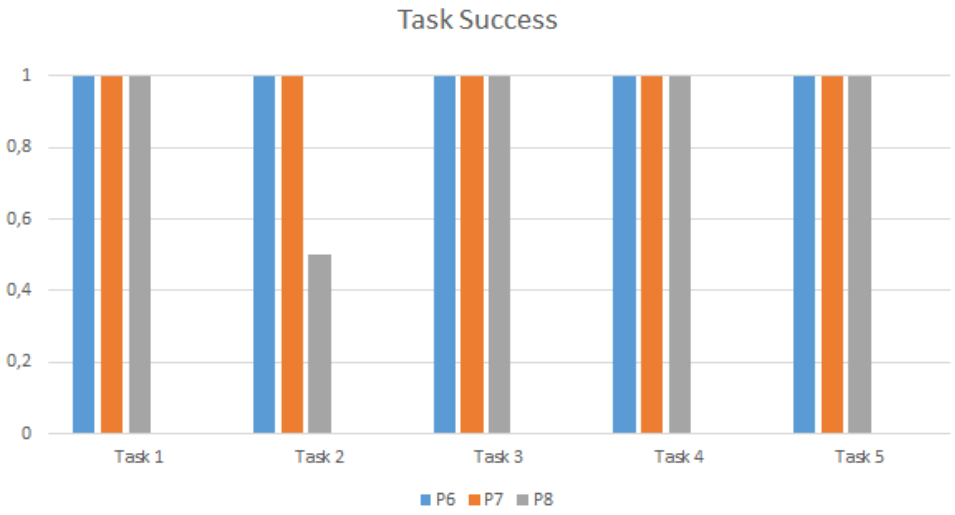

Figure 6.12: Overview - task success (medical experts).

Task succeess, depicted in Figure 6.12, show that *P6* and *P7* completed all the tasks without assistance. As mentioned previously, *P8* required assistance in task two.

6.2.5 Comparing the Expert Groups

Overall, looking at the task comparison results in Table 6.3, there were no significant differences in time spent on each task between the two expert groups. However, a usability problem was detected as the participants spent a lot of time entering the random birth number and telephone number.

Table 6.3: Task result comparison - expert groups.

Average time spent	Seconds	Seconds	Seconds	Seconds	Seconds
Expert Group	Task 1	Task 2	Task 3	Task 4	Task 5
Usability	33.2	54.8	17	14.8	18.2
Medical	46.3	62.6	12.6	21.3	28.6

6.2.6 System Usability Scale Results

The following sections will present the results of the SUS. Moreover, when the participants had completed the SUS questionnaire, they were asked to comment on the overall design and come up with suggestions for improvement. Medical experts received an additional question regarding their opinion of self-reporting in the way it is demonstrated in SafeTHA.

6.2.6.1 Usability Experts

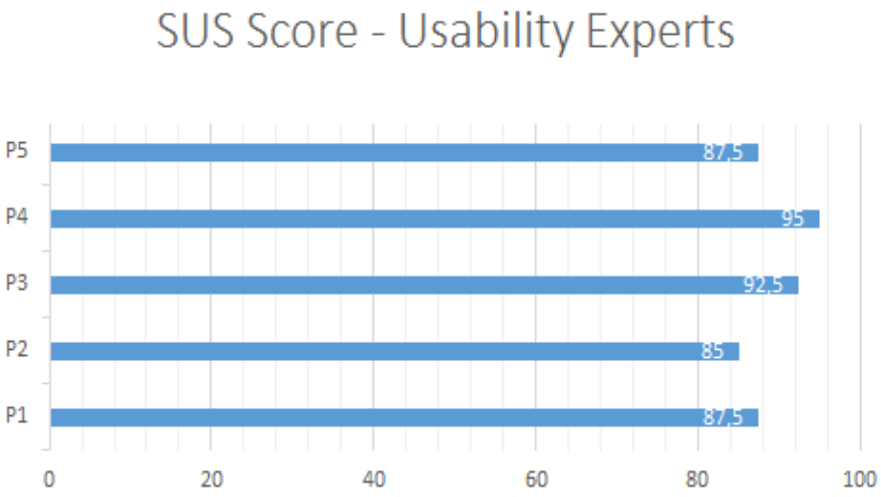

Figure 6.13: System usability scale (usability experts) - results.

Every usability expert scored the prototype 85 or better (See Figure 6.13). According to Brooke (2013), this is an "excellent" result, as research shows that there is a close correlation in terms of adjectives and SUS score. In regards to the usability experts' opinions on the design, *P1* found the "back"-button in the *general information* a bit mispositioned. *P2* mentioned that the prototype's design was very good. *P3* suggested to slightly reposition the confirmation box in the *self-reporting* screens. *P4* thought that an interaction that directed the user to the "home screen" should be added to the application logo.

6.2.6.2 Medical Experts

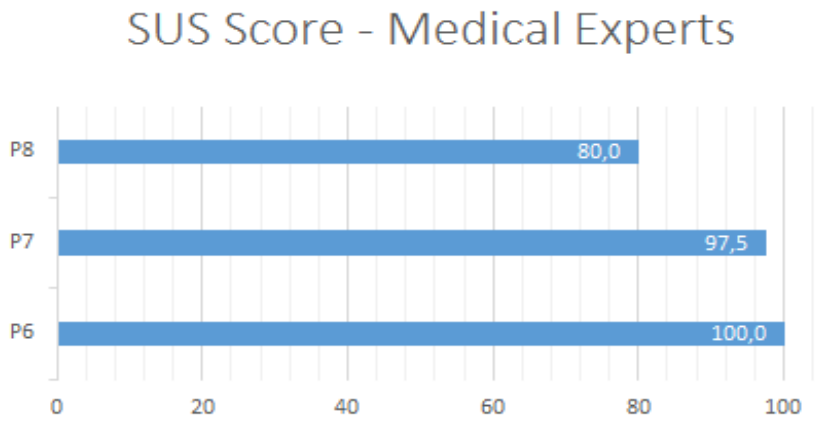

Figure 6.14: System usability scale (medical experts) - results.

The medical experts gave the prototype a score of 80 or above, as displayed in Figure 6.14. *P6* stated that this type of self-reporting application could ease the patients' mindset, as it highlights important factors towards rehabilitation. *P7* thought the application was a great idea, and was curious to see how it would work in a clinical setting. In regards to the design, *P7* proposed to make the whole slider bar in the self-reporting screens interactive, not only the slider. *P8* suggested implementing a baseline patient information comparison with expectations on a given day, e.g. what the patient should expect on day 4, based on the data filled in on day 2.

6.2.7 System Usability Scale Summary

As reported by Tullis and Stetson (2004) in Brooke (2013), a small sample of 8 to 12 users enables one to get a measure of the perceived usability of a system. This evaluation had 8 participants, meeting the requirement of the perceived system usability. The mean score was 90.625, which is a satisfactory result as previously mentioned in Section 6.2.6.1.

6.3 Usability Inspection

The heuristic evaluation was performed after the usability experts had completed the SUS. In the heuristic evaluation, the participants were asked to rate each heuristic dimension from *one* (worst), to *ten* (best) according to the heuristics presented in Section 3.5.2. An explanation of each heuristic was given as well. In addition, they could provide their valuable feedback on each statement at their discretion. Heuristic number seven, *flexibility and efficiency of use*, was removed because the application does not offer any accelerators that might speed up the users' self-reporting process. This was discussed with the usability experts. Table 6.4 summarize the result of the evaluation, whilst the next section will go in-depth of the result of each heuristic separately.

Table 6.4: Heuristic evaluation average score.

Heuristic	Avg. Score
#1 Visibility of system status	8.6
#2 Match between the system and the real world	9.4
#3 User control and freedom	9.4
#4 Consistency and standards	9.8
#5 Error prevention	7.8
#6 Recognition rather than recall	9
#8 Aesthetic and minimalist design	9.8
#9 Help users recognize, diagnose, and recover from errors	7.2
#10 Help and documentation	7.8

6.3.1 Heuristic Evaluation Results

The results of the heuristic evaluation is shown below. In the visualization, *P1* is equivalent to participant 1 and so on.

H1: Visibility of system status

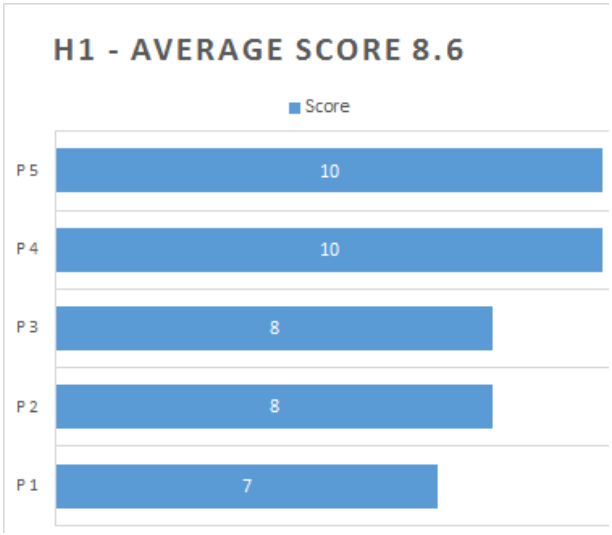

Figure 6.15: H1 - Visibility of system status - results.

As summarized in Figure 6.15, the average score of heuristic number one was 8.6. The lowest score was 7, reported by *P1*, while *P2* and *P3* rated it 8, and *P4* and *P5* gave a score of 10. None of the usability experts had any additional feedback.

H2: Match between system and the real world

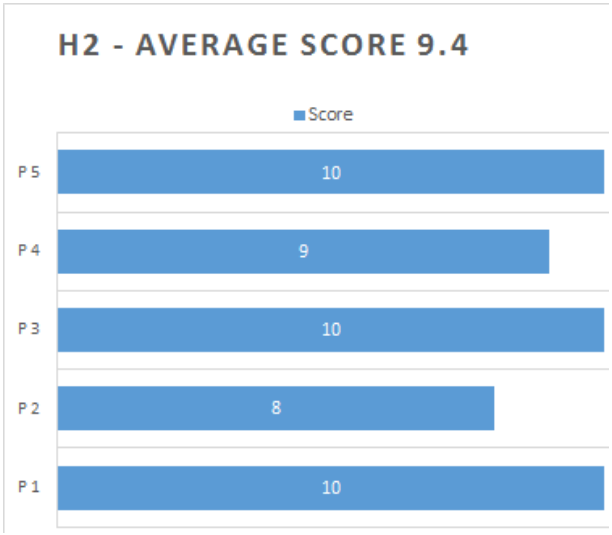

Figure 6.16: H2 - Match between system and the real world - results.

According to the results from heuristic number two, illustrated in Figure 6.16, the average score was 9.4. The highest score was 10, given from *P1*, *P3*, and *P5*. *P4* scored it 9 out of 10, whilst *P2* gave it a score of 8.

H3: User control and freedom

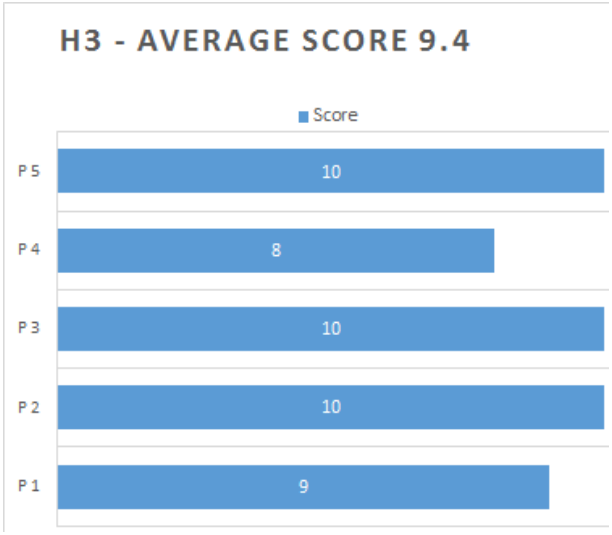

Figure 6.17: H3 - User control and freedom - results.

Figure 6.17 displays the results of heuristic number three. The score was 8 from *P4*, 9 from *P1*, and 10 from *P2*, *P3*, and *P5*, resulting in an average score of 9.4. *P4* mentioned that it is not possible to view the data that is filled in when the modal dialog appears, because the screen is greyed out highlighting the dialog. *P4*

suggested that the data could be presented on a new page, and thereafter the user could be given the possibility to continue the self-reporting process.

H4: Consistency and standards

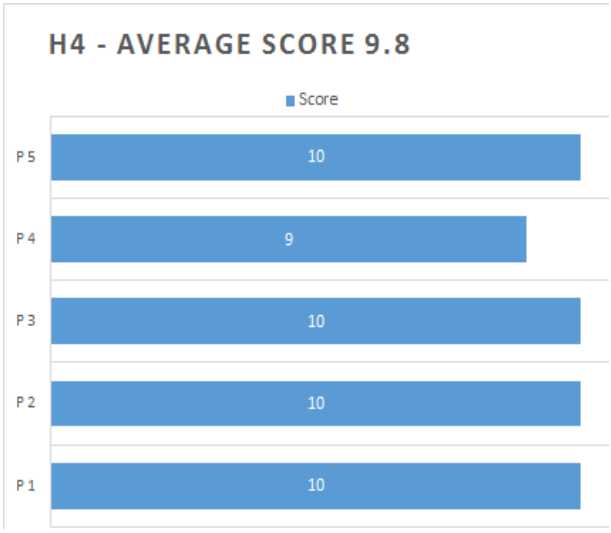

Figure 6.18: H4 - Consistency and standards - results.

The scores from heuristic number four, illustrated in Figure 6.18, show an average score of 9.8. *P4* rated it 9, while the remaining participants rated the prototype a 10.

H5: Error prevention

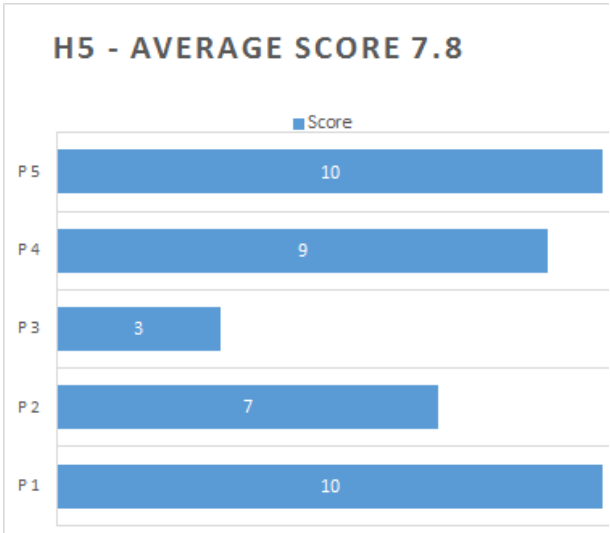

Figure 6.19: H5 - Error prevention - results.

As displayed in Figure 6.19, heuristic number five's average score was 7.8. *P1* and *P5* scored the heuristic a 10, *P4* 9, *P2* 7, whereas *P3* rated it the lowest with

a score of 3. *P3* suggested that the prototype could inform the user about data entered in the personal information screen to be valid or invalid, for example by adding a check box next to it.

H6: Recognition rather than recall

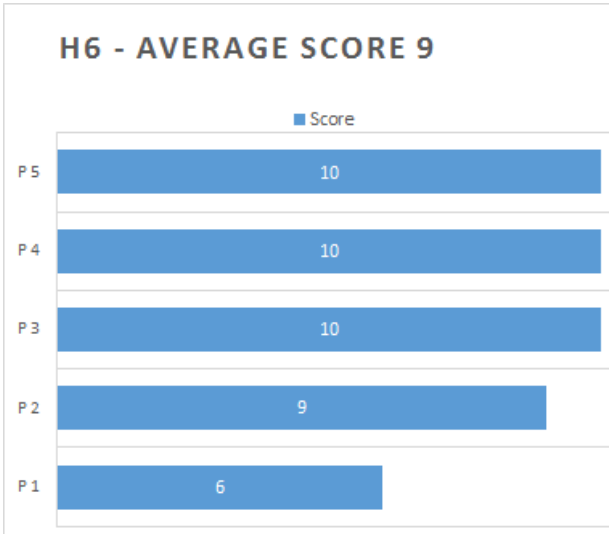

Figure 6.20: H6 - Recognition rather than recall - results.

Heuristic six obtained an average score of 9 (see Figure 6.20). *P3*, *P4*, and *P5* rated it 10, while *P2* rated it 9. The lowest score was 6, from *P1*. *P1* mentioned that instructions or help function was missing.

H8: Aesthetic and minimalist design

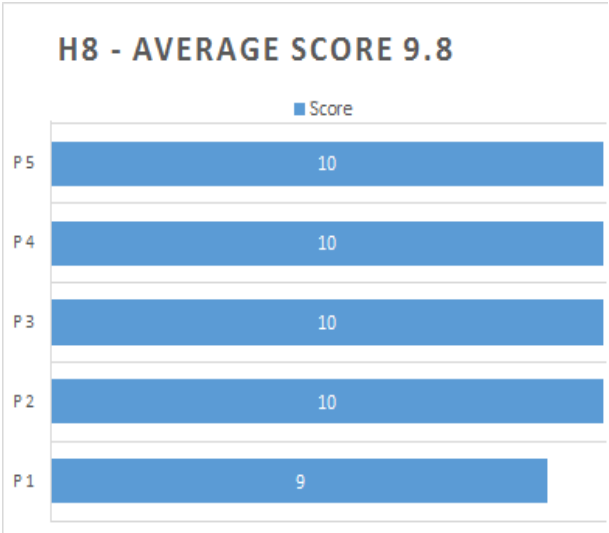

Figure 6.21: H8 - Aesthetic and minimalist design - results.

As illustrated in Figure 6.21, heuristic number eight's average score was 9.8. *P1*

scored it 9, whereas the rest of the participants gave it a top score of 10.

H9: Help users recognize, diagnose, and recover from errors

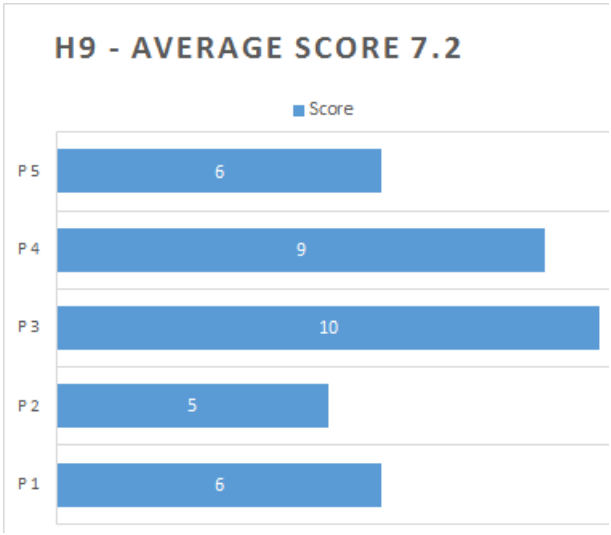

Figure 6.22: H9 - Help users recognize, diagnose, and recover from errors - results.

The score from heuristic number nine, presented in Figure 6.22, averaged 7.2. *P4* suggested that the information regarding country codes in the telephone number field could be written where the input field is, and not after pressing the button that is used to complete or error check the fields.

H10: Help and documentation

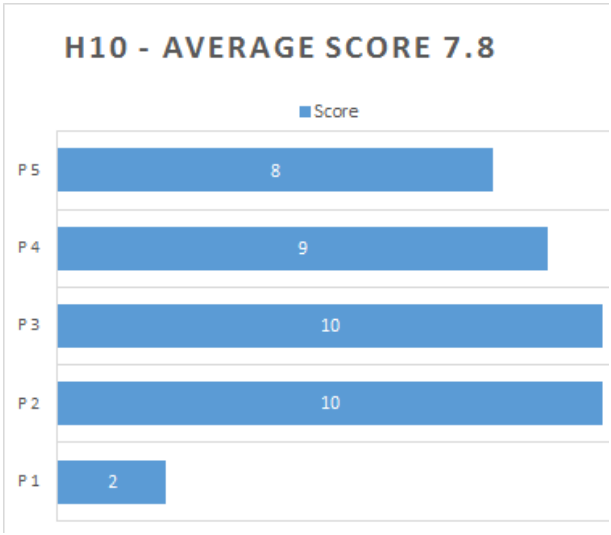

Figure 6.23: H10 - Help and documentation - results.

The tenth and final heuristic, acquired an average score of 7.8, depicted in Figure 6.23. *P3* commented that the users would receive sufficient help through the modal

dialogs in SafeTHA. *P4* suggested that there could be an information button for each question if something was unclear for the user. *P5* mentioned that novice users might not understand the meaning of the more options button. Lastly, *P1* scored it 2, and stated that there were no instructions available, however she felt that the application was intuitive.

6.3.2 Heuristic Evaluation Summary

A total of five usability experts participated in the evaluation to maximise the method's potential as discussed in Section 3.5.2. The prototype's lowest average score was in regards to heuristic number nine with 7.2, whereas heuristic number four and eight were rated the highest with 9.8. The heuristic evaluation has uncovered that there is room for improvement, particularly concerning heuristic five, nine, and ten. The overall result can therefore be considered acceptable.

Chapter 7

Discussion

In this chapter, the high-fidelity prototype, as well as the different methods and methodologies that were utilized in the research will be discussed. Lastly, the research questions from Section 1.2 will be answered.

7.1 Methods and Methodologies

7.1.1 Design Science

The design science framework was used throughout the whole project to integrate methods that were applied in the research. The framework has seven straightforward principles that resulted in an efficient way of carrying out the research. It has been suitable for solving a problem in the medical informatics domain. Section 3.1 shows that all the steps were executed resulting in the artefact. It can be recommended for any domain where different experts and methods needs to be considered and involved.

7.1.2 User-Centered Design

The User-Centered Design (UCD) approach was chosen as it was recommended by Fricker et al. (2015) when designing for the medical domain. The approach recommends to involve relevant stakeholders throughout the design process, and this allowed for valuable feedback regarding the prototypes. UCD emphasizes the *user experience*, which was of great significance when designing for arthroplasty patients.

Furthermore, techniques relevant to the approach such as personas and essential use case were useful to establish the requirements as explained in Chapter 4. It seems that this was an appreciated feature in regards to the patient in iteration one.

7.1.2.1 Usability Goals

The usability goals, explained in Section 3.4.5, were applied to develop the prototype. *Effectiveness* and *efficiency* correlate with the total score of the system usability scale (Borsci, Federici, & Lauriola, 2009). As the mean score of SafeTHA was 90.625, one could argue that these goals have been fulfilled.

Research conducted by Borsci et al. (2009) indicate that SUS statement 4 and 10 (see Section 3.5.3) in a scoring rule suggested by Lewis and Sauro (2009), has a relative correlation with *learnability*. Although the participants struggled with completing task two, mentioned in the previous chapter, this was related to the task device and interaction limitations in the prototyping program. Therefore, it could be argued that *learnability* has been fulfilled, as well.

As for *safety*, the interaction in the prototype limits the user from doing mistakes. However, in a clinical setting, safety is imperative and therefore this will be discussed in the future work (Chapter 8).

In regards to *utility*, the prototype offers the right kind of functionality for a patient that would participate in a self-reporting process, which is also a result of the assessment by the physician in design iteration four. Additionally, he stated that the content of the general information in the prototype was adequate. This was also a finding by the expert in biomedical engineering from the evaluation in iteration two.

Although the participants did not receive any instructions while participating in the usability testing, none of them had any problems in figuring out *how* to complete the tasks. The exception was the previously discussed issue with limitations to usage of the device and prototyping software. This could indicate that the last usability goal, *memorability*, has been accomplished.

7.1.3 Development and Prototyping

The development process in this research was aided by Personal Kanban combined with Trello, discussed in Section 3.3.1 and 5.1.5. This approach worked very well,

as one could get a clear overview over the work that had to be done, as well as the ongoing work enabling a proper allocation of resources.

This research project had two Personal Kanban boards: one dedicated to the holistic work process concerning literature, data gathering, and other preparatory work. The second board contained an overview over what needed to be implemented in the prototype in regards to content, functionality, and requirements. Other agile development methodologies were considered, such as Scrum or XP since the work process has been iterative, however these are better suited for teams with stricter guidelines and different team member roles (Kniberg, 2015).

Furthermore, the emphasis has been on designing several prototypes with different fidelities, and therefore Personal Kanban was a good fit because of its autonomy. The User-Centered Design approach, discussed in Section 3.4.2, requires an iterative development process and therefore a traditional development methodology such as the Waterfall model was disregarded.

Several tools have been used in the development of the prototype, mainly Balsamiq and Axure mentioned in Section 5.1.2 and 5.1.3. The former simplified the process of creating low-fidelity prototypes, whereas the latter was effective in designing both mid-fidelity and high-fidelity prototypes discussed in Section 3.4.1.

Low-fidelity prototypes were very efficient in the early design process to get valuable feedback on requirements and demonstrating the proof of concept. Mid-fidelity prototypes were useful to get feedback in terms of usability and content, as they included some interactivity and were less time-consuming to make than a high-fidelity prototype. The prototyping led to important feedback towards further development. Lastly, the high-fidelity prototype contributed to a thorough evaluation in regards to usability inspection, as well as usability testing. Thanks to the level of detail it clearly suggested functionality and could be recommended for final user testing, especially e.g. for patients as they usually have no medical background.

7.1.4 Data Gathering

7.1.4.1 Interviews

Interviews were used as an approach to gather qualitative data. Semi-structured and unstructured interviews were carried out in iteration one and four. The method worked very good to capture experiences and information one could not find elsewhere. Patient input about the concept and self-reporting, as well as the physician's

opinion on the prototype content, was very valuable.

Moreover, the discussions with medical experts in iterations one and two was of great importance for developing the prototype, because in the beginning the project's scope was exceedingly broad. In addition, they contributed with a lot of knowledge as they are experts in the field of Orthopaedics.

Although the medical experts were generally positive in regards to SafeTHA, one could have interviewed more patients to get several opinions about the application throughout the research. It would be recommended to include other types of patients with different backgrounds, age, and gender.

7.1.4.2 Observation

Direct observation (see Section 3.2.2.2) was employed as the participants were carrying out the tasks related to the system usability testing. Observing the participants while they were working on the tasks could result in the Hawthorne effect, thus affecting the participants' behaviour (McCarney et al., 2007). However, none of the participants indicated that they were stressed, or considered task completion a competition as they were explained that it is the prototype that is being assessed and not their performance.

The method provided rich qualitative and quantitative data. Using only one of them could result in insufficient data, e.g. by only acquiring quantitative data would not explain *why* a task was slowly completed. The observer could also learn from this experience regarding assessment of the participants.

7.1.4.3 Evaluation

Three well-known and established evaluation methods were used in evaluating SafeTHA. Firstly, the *individual expert review*, was conducted by a Professor of Interaction Design and an Associate Professor of Medical Informatics in design iteration three. Their feedback had a great impact on the further development, and resulted in some significant changes to the prototype especially in regards to the interaction flow.

Secondly, the *system usability scale,* which involved medical experts and usability experts highlighted problems that needed to be addressed, although the prototype received an overall excellent score. The information about the tasks that were given prior to the system usability testing could have been given differently, as some of

the participants decided to read the information in the *general information* section, whereas others did not. This had an impact on a varying task completion time. If they had received clearer instructions the time differences could be more similar. Additionally, one could have designed the prototype for e.g. Apple devices as well, since many of the participants seemed to be unfamiliar with the test device (Sony Xperia Z2).

Lastly, the *heuristic evaluation* uncovered issues that could be improved in regards to the user interface. One could argue that another set of heuristics could be used, as the original heuristics created by Nielsen (1995a) are desktop-centred. Current research suggest that there is a need for usability inspection methods customized for mobile devices, however more experiments are necessary in regards to this matter (Inostroza, Rusu, Roncagliolo, Jiménez, & Rusu, 2012). Heuristic number seven, *flexibility and efficiency of use* was removed. Heuristic number ten, *help and documentation*, could possibly be less emphasized, because the intention was to create a prototype that was very straightforward and easy to use. In addition, the heuristic evaluation is subjective, thus some of the findings could be interpreted differently. Design implications will be discussed in Section 7.2.2.

7.1.4.4 Data Validity

As explained in Chapter 3, methodological triangulation was used in this research project (see Section 3.2.4). It involves using more than one method to gather data. The data gathered in this research involved both quantitative and qualitative data, thus resulting in a high degree of data validity.

7.2 Prototype

Different aspects of the high-fidelity prototype will be discussed in this section. As the evaluators of the prototype were either usability experts or medical experts, there may be some data limitations due to the high profile of the evaluators as explained in Section 6.1. Further usability testing should be conducted with patients, since only one patient was interviewed in iteration one. A dynamic patient group could secure a more comprehensive evaluation.

7.2.1 Technical

SafeTHA was designed in Axure RP. While this program is a great prototyping tool, it does not provide the possibility for a complete implementation. Therefore, it would not be possible to use this prototype as a genuine self-reporting tool by having participants test it over a given period of time. The software is also quite limited in terms of data visualization, something that would be beneficial to implement, as highlighted by the expert in iteration three.

7.2.2 Design

The evaluation in Chapter 6 revealed some weaknesses concerning the design that need to be addressed. Firstly, the data that is filled in during the self-reporting could be presented to the user, as suggested by evaluator *P4* (see Section 6.3.1) in the heuristic evaluation. This could increase the data quality, since the user has to review the data that was entered. The personal information screen could be improved in terms of checking the data input, as mentioned by evaluator *P3*. The feedback from the evaluation indicated that one should add more features to aid the user, such as a help button. Lastly, evaluator *P4* stated that a help text should be available for each self-reporting question. Statements regarding *pain* and *anxiety* has the help text available, but one could add an additional icon that enables the aforementioned.

7.2.3 Content

SafeTHA's content was refined in iteration one, two, and three, and thereafter assessed in iteration four by a physician. The physician's opinion was that the prototype could facilitate the patients' rehabilitation process in terms of self-reporting and guidance in a straightforward manner.

Additionally, the system usability testing uncovered that the data collected over time in a clinical setting could help set a base-level of e.g. pain, as suggested by evaluator *P8*. Any significant deviations from the base-level would be a reason for a check-up. The recommendations regarding the pain level ought to be considered, as patients experience and manage pain differently. It would be recommended to set a base level individually for each patient group. With the help of the clinical status, it would be possible to cluster patients and understand their experienced pain levels,

as well as their recovery. This would be a way of combining a subjective patient reporting with the clinical picture considered as objective.

7.3 Limitations

The research has some limitations. Firstly, it could have involved more patients, as they are the primary user group. Secondly, the high-fidelity prototype has some constraints compared to a fully functional application, and therefore future work will be discussed in Chapter 8. Lastly, the prototype could have been tested in a clinical setting. Most of the limitations however are time-related. In addition, acquiring unlimited access to patients involves having a consistent collaboration with healthcare personnel, as well as the ethical approval to conduct proper clinical trials in a clinical environment.

7.4 Answering the Research Questions

As discussed in Section 1.2, this thesis seeks to answer three research questions. The following section will provide an answer to these questions.

RQ1: Is it possible to design a self-reporting tool that can support and empower patients after total hip arthroplasty?

Data gathered from the patient, as well as health professionals that have provided feedback throughout the research, have been considered to answer this research question. The patient was very positive towards this tool with respect to both self-reporting and empowering (see Section 5.2.1.2) and claimed that self-reporting was a great idea and would be a great relief during the postoperative recovery. The health professionals have been unreservedly positive to the tool in regards to both the design and content, as mentioned in design iteration one, two, four, and five.

Furthermore, research conducted by Jackson and Kroenke (2001) argue that information about surgical procedures is highly valued among patients, and might be associated with an improved patient satisfaction. As the self-reporting tool contains relevant information related to the procedure, one could argue that it could be valued by other patients as well. Other disciplines have shown that self-reporting and engaging patients in improving their quality of life have been done successfully, as explained in Section 2.6. The findings show that this could possibly be transferable

to Orthopaedics.

The results of this particular research and the literature, indicate that it is possible to design a tool that can support patients after total hip arthroplasty.

RQ2: Can the safety risks after total hip arthroplasty be reduced through patient involvement according to health professionals?

The tool demonstrated that it could enable communication between the physician and the patient by engaging the patient in self-reporting, using five simple questions. According to Bertakis and Azari (2011), focusing on the patient communication could result in greater knowledge of the patient, as well as improve the relationship between physician. It seems to have a cost-beneficial effect as it reduces the need for hospitalization. This could be explained by patients experiencing less anxiety and increased trust in their physician when actively participating in their own care. The results from the evaluations carried out in design iteration two and four (see Section 5.2.2.3 and 5.2.4.2) correspond with Bertakis and Azari's (2011) findings.

Furthermore, there have been previous attempts to judge the success of total hip replacements by using the Harris Hip Score (Harris, 1969). However, this score is designed by physicians and does not consider patient satisfaction. As SafeTHA tries to capture the subjective patient data such as progress satisfaction, pain, anxiety, mobility, and well-being it reflects the patient experience. Such data was adjudicated to be sufficient by the physician in iteration four.

Patient involvement seems to be imperative in order to reduce the safety risks after total hip arthroplasty, according to this research's findings, as well as the literature.

RQ3: Can the User-Centered Design approach and Human-Computer Interaction principles be utilized to design tools that are used in a healthcare context?

The straightforward answer is *yes*, since the artefact has been created. The User-Centered Design approach enabled a transparent design through several iterations. This secured a good communication and understanding of the development by eliciting feedback from medical experts and design experts throughout the research. The feedback included both summative and formative evaluation for the different prototypes. Applying design principles and usability goals was helpful as they impacted the usability of the system and the user experience.

The approach emphasizes the end-user (patient), thereby the focus was always on this subject when designing the different prototypes. According to Tippey and

Weinger (2017), correctly applying User-Centered Design, could improve several aspects of the patient-healthcare relationship: education and shared knowledge, information flow, patient engagement, collaboration, and respect to the patient's opinion. These findings correspond to the experience of this research, as well.

Moreover, the combination of the aforementioned allowed for designing a tool intended for use in a healthcare context.

Chapter 8

Conclusion and Future Work

8.1 Conclusion

Design science requires some new developed artefact of relevance for a problem and of value for intended users. An artefact has been created for a vulnerable user group, patients, revolving around self-reporting and empowerment. All the evaluators suggest that one might have succeeded at that and delivered an artefact of practical use.

The results of this study are providing a subjective patient perspective, and are a part of evidence based practices, only that the data generated is a result of self-reporting. This data could result in capturing an unique patient situation, by keeping patients in an active role towards rehabilitation, and focusing the care on them. The five questions that measure anxiety, pain, progress, mobility, and quality of recovery in SafeTHA , could be sufficient in detecting adverse events as more questions could have been too many according to the findings. The purpose is to streamline the self-reporting and lower the threshold of patient participation during the postoperative recovery by capturing the most essential data.

The User-Centered Design approach could be recommended for creating such artefacts, as it requires to involve relevant stakeholders throughout the design process. In this research, physicians, biomedical engineers, a Professor of Interaction Design, an Associate Professor of Medical Informatics, and a patient contributed in establishing requirements, as well as eliciting feedback on the different designs. Since the high-fidelity prototype is intended for the general population, the design as well as functions, are kept simple. Following are the thoughts on the future work.

8.2 SafeTHA

The next step for further development of SafeTHA is to develop the application natively for Android and iOS. Additionally, one would need to have a working algorithm to determine the risk factors based on data from the patient. This would enable a tailored plan on how to reduce risk factors, instead of only having general information available in the application.

As mentioned in Chapter 7 regarding the usability goal *safety*, there are several factors that need to be addressed when creating an application involving patients. The primary concern for SafeTHA is the PDF report that will be sent to the physician. The PDF would have to be encrypted to assure that only authorized individuals read the report. This can be solved by encrypting the file with the help of GnuPG, as it supports the cryptography standards OpenPGP and S/MIME (X.509) (GnuPG, 2017). The user profile could be created before the user has downloaded the application, by having the birth number and telephone number as unique identifiers. This would be most convenient for the user, as the user does not have to fill in the identifiers other than the first time the application starts. An even more secure approach would be to use two-factor authentication which involves a physical factor and a knowledge factor (Rosenblatt & Cipriani, 2015).

Throughout the research process, several experts have shared their ideas for the next development stages of the tool. Firstly, SafeTHA can be integrated with Internet of Things, such as tracking patient mobility via smart-watches by measuring steps per day. Physiological data, e.g. heart rate, could also be measured with the help of smart-watches and be included in the report to the physician. This would enable even more precise monitoring. An automated reminder in regards to self-monitoring would also be necessary to implement, as this would especially benefit patients that suffer from dementia.

When a patient has filled in data for a given time period, there could be a possibility to generate a graph that represent the patients' statistics, and possibly compare the data with other patients that use the application. Furthermore, one could try to make the self-reporting habit forming by applying the Hook Model, which is a part of a framework that was created in order to make a habit-forming product (see Figure 8.1). It contains four elements that are crucial to make a product habit-forming (Eyal, 2014):

1. **Trigger**. A trigger initiates behaviour. There are two types of triggers: internal and external. An external trigger can be an alert from a device, such as

receiving an email or a message on a smart phone. A hint in the user's environment that provides information about the user's next step. Internal triggers rely on associations in the user's perception that induces activity. The most common internal trigger is emotion.

2. **Action**. Following a trigger, action occurs. This is the behaviour that is done when expecting a reward. This behaviour should be effortless to carry out.
3. **Variable Reward**. Contrary to a regular feedback loop that is considered predictable with regards to a reward, the Hook Model focuses on variable schedules of reward. Instead of giving the user exactly what he predicts, the reward will be unpredictable.
4. **Investment**. This phase increases the likelihood of the user's willingness to go through a new hook cycle in the future. The user invests in the product by doing something for it. This can make the trigger more appealing, the action trouble-free, and the reward more exhilarating.

Figure 8.1: The hook model (Eyal, 2014, p. 16).

Lastly, there could also be implemented rehabilitation exercises in the application. To execute the exercises correctly, the application could be paired with bluetooth sensors that are attached to the patient.

8.2.1 Suggested Data Visualization

According to Tufte (2001), data should be communicated with clarity, precision, and efficiency. As the self-reporting generates a lot of data it should be visualized

to present the information in a simple way. Figure 8.2 illustrates a suggestion of visualizing pain levels over several days.

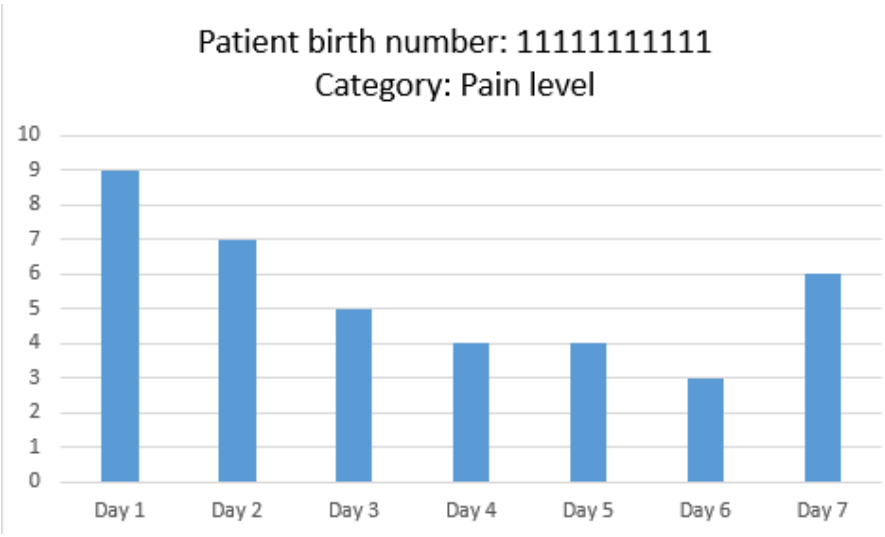

Figure 8.2: Suggested visualization of pain levels.

8.3 Learning and Decision-Support Platform

There are several possibilities regarding the development of the safety-reporting platform. It can enable learning, as well as contribute towards decision-making which was discussed in Section 5.2.1. The following sections will elaborate on the platforms' future development regarding e-learning and decision-support.

8.3.1 E-Learning

E-learning, or "electronic learning" was established in the 1990s, when both teaching and learning methods became more varied with the help of computer- or internet-based media (Thalhammer, 2014). According to Thalhammer (2014), a broad use of the idiom allows including all forms of teaching and learning in which digital media play a crucial role, and is used as a tool in aiding the learning process.

Its efficiency has been proven in the medical education domain, as reported by Back et al. (2014). The use of an e-learning program called NESTOR (Network for Students in Traumatology and Orthopaedics) in traumatology and orthopaedics at the University of Berlin, showed that it was highly effective in supporting gain in knowledge and enhancing satisfaction among the test participants. The students

that tried out the e-learning program in this subject displayed a significantly higher increase in knowledge as compared to non-users (Back et al., 2014).

The main advantage of e-learning is its access. It enables the learner to become independent of time and location, at home or when commuting. This type of learning environment is something that educationalists were not able to do many years ago, whereas now learning can happen in many different contexts (Walsh, 2015). Patients at home could be one group to benefit from this.

A second advantage with using mobile learning is the cost. Most students already have mobile phones or tablets with the required software to use different applications. Medical education is expensive, and by possibly replacing some of the curriculum with an application might lead to a significant cost reduction (Walsh, 2015). The same is valid for patients, as practically all of them have mobile devices that could be used for learning.

By implementing e-learning with the aim of educating both medical personnel and medical students from previous events as well as having a general knowledge base, it is reasonable to assume that it would reduce the occurrence of adverse events in Orthopaedics.

8.3.2 Decision-Support

The decision-support part of the system involves collecting, organizing, and analysing data from several repositories such as patient electronic records, registry, safety reporting data with the results of information retrieval, patient self-reporting data, and biomedical databases. As these data sources contain valuable information, it should contribute to the safety of patients and design of better IT services (Krumsvik & Babic, 2017).

It would also be beneficial to integrate semantic data in the platform, because some of the data coming from the different sources is unstructured, such as patient notes from health care professionals. All three different modules could be a part of the platform described in Section 5.2.1.

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Appendix A

Approval from NSD

Ankica Babic
Institutt for informasjons- og medievitenskap Universitetet i Bergen
Fosswinckelsgate 6
5007 BERGEN

Vår dato: 02.11.2016 Vår ref: 50140 / 3 / IJJ Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 22.09.2016. Meldingen gjelder prosjektet:

50140	*Building IT platforms for post-operative adverse effects in Orthopaedics*
Behandlingsansvarlig	*Universitetet i Bergen, ved institusjonens øverste leder*
Daglig ansvarlig	*Ankica Babic*
Student	*Ole Andreas Krumsvik*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/meldeplikt/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 01.06.2017, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Kjersti Haugstvedt

Ida Jansen Jondahl

Kontaktperson: Ida Jansen Jondahl tlf: 55 58 30 19
Vedlegg: Prosjektvurdering

Dokumentet er elektronisk produsert og godkjent ved NSDs rutiner for elektronisk godkjenning.

Personvernombudet for forskning

Prosjektvurdering - Kommentar

Prosjektnr: 50140

FORMÅL
Formålet er å skape en prototype til en applikasjon som vektlegger læring angående ortopediske inngrep (postoperativ, bivirkninger) for pasienter, leger og medisinstudenter.

UTVALG OG REKRUTTERING
Utvalget består av pasienter, ortoped, medisinstudenter og medstudenter. Pasienter skal intervjues om kunnsskap om inngrepet, holdning før og etter operasjon, oppfølging og informasjonsanskaffelse. Ortoped skal intervjues om informasjonsdeling til pasient, viktige data i rapportering av uheldige hendelser, pasienters deltakelse generelt, oppfølging og innrapportering. Medisinstudenter eller medstudenter skal utføre brukertesting av prototypen og svare på tilhørende spørreskjema om brukertestingen. Medstudenter skal utføre heuristisk evaluering.

Ortoped skal rekrutteres via veileder. Pasientene vil bli rekruttert via ortoped. Medisinstudenter og medstudenter skal rekrutteres via eget nettverk.

INFORMASJON OG SAMTYKKE
Utvalget informeres skriftlig og muntlig om prosjektet og samtykker til deltakelse. Informasjonsskrivet er godt utformet. Merk at NSD har byttet navn til NSD - Norsk senter for forskningsdata.

TAUSHETSPLIKT OG TREDJEPERSON
Vi minner om at ortoped har taushetsplikt. Student/veileder og informant har et felles ansvar for at det ikke kommer taushetsbelagte opplysninger inn i datamaterialet:
- Studenten må stille spørsmål på en slik måte at taushetsplikten kan overholdes.
- Informanten må utvise varsomhet ved bruk av eksempler, og man må være oppmerksom på at ikke bare navn, men også identifiserende bakgrunnsopplysninger må utelates, f.eks. alder, kjønn, tid, sted, diagnose og eventuelle spesielle forhold.

Vi anbefaler at du i forkant av intervjuene med pasientene snakker med dem om at de ikke skal navngi eller på annen måte identifisere personer som selv ikke deltar (tredjepersoner), som helsepersonell.

SENSITIVE OPPLYSNINGER
Det behandles sensitive personopplysninger om helseforhold, og dette er derfor lagt til.

INFORMASJONSSIKKERHET
Personvernombudet legger til grunn at student og veileder følger Universitetet i Bergen sine rutiner for datasikkerhet. Dersom personopplysninger skal lagres på privat pc/mobile enheter, bør opplysningene krypteres tilstrekkelig.

Appendix B

Informed Consent Form

Forespørsel om deltakelse i forskningsprosjektet

"Building IT platforms for post-operative adverse effects in Orthopaedics "

Bakgrunn og formål med masteroppgaven

Jeg er masterstudent i informasjonsvitenskap ved Universitetet i Bergen og holder nå på med den avsluttende masteroppgaven.
Formålet med denne studien er å samle inn data som kan bidra til å skape et selvrapporteringssystem som skal redusere forekomsten av postoperative uheldige hendelser i forbindelse med total hofteartroplastikk. Dette for å styrke kunnskapen hos pasienter og helsepersonell. Din deltakelse i studien blir sett på som svært verdifull til å utvikle dette selvrapporteringssystemet.

Hva innebærer deltakelse i studien?

For å finne ut av nevnte spørsmål, ønsker jeg å intervjue ca. 15-20 personer i alderen 18-60 år. Spørsmålene vil for pasienter hovedsakelig omhandle pasientens kunnskap angående inngrepet, holdning før og etter operasjon, oppfølging og informasjonsanskaffelse.
Spørsmål til helsepersonell vil ta for seg informasjonsdeling til pasient, viktige data i rapportering av uheldige hendelser, pasienters deltakelse generelt, oppfølging til pasient, tanker om innrapportering av uheldige hendelser og deres egen erfaring med innrapportering.
Til intervjuene vil jeg gjerne benytte båndopptaker og ta notater mens vi snakker sammen.

For personer som skal teste prototypen til dette systemet, ønsker jeg rundt 10-15 studenter i alderen 20-40 år. Denne testingen blir en brukertest der individet får noen oppgaver de skal utføre når de blir observerte. Det blir også utdelt et spørreskjema som skal fylles ut angående designet til prototypen. Brukertesting og utfylling av spørreskjema vil ta rundt 30 minutter. Under observasjonen vil jeg ta notater og måle tid brukt på hver oppgave.

Hva skjer med informasjonen om deg?

Alle personopplysninger vil bli behandlet konfidensielt. Den eneste som vil ha tilgang til personopplysningene er student, Ole Andreas Krumsvik og veileder, Ankica Babic.
Deltakerne vil ikke kunne gjenkjennes i publikasjonen med mindre de ønsker dette.

Prosjektet skal etter planen avsluttes 1. Juni, 2017. Etter denne datoen vil alle personopplysninger og eventuelle opptak anonymiseres. Det endelige tidspunktet for anonymisering er 30. Juni, 2017.
Det endelige resultatet av informasjon som blir samlet inn i denne studien vil bli analysert og kan bli publisert i vitenskapelige journaler.

Frivillig deltakelse

Det er frivillig å delta i studien, og du kan når som helst trekke ditt samtykke uten å oppgi noen grunn. Dersom du trekker deg, vil alle opplysninger om deg bli anonymisert øyeblikkelig.

Dersom du har spørsmål til studien kan du ringe meg på 47 65 17 78, eller sende en e-post til ole.krumsvik@uib.no. Du kan også kontakte min veileder Ankica Babic ved institutt for informasjons- og medievitenskap på telefonnummer 55 58 91 39, eller på e-post: ankica.babic@uib.no.

Studien er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste (NSD).

Samtykke til deltakelse i studien

Jeg har mottatt skriftlig informasjon om studien, og er villig til å delta

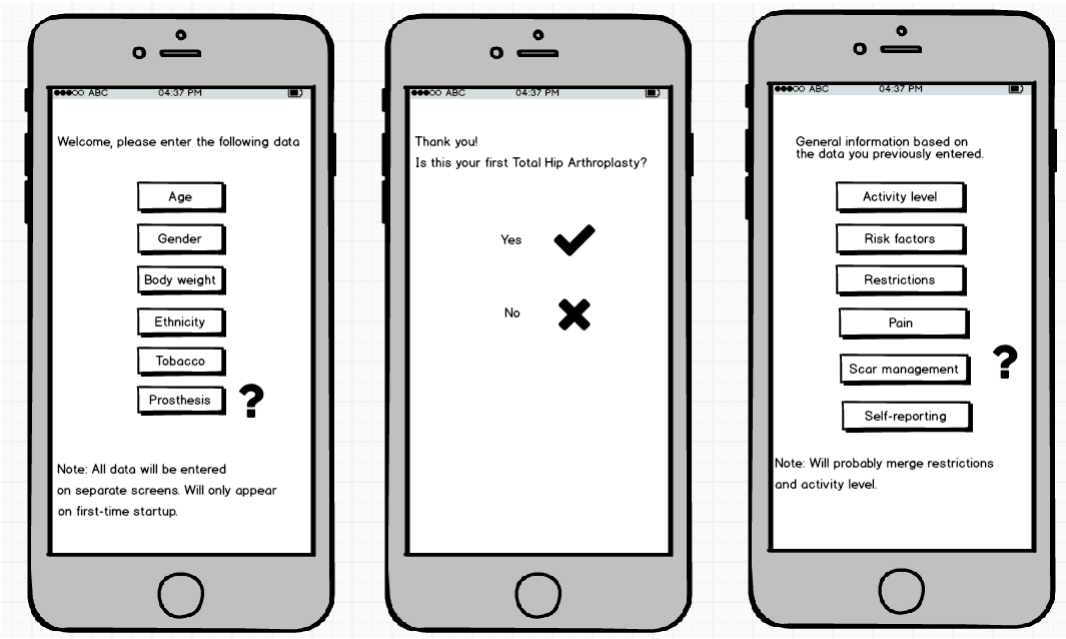
Signatur og dato ……...

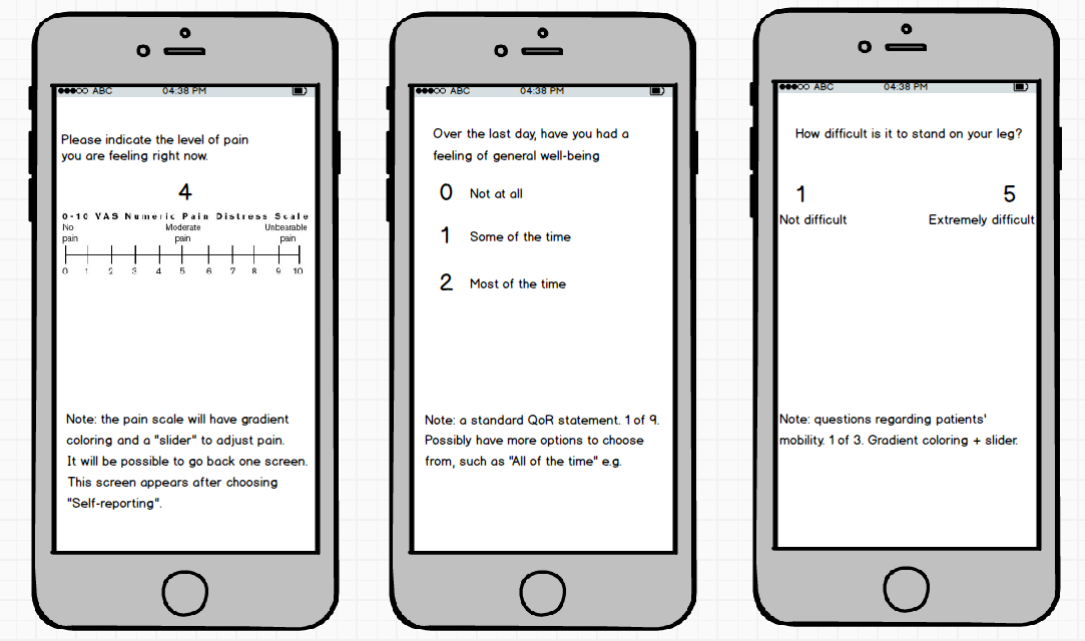
Telefonnummer ……...

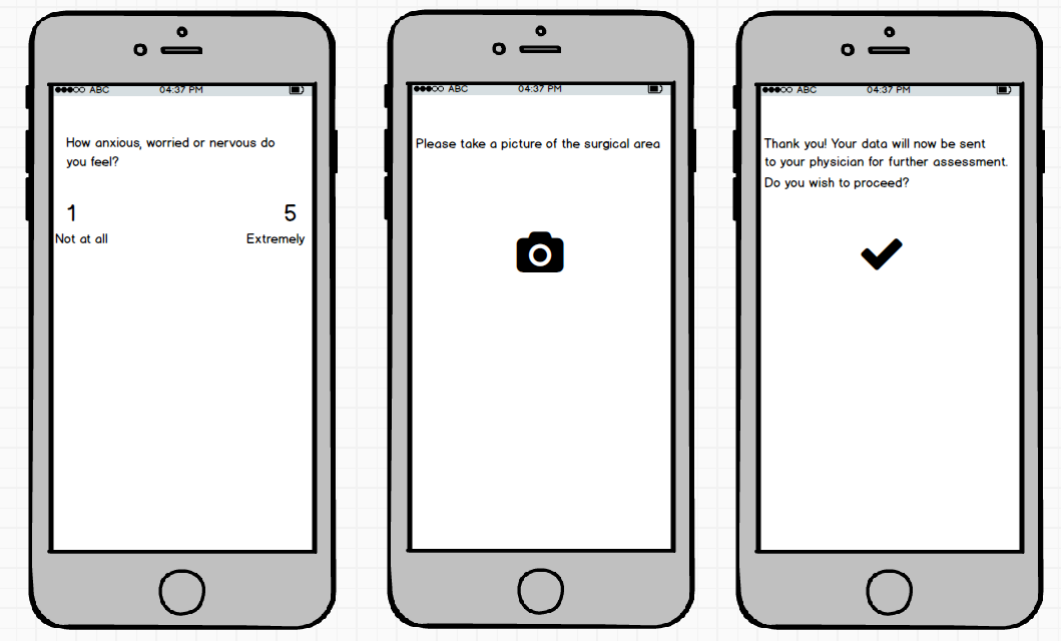
Appendix C

SafeTHA Screenshots

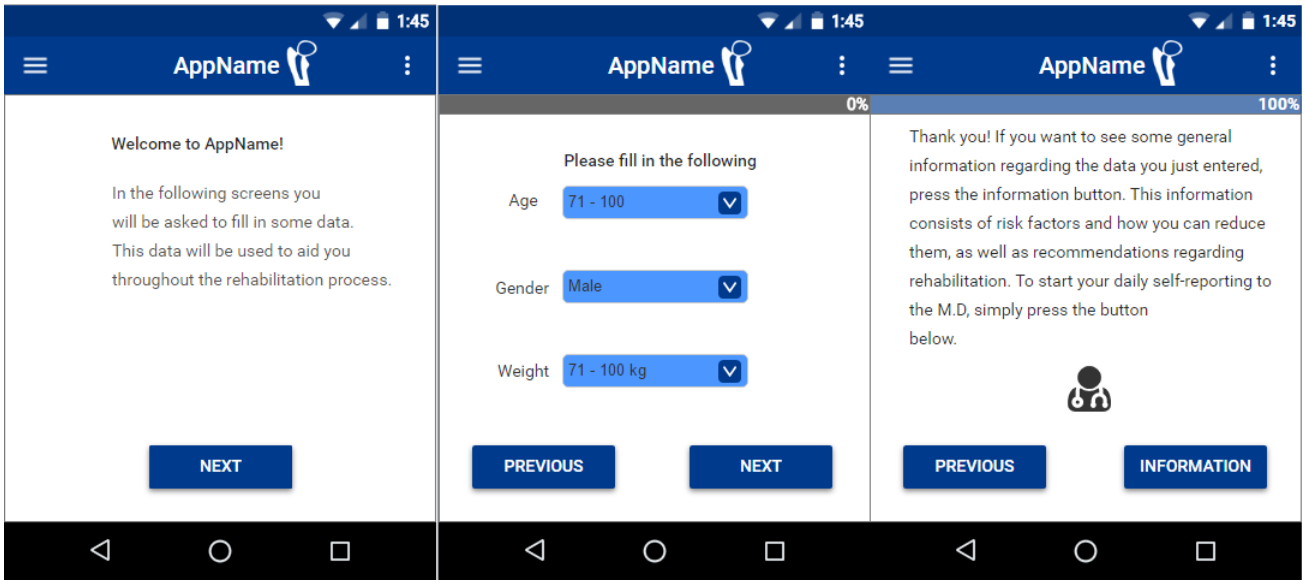
C.1 Low-Fidelity Prototype

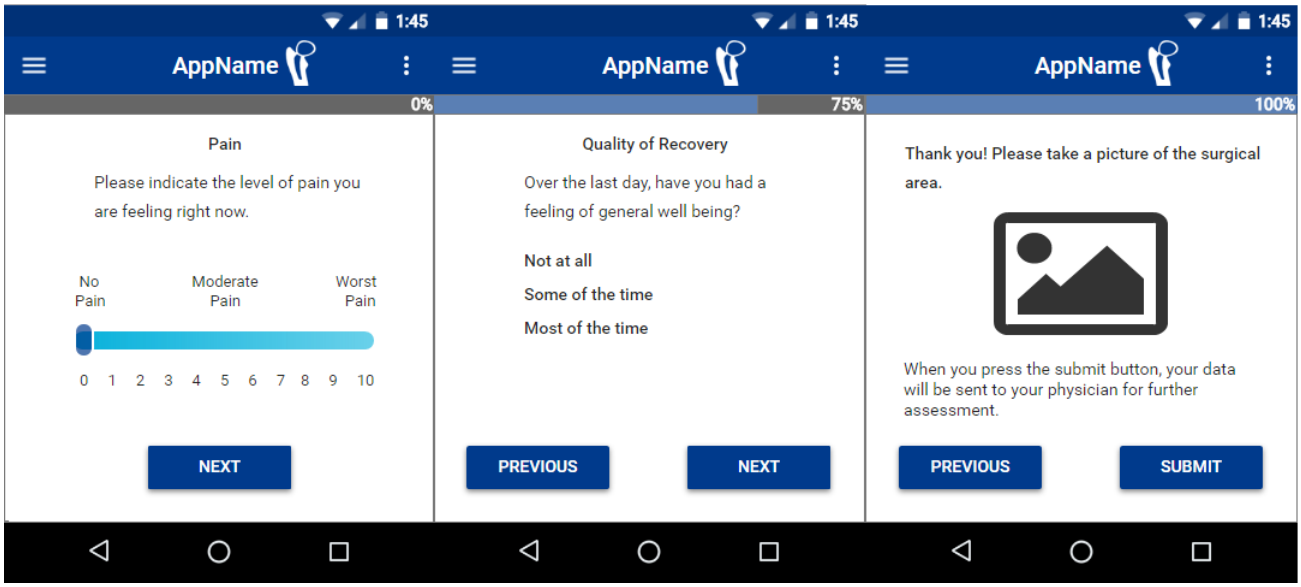



ABC 04:38 PM
Please indicate the level of pain you are feeling right now.
4
0-10 VAS Numeric Pain Distress Scale
No pain
Moderate pain
Unbearable pain
0 1 2 3 4 5 6 7 8 9 10
Note: the pain scale will have gradient coloring and a "slider" to adjust pain. It will be possible to go back one screen. This screen appears after choosing "Self-reporting".
ABC 04:38 PM
Over the last day, have you had a feeling of general well-being
0 Not at all
1 Some of the time
2 Most of the time
Note: a standard QoR statement. 1 of 9. Possibly have more options to choose from, such as "All of the time" e.g.
ABC 04:38 PM
How difficult is it to stand on your leg?
1
Not difficult
5
Extremely difficult
Note: questions regarding patients' mobility. 1 of 3. Gradient coloring + slider.

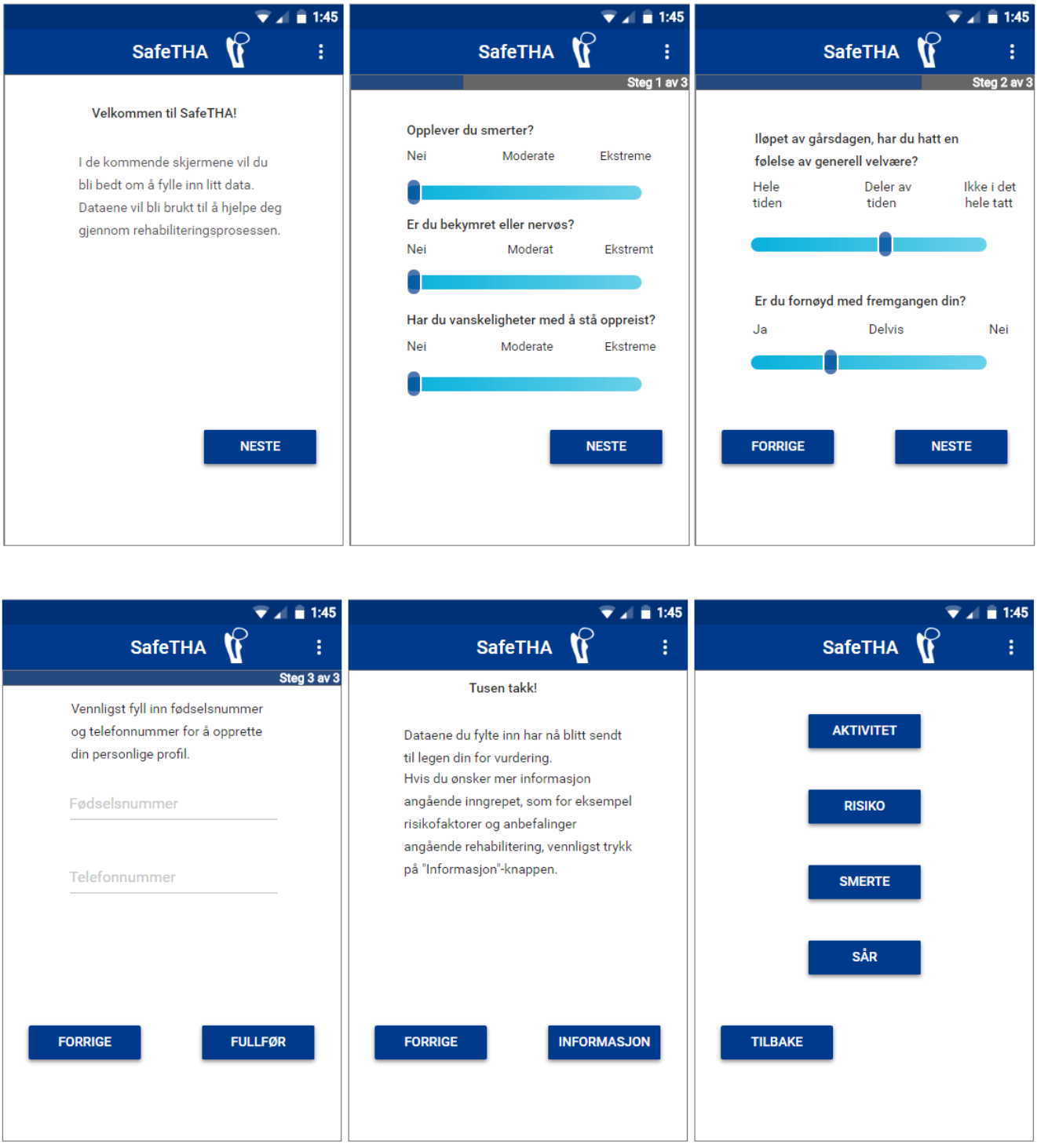

ABC 04:37 PM
How anxious, worried or nervous do you feel?
1
Not at all
5
Extremely
ABC 04:37 PM
Please take a picture of the surgical area
ABC 04:37 PM
Thank you! Your data will now be sent to your physician for further assessment. Do you wish to proceed?

C.2 Mid-Fidelity Prototype

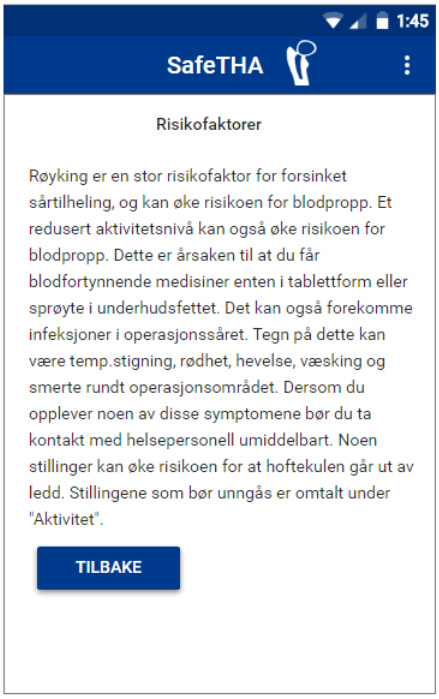




C.3 High-Fidelity Prototype

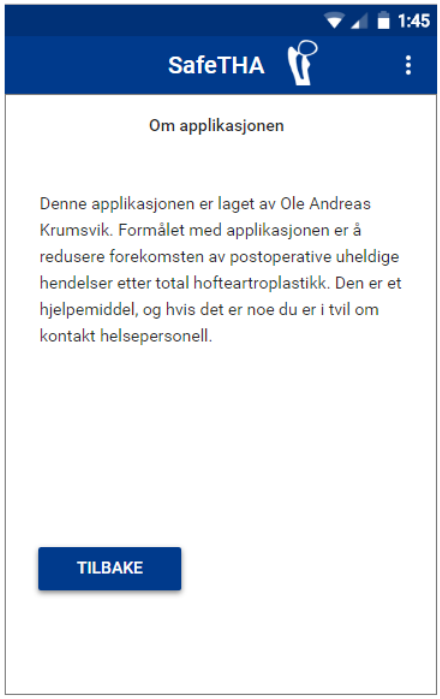



1:45
SafeTHA
Anbefalt aktivitetsnivå
Protesen din tåler full belastning, og derfor anbefales det å mobilisere så fort som mulig avhengig av smertenivå. Når du skal på toalettet bør du bruke toalettforhøyer. Aktiviteter som gir stor belastning på hoften, som til eksempel løping, hopping, bæring av tyngre ting, løfting fra lav høyde og kraftig vridning bør unngås de første 6 ukene. Deretter kan du gradvis begynne å øke belastningen. Du bør heller ikke sitte i dype stoler. Coxitstol anbefales første uken, og deretter en høy stol som spisestue-/kjøkkenstol de første 3 mnd. etter operasjonen.
TILBAKE


1:45
SafeTHA
Risikofaktorer
Røyking er en stor risikofaktor for forsinket sårtilheling, og kan øke risikoen for blodpropp. Et redusert aktivitetsnivå kan også øke risikoen for blodpropp. Dette er årsaken til at du får blodfortynnende medisiner enten i tablettform eller sprøyte i underhudsfettet. Det kan også forekomme infeksjoner i operasjonssåret. Tegn på dette kan være temp.stigning, rødhet, hevelse, væsking og smerte rundt operasjonsområdet. Dersom du opplever noen av disse symptomene bør du ta kontakt med helsepersonell umiddelbart. Noen stillinger kan øke risikoen for at hoftekulen går ut av ledd. Stillingene som bør unngås er omtalt under "Aktivitet".
TILBAKE


1:45
SafeTHA
Smerte
Smertene du opplever i forbindelse med inngrepet kommer til å være på sitt verste de 10 første dagene etter inngrepet. For å lette smertene, bør du ta smertestillende som anbefalt av lege. I utgangspunktet skal man ha så milde smerter ved utskriving at reseptfrie smertestillende skal tilstrekkelig som smertelindrende. Nedising av området kan virke lindrende. Selv om det er viktig å mobilisere, skal man få tilstrekkelig med hvile. Smertene du opplever er som regel forbundet med selve inngrepet. Hvis du opplever økende smerter etter utskriving bør du kontakte lege.
TILBAKE


1:45
SafeTHA
Hvordan håndtere operasjonssåret
Operasjonssåret har blitt lukket ved hjelp av selvoppløsende tråd eller hudstifter. Tråden løser seg opp i huden og blir nedbrutt av kroppen. Hudstiftene skal fjernes av helsepersonell. Strips skal sitte over operasjonssåret i 14 dager. Bandasjen du drar med fra sykehuset kan sitte inntil 7 dager med mindre den blir våt eller gjennomblødd. Skifte av bandasje skal bli utført av helsepersonell. For at såret skal gro fint og arret bli lite synlig, bør man legge strips over og gjerne bruke medisinsk tape så lenge som mulig. Så lenge arret er rødt bør man beskytte det, gjerne med medisinsk tape. Man bør heller ikke utsette det for soleksponering.
TILBAKE


1:45
SafeTHA
Om applikasjonen
Denne applikasjonen er laget av Ole Andreas Krumsvik. Formålet med applikasjonen er å redusere forekomsten av postoperative uheldige hendelser etter total hofteartroplastikk. Den er et hjelpemiddel, og hvis det er noe du er i tvil om kontakt helsepersonell.
TILBAKE

Appendix D

System Usability Scale Form

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Alder:

Kjønn:

Yrke:

Oppgaver:

1. Fullfør selvrapportering.
2. Tast inn et tilfeldig fødsels- og telefonnummer.
3. Finn frem til anbefalt aktivitetsnivå.
4. Finn frem til risikofaktorer.
5. Finn informasjon om applikasjonen

Appendix E

Related Publications

E.1 Full Paper - Informatics for Health 2017

Conference location and date: Manchester (England), 24-26 April, 2017.

A full paper was accepted and presented at the conference. The paper has been published by IOS Press in *Studies in Health Technology and Informatics*.

Informatics for Health: Connected Citizen-Led Wellness and Population Health
R. Randell et al. (Eds.)

doi:10.3233/978-1-61499-753-5-348

Designing an E-Learning Platform for Postoperative Arthroplasty Adverse Events

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[a] *Department of Information Science and Media Studies, University of Bergen, Norway*
[b] *Department of Biomedical Engineering, Linköping University, Sweden*

Abstract. This paper presents a mobile software application development for e-learning based on the adverse events data within the field of arthroplasty. The application aims at providing a learning platform for physicians, patients, and medical students. Design of user interface aims to meet requirements of several user groups concerned with the adverse events of the knee and hip implants. Besides the clinical patient data, the platform wants to include even electronic patient data as a result of self-monitoring. Two different modules were created, one for medical staff and one for patients, both divided into the knee and hip areas. Knowledge is represented in forms of statistics, treatment options, and detailed, actual adverse event reports. Patients are given a choice of recommendation for two main situations: '*about your diagnosis*', and '*what if you get a problem'* as advice and guidance during the postoperative rehabilitation. Expert evaluation resulted in acceptance of the concept and provided feedback ideas. The patient evaluation has also been positive. Implementation will mean that a high-fidelity prototype will be developed and tested in larger user groups (medical staff, patients).

Keywords. Adverse events, arthroplasty, HCI, e-learning, low-fidelity prototype evaluation, mobile application

1. Introduction

The occurrence of adverse events creates a lot of unwanted costs and distress for society. In Norway, from 2011 to 2015, 16838 compensation claims were filed. 5308 got compensated, which lead to 3,4 billion NOK in compensation costs. In addition to these costs comes patient suffering and absence from work, as well as diminished life quality. The leading field regarding adverse events in Norway was Orthopedics, with 37% complaints nationwide [1]. Currently, there are no known learning platforms or solutions that can help us prevent this problem concerning the field of Orthopedics. Therefore, we are suggesting a learning platform that can support several user groups (physicians, patients, and medical students) to learn from postoperative adverse events in Orthopedics, more specifically arthroplasty. The main motivation behind this learning platform is to utilize meaningful, useful data that can be used as educational material which is not being wasted. Efficient learning from and preventing adverse events can contribute to significant learning purposes. The idea is to base the learning platform on data that is generated through several medical sources, one of them being the application dedicated to safety reporting [4] and other relevant sources such as

[1] Corresponding Author: Ole Andreas Krumsvik, e-mail: oa.krumsvik@gmail.com

biomedical databases, patient electronic records, and the Norwegian Arthroplasty Register. By continuously using this data as educational material for the several above-mentioned user groups, the occurrence and severity of adverse events could decrease. Another beneficial effect is that the patient care can be improved and the excess costs reduced. An important factor would be to empower patients in recognizing an adverse event because the average number of hospital discharges is increasing, and therefore shortening hospital stays in most countries presumably leading to uninformed patients [2][8]. The typical length of stay after e.g. total hip arthroplasty is one or two days [6]. A similar learning platform for oncology has been developed in the U.S seeking to improve cancer care (CancerLinQ) which was done with great success by using data from 170 000 previously treated patients [3].

The prototype is divided into two modules, one for medical students and physicians and one separate module for patients. It is designed for mobile devices, which enables context-independent learning.

2. Method

The platform was created using multiple development methods. Firstly, a literature study combined with field studies have been conducted to define the information and user needs of the platform. Subsequently, a model of the architecture was created on the basis of this information, which is illustrated in the results section. Following that, a proposed design solution for the concept was created with the software *Axure RP Pro*. Lastly, the concept was evaluated through judgment of feasibility by two experts in biomedical engineering with emphasis on the module for medical students and physicians. The patient module was evaluated by a patient that has underwent hip replacement. All the users have participated in design [5] by suggesting their improvements or wishes for changes and adding some functionality. Additionally, to further assess the module, a mini focus group with 8 questions was conducted with a senior surgeon and four nurses.

3. Results and Discussion

A low-fidelity prototype of the e-learning platform for the physicians and medical students was made to assess the concept and aid further development. Additionally, a model of the platform architecture (Figure 1) was created in collaboration with other developers [4] and the medical staff at the Haukeland University Hospital in Bergen. The architectural foundation is based on various databases such as patient electronic records, registry, and safety reporting data with the results of information retrieval, patient self-reporting data, and biomedical databases maintained by the Biomedical Laboratory. All of these data sources have valuable information that should contribute to the safety of patients and design of better IT services. HL7 standards will be used to exchange, integrate, share, and retrieve data [7]. Developing two different sets of applications, namely *Safety reporting application* and *Safety learning* would make a great use of the existing data and contribute new data to the less covered aspects of safety reporting in line with the occurrence and adjudication of adverse events. The learning part (Figure 1) of the architecture is quite unique as it attempts to make applications for several user groups interested in learning about the safety. Those are

physicians, medical students, biomedical engineers, and patients as a completely new group. Data regarding postoperative patient care as well as the education can be enabled using the IT technology.

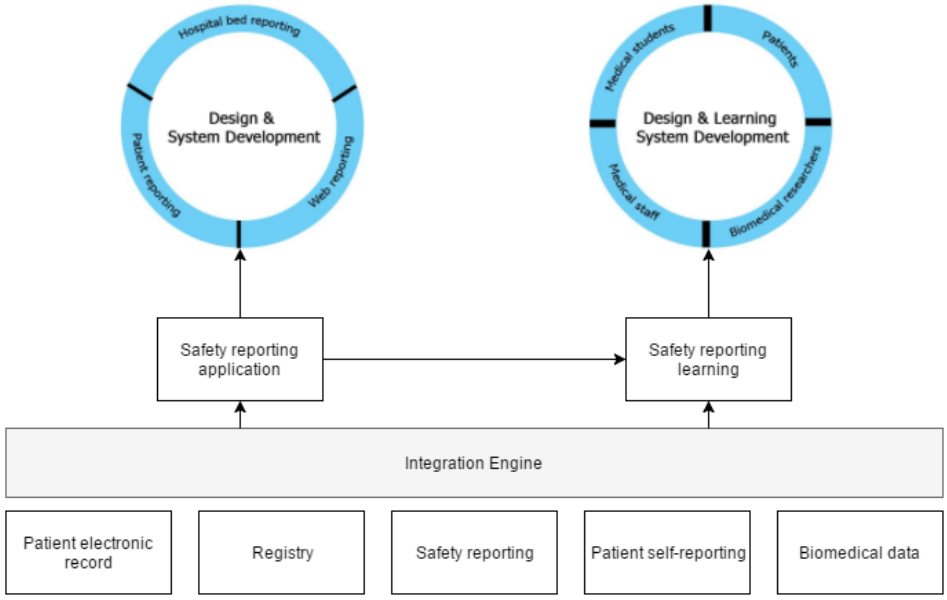

Figure 1: Platform architecture. Author's module – Design & Learning System Development.

Figure 2 (a) shows an overview of the knee. The red dots indicate an area of the knee in which a surgical procedure was performed. Figure 2 (b) presents a list of related adverse events in the given area that was chosen in Figure 2 (a). In this example sorted by severity. Figure 2 (c) displays three different options concerning the adverse event chosen in Figure 2 (b).

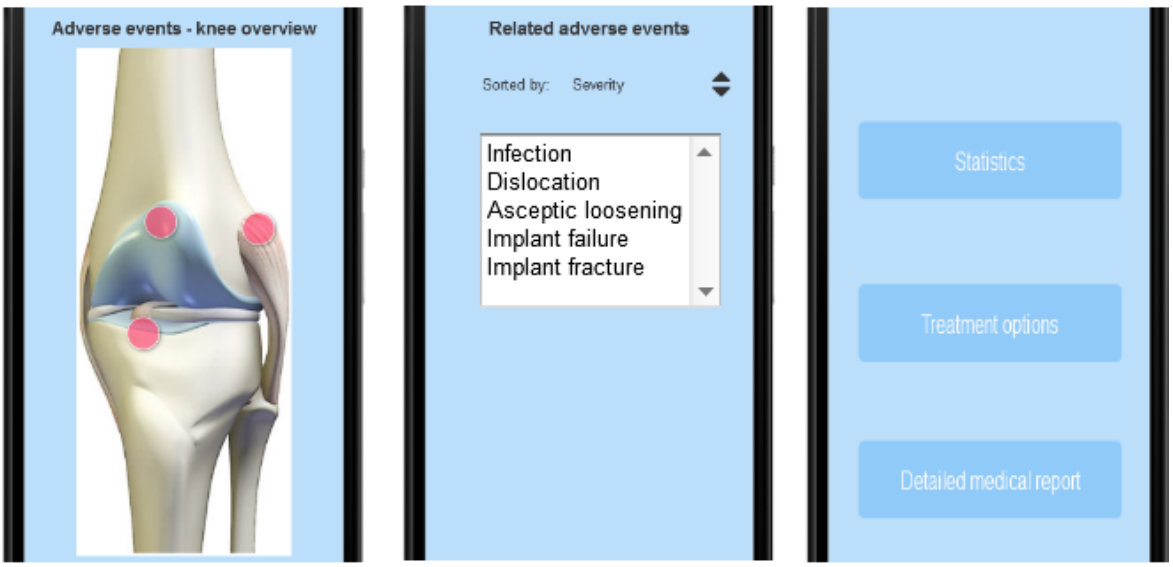

Figure 2. (a)Selecting an adverse event in the knee example (Screenshot); (b) List of adverse events sorted by severity example (Screenshot); (c) Three different options after selecting an adverse event from Figure 2 (b) (Screenshot).

The judgment of concept has been unreservedly positive. The clinician, a senior surgeon, has seen its potential to educate different types of patients and was very positive towards learning and using data for both students and patients. A profiling of the patient population that would be enabled by the common platform could be utilized to address patients' specific needs. One of the experts in biomedical engineering had considered the platform to be a very good concept, and definitely a feasible one. He had viewed it as a great use of existing new technologies, such as big data and internet of things. Furthermore, he suggested that it can be viewed as a tool for decision support making, and not solely a learning platform. He had provided suggestions on the design structure for further development. In particular, the design should give a possibility to add a rotatable model of the knee to the Figure 2(a), and to enable selecting several areas if the patient had multiple injuries. Additionally, in Figure 2(c) it could be reasonable to combine statistics and treatment options since each treatment would have a statistic associated with it. "Detailed medical report" would be better presented as "Case studies", with a list of cases that match the patient, adverse event, and treatment options. Lastly, he suggested to add a screen for patient details with basic options to cover the major risk factors such as age, sex, height, weight.

Presently, the patient module is design to contain relevant pre- and post-operation information, as well as relevant rehabilitation information to aid the patient throughout the whole treatment and to enable self-monitoring. One patient, a female, 51 years of age, who had recently undergone the hip replacement had evaluated the concept. Her assessment of the patient module was that it was *'a great idea'*. She appreciated that the information was easily accessible. By making the clinical and patient information available in any context, pre- or post- operatively, would make it beneficial for patients. The process would be easier both physically and mentally for the patient, especially during rehabilitation. The person has stated that the idea of self-monitoring with the help of this platform would be *'a great relief'*. Moreover, the focus group which consisted of a senior surgeon and four nurses from Linköping University Hospital, were very positive towards the module and emphasized its importance concerning patient safety.

4. Conclusion

Adverse events are difficult to manage from many points of view. The urgency of care, severity of cases and pressure to document the course of events are challenging for both medical staff and patients. It seems to be difficult to learn and utilize the knowledge of past events in a cost-beneficial way. This study has explored possibilities of using mobile and web technologies to define a concept and platform that would integrate data resources and create tools useful for medical staff and patients. The resulting conceptual design has been met with appreciation and several suggestions as how to improve the design solutions. Future steps will include designing the study cases, their presentations for physicians and students through different learning options. Patients' educational needs, and their options for self-monitoring, will be subject of design studies, as well.

Acknowledgments

The authors would like to thank Paul Johan Høl, PhD, Peter Ellison, PhD, and Geir Hallan, MD, PhD for their valuable insights into the design and the field based comments.

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E.2 Abstract - European Medical and Biological Engineering Conference 2017

Conference location and date: Tampere (Finland), 11-15 June, 2017.

A one-page abstract has been accepted to the conference.

A self-reporting tool to reduce the occurrence of postoperative adverse events after total hip arthroplasty

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I. INTRODUCTION & AIM

The occurrence of adverse events in health care creates a lot of unwanted costs and distress for society. In Norway, from 2011 to 2015, 16838 compensation claims were filed. 5308 people got compensated, which lead to 3,4 billion NOK in compensation costs. In addition to these costs comes patient suffering and absence from work, as well as diminished life quality. The leading field regarding adverse events in Norway was orthopedics, with 37% complaints nationwide [1].

Therefore, a self-reporting mobile application prototype for Android has been developed to help reduce these severe outcomes, more specifically regarding postoperative adverse events after total hip arthroplasty. The application is a segment of a safety reporting platform.

The aim of this study was to assess the feasibility of the prototype in the aforementioned setting, as well as evaluating the design.

II. METHOD

A user-centered design approach was utilized in order to develop the prototype [2]. Thereafter, an individual expert review was conducted with two experts in Interaction Design to evaluate it [3]. The review consisted of prototype testing, followed by a discussion.

Furthermore, an interview was carried out with a physiotherapist assessing the questions regarding self-reporting and the prototype

III. RESULTS AND DISCUSSION

The application enables the patient to report pain, anxiety, quality of recovery, mobility, and to take a picture of the surgical area which is expected to reduce the occurrence of adverse events. In addition to that, recommendations for the patient on how to reduce risk factors are also included.

The HCI experts stated that it was a useful application and very suitable for mobiles. Expert number one suggested to let some features directed towards self-reporting be optional, e.g. a picture of the surgical area. Expert two highlighted the importance of adding feedback from the application to the patient, such as *'the report has been read by your physician'*.

The physiotherapist was pleased with the self-reporting questions, as well as with the prototype itself. He has also suggested to add a question concerning if the patient had trouble getting in and out of bed.

The findings indicate that the prototype is very feasible in terms of postoperative self-reporting after total hip arthroplasty. Using the application to gather more data will contribute to a long-term improvement of patient self-reporting. In addition, patient data will help to complete the clinical picture during the postoperative recovery.

ACKNOWLEDGEMENTS

The authors would like to take this opportunity to thank professor Jonas Löwgren, professor Magnus Bång, and physiotherapist Arnold Nilsen for their contributions.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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3. Wilson, C. (2013). User Interface Inspection Methods. Burlington, Massachusetts

E.3 Full Paper - International Conference on Informatics, Management and Technology in Healthcare 2017

Conference location and date: Athens (Greece), 7-9 July, 2017.

A full paper has been accepted and will be presented at the conference. The paper will be published by IOS press as e-book and indexed in *MEDLINE*.

Designing a safety reporting smartphone application to improve patient safety after total hip arthroplasty

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Abstract. This paper presents a safety reporting smartphone application which is expected to reduce the occurrence of postoperative adverse events after total hip arthroplasty (THA). A user-centered design approach was utilized to facilitate optimal user experience. Two main implemented functionalities capture patient pain levels and well-being, the two dimensions of patient status that are intuitive and commonly checked. For these and other functionalities, mobile technology could enable timely safety reporting and collection of patient data out of a hospital setting. The HCI expert, and healthcare professionals from the Haukeland University Hospital in Bergen have assessed the design with respect to the interaction flow, information content, and self-reporting functionalities. They have found it to be practical, intuitive, sufficient and simple for users. Patient self-reporting could help recognizing safety issues and adverse events.

Keywords. User-centered design, HCI, adverse events, self-reporting, patient empowerment

Introduction

Patient safety is a subject of concern for healthcare providers and the industry. In the field of arthroplasty, safety enhancing procedures are developed for both staff and patients. Information given to patients is mainly in the form of instructions concerning the perioperative treatment. Currently there are no technological solutions that could enable patients to report severe adverse events and prevent damages. There is evidence of cases when patients come to hospitals with significant postoperative injuries and long periods of sustained pain.

The outcome of adverse events has a negative impact on patient well-being, societal costs, as well as the reputation of healthcare. In Norway, from 2011 to 2015, 3,4 billion NOK was paid out in compensation costs related to the outcome of adverse events. The field of Orthopedics was responsible for 37% of the compensation claims [1]. Therefore, one could take advantage of mobile technology to prevent the occurrence of severe adverse events.

This research sees value of empowering patients not only through the general information, but also through capturing patient main data such as pain level, anxiety,

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mobility, progress, and quality of recovery. Similar efforts have been done by Nelson et al. [2] and Dine et al. [3].

The design described in this paper is based on the clinical practices in Norway which informs patients about the major course of recovery, risks, expected level of pain, mobility, and surgical area management [4].

A possible advantage of mobile technology is to facilitate for communication and interaction between patients and healthcare staff. Successful experiences have been seen in oncology [5] and heart disease [6] resulting in improving the quality of patient care.

A safety reporting smartphone application was created to prevent the occurrence of severe postoperative adverse events. This was done by enabling self-reporting throughout the whole course of rehabilitation.

1. Method

A user-centered design approach [7] was utilized in order to achieve an optimal result regarding user experience, as the framework extensively emphasizes requirements by addressing possible users in the design process, prototyping, and evaluation. The application requirements were gathered at an early stage in the development process through a field study and a literature search, combined with a discussion involving biomedical experts and a chief surgeon at the Haukeland University Hospital in Bergen, Norway.

Firstly, to evaluate the application's interaction flow and design, an expert review [8] was carried out with an experienced academic in Human-Computer Interaction.

Secondly, SafeTHA's content and suitableness was discussed with a physician in an open interview. In addition, the physician tested the prototype by completing the self-reporting process.

Thirdly, a female nurse, 51 years of age, that has recently undergone total hip arthroplasty tested the application and provided feedback.

Lastly, a physiotherapist assessed the statements regarding mobility as well as the prototype.

2. Results and Discussion

The field research has influenced the content and functionalities of the application, which was designed primarily for Android devices by using a prototyping application named Axure RP Pro [9]. SafeTHA enables and aids patients, the primary user group, to self-report important factors and prevent postoperative adverse events such as pain, anxiety, mobility, as well as help with the progress, and quality of recovery. Additionally, it informs patients about recommended activity levels after surgery, risk factors and how to reduce them, manage the surgical area, and pain aspects.

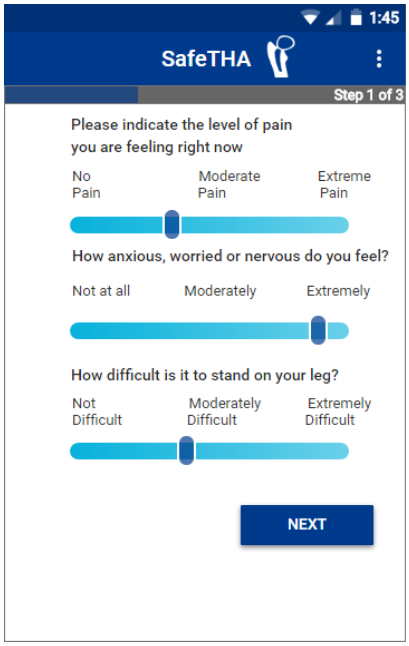

Figure 1. Self-reporting of pain, mobility, and anxiety (Screenshot).

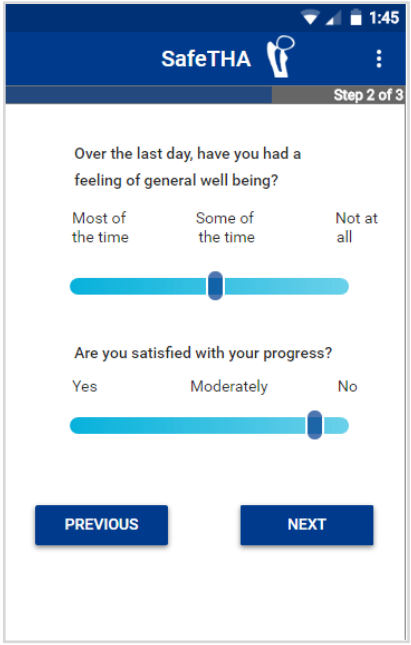

Figure 2. Self-reporting of quality of recovery and progress (Screenshot).

The first self-reporting screen, depicted in Figure 1, enables the user to assess pain, anxiety, and mobility. The physiotherapist suggested that one could add several statements to mobility, e.g. "*do you have any problems getting in and out of bed*?", however the HCI expert advised against it. The expert highlighted the importance of making the self-reporting process as effortless as possible. The physician had a similar point of view; to lower the threshold of self-reporting. In addition, he suggested to add a help text to the pain and anxiety statements, as there could be a misconception regarding how they are interpreted in this self-reporting context.

Figure 2 illustrates the second self-reporting screen, which contains a quality of recovery statement and a statement regarding the patients' progress. One of the previous designs included a possibility of taking a picture of the surgical area, however the expert in HCI was against it and claimed that it would lead to low-quality data. Initially, the physician thought gathering pictures was a great idea, however it could increase the possibility of contamination and could lead to an increased risk of adverse events. Therefore, he suggested to add a statement concerning patient progress instead.

Furthermore, the physician found the self-reporting statements to be satisfactory for gathering data, as well as useful and sufficient for preventing the occurrence of adverse events. As for reporting frequency, he recommended that patients could report daily the first postoperative week, followed by two times the second week, and once in week three and four respectively. The former patient thought the application was straight-forward, easy to navigate, and would be a simple way to carry out the self-reporting. Moreover, she proclaimed that by having health personnel monitor the patients' current status would be a "*great relief*". Mobile technology is widely available and makes it possible to access the general information about the patient context-independently. Most patients carry their smartphone everywhere, which could be highly valuable for self-reporting and capturing the data regarding discomfort and pain.

The physician stated that the general information in SafeTHA was adequate, as it covers all the information that patients are concerned with after hospital discharge. The information given to patients vary greatly from hospital to hospital, but the essential information is captured within the current design.

When a patient has completed the self-reporting, starting at day 1 after the surgery, a summary of the report in PDF format is sent to healthcare personnel, the second user group. Thereafter, if they notice any major differences such as pain level at day 6 is worse than at day 1, there is a possibility for a timely intervention via direct contact

with the patient. A staff member has the opportunity to assess the patient situation and advise. An example of the self-reporting visualization regarding pain level can be viewed in Figure 3. The data filled in by the patient is on the scale from one (best) to ten (worst).

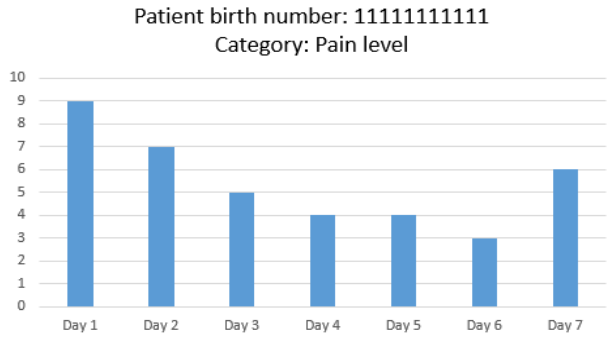

Figure 3. Example of pain level visualization (Screenshot).

The purpose of SafeTHA is to assist the detection of adverse events, however one cannot solely rely on the application. According to the physician, the application could also uncover how good healthcare is at providing services, not only limited to the surgical domain. Lastly, he added that self-reporting in general is highly relevant and of great importance.

3. Conclusion

The design has enabled a simple, straightforward way of self-reporting the patient's current state post-surgery. The findings indicate that the application is capable of capturing an early onset of adverse events. It affords an interaction between patients and healthcare staff in a simple, easy to follow manner. Evaluation has been carried out with an HCI expert and healthcare professionals. They have evaluated the interaction flow, content of information, as well as self-reporting, and found it to be practicable, intuitive and sufficient.

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