University of Bergen

Master Thesis

Mobile Design For Adverse Event Reporting And Pharmacovigilance

Author:
Hanne Åserød

Supervisor:
Ankica Babic

A thesis submitted in fulfillment of the requirements for the degree of Master of Information science

in the Department of information science and media studies

June 1, 2017

List of Figures

Abstract

Patient safety is concerned with protecting patients from errors, injuries, accidents, and infections. It is also concerned with capturing adverse events and understanding their severity. Reporting of adverse events help prevent poor patient outcomes in their acute phase. Another way of dealing with adverse events is by preventing them through the practice of monitoring the effects of drugs, medical devices including the detection, assessment, and understanding of an adverse event; this approach is called pharmacovigilance. Design Science framework was used for creating two mobile design solutions in the field of arthroplasty: one for the adverse event reporting and the other one for the pharmacovigilance. User centered design was utilized to understand requirements, context, and possibilities of managing and retrieving information of relevance for patient safety. Firstly, a mobile design for reporting of adverse events has proposed user interface to enable entry of data specific for knee and hip implants. Besides that, the system supports entry of the adverse event, its classification (serious, non-serious), its follow-up. Safety reports can be initiated and retrieved on request and depending on the adjudication of the event. Suspected severe events should be followed up and reported internally as well as to the national regulatory authorities until they are resolved and concluded. Expert evaluation of the first design solution was performed using low fidelity prototype. It has shown that design was relevant, straightforward, done in a way that official reporting would commence. Some users were positive to the reporting; some felt it would demand more work. The second design was focused on pharmacovigilance which seemed to be more appealing to the target group. It deals with the safety of medical devices (implants) by understanding the risks and dangers already reported by other clinicians or researchers. Internet resources such as the Manufacturer And User Facility Device Experience (MAUDE) web-site are often retrieved due to the lack of internal, local safety databases. The designed mobile solution for pharmacovigilance was based on the web system called WebBISS (Web-based implant search system) using HCI approach. The goal was not only to improve usability, but also to stimulate physicians to enter their safety data and become contributors, and not only users of information. The expert evaluation has been positive and encouraged developing stronger help and error reporting functions regarding the mobile application.

Acknowledgments

Firstly, I would like to thank my supervisor, Dr. Ankica Babic for sharing her knowledge, providing guidance, feedback, and motivation.

I would also like to thank Dr. Peter Ellison at the Imperial College London and the Biomaterial Research group at Haukeland University Hospital and Dr. Paul Johan Høl at the Biomaterial Research Group at Haukeland University Hospital for taking the time to discuss, review and give me feedback at different times during the thesis.

Secondly, I would like to extend my gratitude towards Professors Jonas Löwgren and Magnus Bång from Linköping University for the feedback and review of my work.

I am also thankful for my roommates at 635, Ole Andreas Krumsvik, Simen Jensen and Eivind Flobak for the laughs, motivation, help and support.

Huge thanks also goes to my family and friends for encouraging words, support and distracting me when needed. And last but not least I would also like to thank all participants in my research for their time and help.

Contents

Chapter 1

Introduction

In this chapter, the most important aspects of the research and development will be reflected on. Challenges, potential methods will be addressed, and research questions will be formulated. The research considers utilizing Design Science Research approach was as the guiding principle throughout the master thesis project. Following the guidelines by Hevner[8] is instrumental in securing the holistic structure of the research. Two separate designs were considered and tested for reporting of adverse reports after arthroplasty. This is done as a part of expert knowledge elicitation and according to wishes of the clinical staff. One mobile solution was to be dedicated to adverse event reporting starting from the patient bedside, for the second one pharmacovigilance was considered as means of monitoring and predicting adverse events. Both of them are intended to contribute to patient safety, although in different ways. Only one of the design solutions (pharmacovigilance) seemed to have more appeal to the medical staff with the reason being not the design, but rather the clinical routines and attitude towards the safety reporting. Literature suggests different attitudes towards reporting[9, 10, 11]. Additional work burden and a threat to the professional reputation are reported as obstacles for an adverse event reporting. There is a possibility that the web and mobile technology could be combined to support reporting process, but they might not be the whole answer to the challenges.

1.1 Methods

Several methods could be used to acquire requirements, create designs and involve potential user groups to elicit knowledge and evaluate the design solutions (artifacts). A literature review can be a starting point to assemble the information needed for the safety reporting design(Chapter 2). Due to the well-known facts, and needs for the safety reporting as a part of patient safety, surprisingly many details are available. The process of reporting could be delineated in general terms which are useful to create a design to which clinical staff could easily relate and suggest changes and comments.

Semi-structured interviews were used to elicit expert knowledge from human computer interaction experts and the clinical staff regarding their current clinical routines and needs for safety reporting (Chapter 5). This has been a very good approach especially regarding the design concept and evaluation to which both the experts and clinical staff responded. When it comes to eliciting the knowledge from clinical staff the most cooperative and constructive was the participants from the Biomedical Laboratory at the Haukeland University Hospital in Bergen (Chapters 2, 9, 10). They are dealing with the safety reporting daily and would benefit from a fully functioning online safety reporting system.

Design Science Framework was used for designing and assessing user experience. It was flexible to secure the purpose driven creation of two artifacts as a solution for the relevant problem (adverse event) using four research cycle (Chapters 2, 8). User experience was central to artifacts (Chapters 2, 10) since they are intended for end users who already feel reluctant to do the reporting.

Observation was used only during the evaluation when the observer was present to answer possible questions and observe if there were difficulties using the device with a high-fidelity prototype (Chapter 10, 11).

1.2 HCI methods

Interaction design and UX methods were applied to aid in the design process. The design iterations consisted of sketches, mock-ups, requirements and eval-

uation before repeating for the next step. Involving stakeholders at an even earlier point as possible would create better design and requirements. Also, a larger number of evaluators would be a good choice.

The last two steps should be creating a prototype and testing or evaluating the prototype depending on if it is a low or high fidelity.

Starting from a low fidelity prototype and continuing up to a high fidelity prototype creates a solid design basis to make choices and to also get concrete feedback from evaluators. Prototyping is necessary to avoid spending a large amount of time and money on developing something that users either don not like or find too hard to use, so that do not abandon it or find an alternative.

Development methodology was mainly adapted Kanban[12] that was instrumental in keeping control over the work and timelines. This simple and easy to follow method was efficient and recommendable for a single project developer. More complicated Agile methods would demand the presence of the stakeholders, potential users who would be hard to secure on the permanent basis in master thesis type of project. This has not excluded experts who were present in the elicitation and evaluation work (Chapters 9, 10).

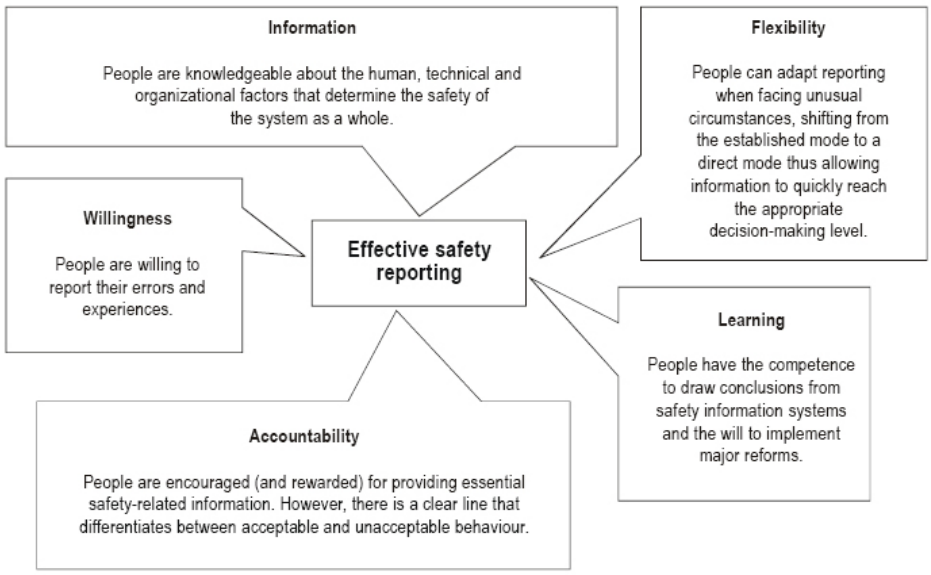


Figure 1.1: Factors influencing effective safetyreporting[1]

Safety reporting is a complex process as illustrated in figure 1.1. That is very important for all involved in health care, medical and pharmaceutical industry. The ever growing number of devices, medicines, and related treatments is ever high. Monitoring and reporting adverse events is of vital importance. The ways of reporting are not often consistent, well designed or transparent. The attitude towards reporting is defined by several key moments: information, willingness, accountability, feasibility, and learning which is explained in figure 1.1[1]. The research has also identified additional factors that can impact the clinical reporting: the work burden, professional reputation, and poor consistency of reporting. In this research we were not dealing with the attitudes, but rather looking into possibilities of designing solutions that would be acceptable. The clinical processes are too complex to interfere with. Another major issue with a project like this is getting enough time with medical staff. Some of the junior staff and newly graduated were unsure and did not really know about adverse event reporting. More senior staff knew what to do, but felt they were not as compliant with the reporting as they could be. During the interviews, it was revealed that the first reason for this was the work burden. Whatever the reason, the design should not be imposed on anybody as the means of changing the attitude.

1.3 Research Questions

Research Question 1: How could mobile technology design support adverse event reporting?

Research Question 2: How can interaction design support building sustainable and appealing solutions for adverse event reporting?

Chapter 2

Research overview

This chapter will present topics relevant for this thesis. The research is multidisciplinary and relies on several well established fields. The main objective is to design good mobile solutions for which theory about Human Computer Interaction (HCI), interaction design and Ux which are central. There are several other fields offering methods and structure that are necessary for the work of this thesis. The application domain is within p reporting, but some relevant examples from other fields are given to illustrate importance of the interaction, interface, placement and appeal to users.

2.1 Medical informatics

The field of Medical informatics is the study and application of methods to improve management of patient data, clinical knowledge, and other information that is relevant to patient care and health. It is a multidisciplinary field, which includes clinical sciences, public health, cognitive computing and information sciences [13]. Medical Informatics is also concerned with the management and use of information in biomedicine. The individuals working in Medical Informatics have diverse backgrounds and levels of training. According to Hersh(2002) some core themes in Medical Informatics are information systems, terminology, system integration, standardization to help data move easier across systems and platforms. One of the core themes in is also usability. The systems should be integrated into the workflow and offer

benefits if they require some extra time or effort from the user. A crucial part of the field is to account for the needs and concerns of everyone who is a part of the process. This would mean patients, clinicians, payers, and governments[14].

2.2 Safety reporting

Patient safety is concerned with protecting patients from errors, injuries, accidents, and infections. It is also concerned with capturing adverse events and understanding their severity. Safety reporting commence through safety reports which contain information about an adverse event or near miss event.

Adverse event is 'any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment [15]. Near miss is an incident that almost happened. It is any event that arises during care that might have, but did not lead to unexpected harm, loss or damage.

Reporting of adverse events from the point of care is voluntary in the majority of countries which does not apply to the severe adverse events. Healthcare professionals and consumers may also report these events to the products' manufacturers. If a manufacturer receives an adverse event report, it is required to send the report to national regulatory authorities as specified by regulations.

2.2.1 Safety report

A report that contains information about a suspected adverse event or near miss. It varies from country to country if near misses are reported or not, the same for adverse events.

This chapter will present topics relevant to this thesis. The research is multidisciplinary and relies on several well-established fields. The primary objective is to design a good mobile solutions for which theory about Human Computer Interaction (HCI), interaction design and Ux which are central. There are several other fields offering methods and structure that are necessary for the work of this thesis. The application domain is within patient

safety reporting, but some relevant examples from other fields are given to illustrate the importance of the interaction, interface, placement and appeal to users.

2.3 Medical informatics

The field of Medical Informatics is the study and application of methods to improve management of patient data, clinical knowledge, and other information that is relevant to patient care and health. It is a multidisciplinary field, which includes clinical sciences, public health, cognitive computing and information sciences [13]. Medical Informatics is also concerned with the management and use of information in biomedicine. The individuals working in Medical Informatics have diverse backgrounds and levels of training. According to Hersh(2002), some core themes in Medical Informatics are information systems, terminology, system integration, standardization to help data move easier across systems and platforms. One of the core themes in is also usability. The systems should be integrated into the workflow and offer benefits if they require some extra time or effort from the user. A crucial part of the field is to account for the needs and concerns of everyone who is a part of the process. This would mean patients, clinicians, payers, and governments[14].

2.4 Safety reporting

Patient safety is concerned with protecting patients from errors, injuries, accidents, and infections. It is also concerned with capturing adverse events and understanding their severity. Safety reporting commence through safety reports which contain information about an adverse event or near miss event.

An adverse event is 'any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment[15]. Near miss is an incident that almost happened. It is any event that arises during care that might have but did not lead to unexpected harm, loss or damage.

Reporting of adverse events from the point of care is voluntary in the majority of countries which does not apply to the severe adverse events. Healthcare professionals and consumers may also report these events to the products' manufacturers. If a manufacturer receives an adverse event report, it is required to send the report to national regulatory authorities as specified by regulations.

2.4.1 Safety report

A report that contains information about a suspected adverse event or near miss. It varies from country to country if near misses are reported or not, the same is true for adverse events.

2.5 Pharmacovigilance

The World health organization defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects." They have also widened the definition to include: herbals, traditional and complementary medicines, blood products, biological, medical devices, vaccines. Pharmacovigilance goal is to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions, improving health and safety when it comes to using of medicines, contributions to assessment of benefit, harm, effectiveness, and risk of medicines, encourage safe and rationale use, promote understanding education and training in pharmacovigilance and effectively communicate with the public [15]

The number of adverse drug reactions (ADRs) has resulted in an increase of data that needs to be handled and also an increase in the need to understand pharmacovigilance. Expertise is required to be able to detect risk and defending products against inappropriate removal. Pharmacovigilance plays an important role in ensuring that there is enough information, so that doctor and patients know enough to make an informed choice. And it is essential that when ADRs occur, especially previously unknown. It is very important that these are reported and analyzed and also communicated[16] Monitoring

through pharmacovigilance activities, mining, spontaneous reporting, observation, and database studies allow for post-market monitoring and longer follow-ups for periods of patients. With a broad range of characteristics, providing valuable means for detection, quantification, and where reduction of ADRs is possible. It could also lower health care costs in the process [17]

Pharmacovigilance is important in ensuring that doctors and patients have enough information to make a decision when it comes to choosing drugs for treatment[18]

2.6 Adverse Event Reporting and Pharmacovigilance

Adverse event reporting systems can only facilitate learning and prevent harm if good data are collected. Indeed, on some occasions, adverse event reporting systems were described as little more than data-collection tools to generate a hypothesis that can trigger further investigation of the adverse event and lead to action if required.[19]

"If the healthcare industry wants to learn from its mistakes, miss or near miss events, it will need to take incident reporting as seriously as the health budget" [19, p. 1]

Five key challenges emerged as reasons why incident reporting systems had been unable to reach their full potential: (1) reports were inadequately processed; (2) there was inadequate engagement of clinicians, particularly doctors, to report incidents; (3) there was insufficient action enacted in response to reports; (4) there was inadequate funding and institutional support of incident reporting systems and (5) reporting systems were not taking full advantage of the evolving health information technology developments.

Both doctors and nurses believe they should report most incidents, but nurses do so more frequently than physicians. To improve incident reporting, especially among physicians, clarification is needed on which incidents should be reported, the process needs to be simplified, and feedback given to

reporters.[10]

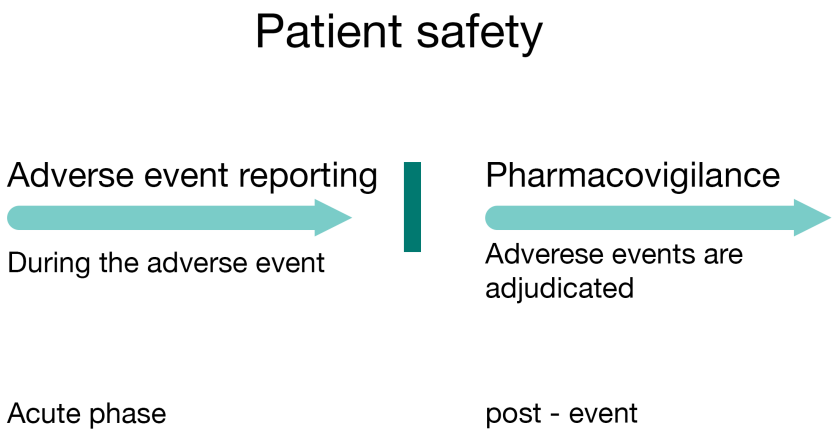


Figure 2.1: Patients safety model

The thesis researches both adverse event reporting and pharmacovigilance. The main difference is the time perspective: adverse event reporting covers the acute phase of adverse events, as it is happening while pharmacovigilance puts to use the already published adverse events.

2.7 Arthroplasty

Arthroplasty is a surgery that is performed to restore patients range of motion and in some case to also relieve pain. This is done by operating on a dysfunctional joint, and either realigning or reconstructing[20]. Arthroplasty is the field of medicine dealing with the surgical reconstruction and total replacement of degenerated joints. Arthroplasty requires the use of prosthetics; thus key factors such as biomechanics, prosthetic design, metallurgy, and biomaterials are taken into account for surgical procedures[21]. Figure 2.2 and 2.3 Shows implants and anatomy of the hip and knee joint. The images show implants related total hip replacement and total knee replacement.

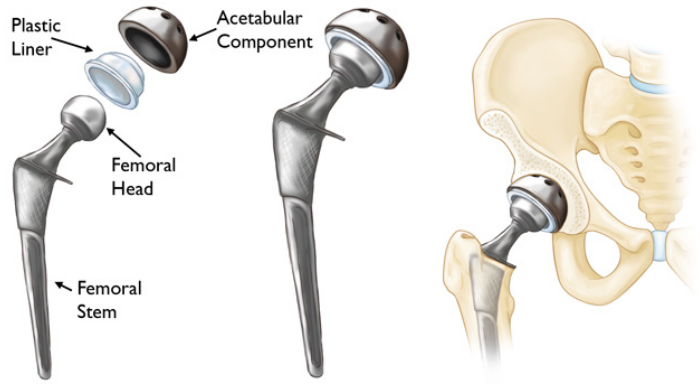


Figure 2.2: (Left) The individual components of a total hip replacement. (Center) The components merged into an implant. (Right) The implant as it fits into the hip. [2]

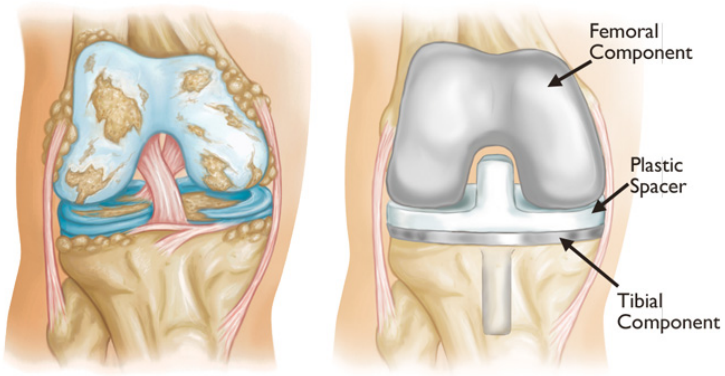


Figure 2.3: (Left)Left) Severe osteoarthritis. (Right) The arthritic cartilage and underlying bone have been removed and resurfaced with metal implants on the femur and tibia. A plastic spacer has been placed in between the implants [3].

2.8 Human Computer Interaction(HCI)

In HCI it is important to understand practices and activities as requirements and envisioning possibilities for design. Venturing into the exploration of

new design spaces and comprehending new systems and devices through an evolution of activity and artifact together. The significance of HCI is that the field investigates, develops and harnesses areas of possibility as a means to enhance the human experience and activity. One of the first export from the field of HCI was user experience design and interaction design [22].

2.8.1 Human Computer Interaction for mobile devices

There are five main challenges present for HCI-designers when trying to design for mobile.

1. *Designing for mobility* The user may have far from the ideal working environment because they are mobile, they are more likely *on the go*. With that, the working environment changes drastically depending on the users with space and movement[23].
2. *Designing for widespread population* Many users will lack formal training in the technology and might consider their mobile devices as devices to be used and not as computers to be maintained [23].
3. *Designing for limited input/output facilities* Screen sizes will be considered small even if visually things might look better. The output of sound will vary greatly in quality and also keyboards other pointing devices will be difficult to use while on the go [23].
4. *Designing for incomplete and varying context* Various sensors and networks mobile devices can be made aware of their context(current location etc). This gives the system new information but also brings issues of implying task and user level activities from sensor information and unreliable or patchy sensor coverage [23].
5. *Designing for users multitasking at levels unfamiliar to most desktop users* The frequency and possibility of interruptions are greater when using mobile devices compared to when using desktop [23].

2.8.2 Human computer interaction in health care

There are things that are important such as how the interface works and looks in different situations related to health. Not just the type of system being designed, but also show what dangerous situations that might arise from badly designed interfaces. Such as choosing wrong setting on button when in a stressed situation of misunderstanding the choice that can be made. While not all errors are fatal, it is important to avoid accidents when in hospitals. I have also taken a look at other systems that have been a digitalization of previously paper-based procedures.

Mival and Benyon have designed an example medical application with a focus on UCD. The project uses RFID technology to connect surgical towels and potentially any other surgical devices that are being used and let them communicate and share information between them. The idea is that if a system can identify surgical towels, track them and share their location to other systems. This would help to reduce the number of cases where these towels are forgotten. RFID antennas are installed in the operating room; this enables the system to track the towels over three chosen locations. And more importantly, will contribute to nurses and surgeons' certainty that no towels are missing or forgotten in the abdominal cavity. The three chosen locations are the mayo stand which is a sterile tray on which surgical tools and towels are laid out for the team. The operating table where the patients are, and also the trash can where surgical paraphernalia and the towels are placed when finished.

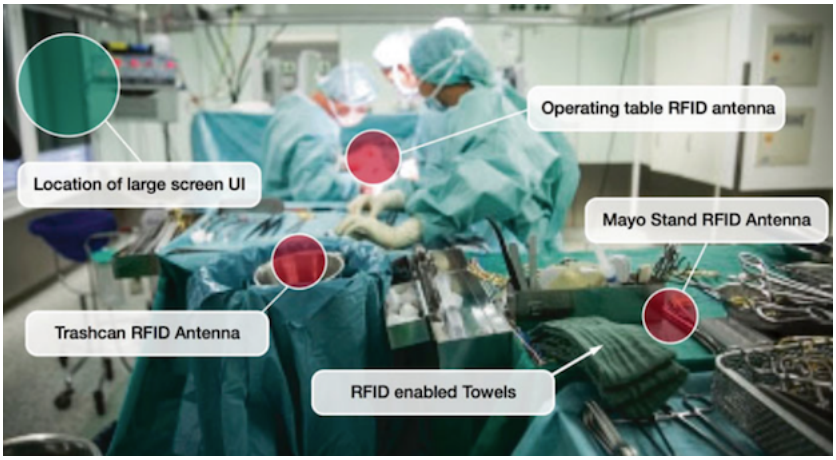


Figure 2.4: Locations of User interface(UI) and RFID antennas[4].

The solution proposed provides nurses and surgeons an intuitive way to visualize the position of towels. The visualization is on a central display in the operating room and on tablets that the nurses use. The intention is to enable nurses to detect missing towels as fast as possible, and only having to glance at the display or tablet for the information needed.

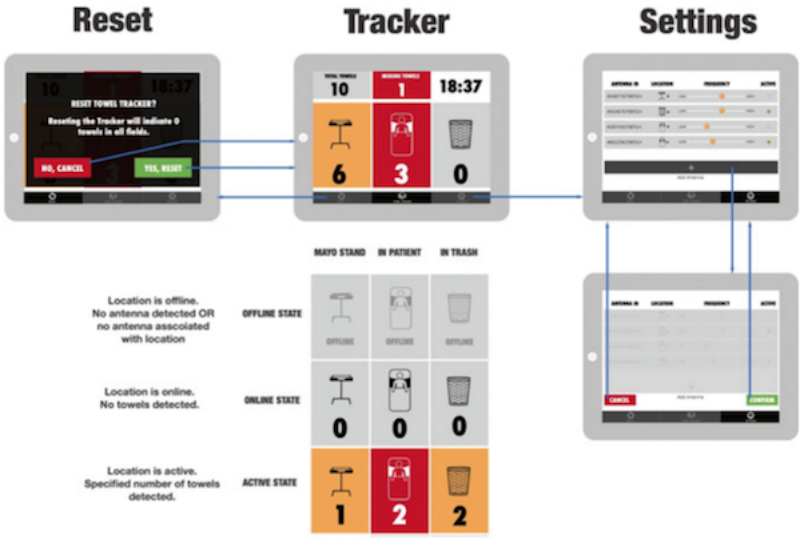


Figure 2.5: Wireframe of the user interface[4].

The principal purpose of the RFID tracker is to prevent towels from being left in the patient: hence whenever a towel is detected in the patient, the representation turns red with a numeric representation. Questions that need to be answered are first "are there any towels left in the patient?" and the second is "do we know where are the towels are?" Resolving these key user problems led to a simple but clear UI design which allows operating theater staff to know the answers to these questions with a simple glance. Figure 2.5 illustrates how effective a straightforward and clear design can be[4].
Adverse incidents in hospitals are underreported, and for legal, privacy and other reasons are not often discussed widely. The incidents that do reach the research literature are typically addressed from a clinical point of view. (example: how to treat a patient after the incident).

A 4-hour study readily highlighted serious problems that raise concerns that the manufacturer either failed to do any usability analysis of its product or it did but for some reason ignored or was unable or unwilling to use the insights from its studies.

This article by Acharya et al.(2010) focuses on hospital beds and adverse events and points out the importance of having and easily understood interface. For example, if a patient requires CPR it is important that the bed harden and flatten quickly by just touching a button. But to do that quickly the bed needs to have power. The battery LED is an example of bad feedback. When connected to a power source the standby LED glows indicating the device is functional, and when the devise is not connected to power source, both standby and the battery LEDs do not glow. But as long as there is some power left on the battery backup the device is still functional. And when the user continues to use the device there is no feedback to indicate when the battery drains out. They found that the control panel of the bed violates well known and conventional HCI principles. A key example of this is the standby symbol which is a false affordance. It should either be a switch or a button. The participants of the study pressed the symbol, and nothing happened. They then realized it was not a button it was a graphical symbol for the standby LED. So the design confused the participants, there are many confusion possibilities her because of the icons. The icons circled in red in figure 5 are icons that mirror the bed, which can lead to even more confusion about how to operate the bed.

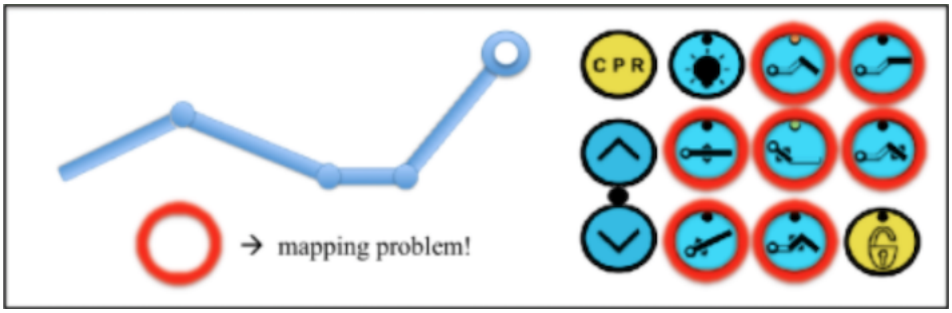


Figure 2.6: mapping problems of icons [5].

They propose a prototype and a solution to all the problems with the bed. The authors also make some points that can be made about the contribution of healthcare to the usability of devices. Near misses are rarely reported or acted on, typically an incident is only reported if it results in the adverse clinical event. For example, in the operating theater, there have been devices crashing and being rebooted. This has become standard practice and is not reported (providing there is no immediate clinical outcome). Adverse events are rarely explored from any perspectives other than their clinical implications. For example, how a patient is treated after and overdose is and clinical issue, but the HCI and latent condition leading to the incident are generally ignored [5].

2.9 Related work: mobile application

Launched in September 2014; our ground-breaking three-year project seeks to utilize the powers of social media and new technologies for pharmacovigilance purposes. It arose in response to the ninth call for Innovative Medicines Initiative (IMI) projects 'WEBAE – Leveraging Emerging Technology for Pharmacovigilance', and is based on the belief that modern pharmacovigilance practices should adapt to these new ways of communicating [24].

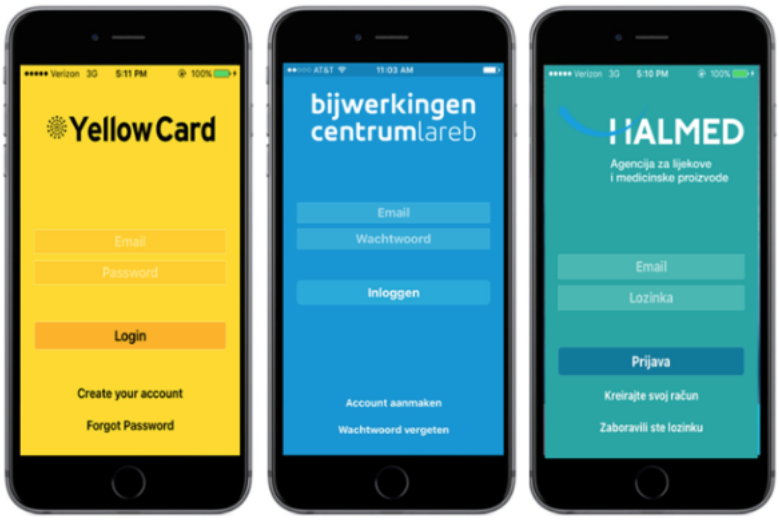


Figure 2.7: Interfaces of the mobile applications; Yellow Card, LAREB and HALMED [6]

A prime example of how relevant such a mobile system is would be the application WEB-RADR. This application is a mobile app for patients and professional and is intended to allow them to report suspected adverse drug reactions to national EU regulators. The intention was to investigate if publicly available social media data has the potential to be used for identifying drug safety issues. Received reports from the mobile application will be set side by side with established schemas to check the completeness, quality, and value for detection of safety issues. The application is designed for three different countries and has been launched in UK where it is named Yellow Card, Netherlands where its name is LAREB and Croatia where the name is HALMED [25].

2.10 Interaction design

Interaction design is the specification of digital behavior in response to human or machine, interaction design is a complex discipline. Interaction designers should ideally be able to combine knowledge of technological possibilities,

systems, aesthetic judgment and empirically informed about users [26] Interaction design can be said to be a subset of UX design, but that does not mean that they are the same thing [27].

One of the reasons to focus on the user experience is that, if an application is not engaging people will not use it. The consequence might be that the user will try to find a better alternative, but if it is the only option that is available the user would be forced to use it. A confusing user experience can potentially be vulnerable to user mistakes and misuse, which means the effectiveness and safety will be compromised. It is very important to deliver a good user experience when developing interactive products and services. UX design is concerned with all the issues that enable an engaging and enjoyable experience for people in both the short and longer term. This includes aesthetics, pleasure and emotional engagement regarding both the product and the service provided. In particular, it is important to consider experiences at a physical, behavioral and social level and regarding the meanings people derive from their experiences [4].

2.10.1 Design principles

Interaction designers use design principles to assist their way of thinking when designing for the user experience. The principles are abstractions that help the designer to look at and think more in detail about the designs. The principles are a mix of theory based knowledge, experience, and common sense. Usually, they are written suggestively, to guide designers into knowing what to provide and what to avoid in the interface. Using the principles, the designer should be able to explain and improve their designs. They are not used for specifying how to design the actual interface. The most common and well known principles are focused on how the designer should decide what should be available for the users to see and do when using the product [28]

Visibility

The principle visibility focuses on the more visible the functions are, then it is more likely for the user to know what to do. This means eliminating guesswork from the users and making it intuitive to use [28].

Feedback

The principle feedback is about what happens after a chosen action is performed, it relates to the sending of information about what has been accomplished, so that the user can continue to the next step. There are different types of feedback that are available, audio, tactile, visual or combinations of all these [28]. Visual feedback; this is because in a hospital setting the audio could be disturbing to others around and would be more intrusive. Using the right kind of feedback in the right setting will ensure that the users will know what to do next.

Constraints

Constraints refer to how a designer can restrict the kinds of user interaction that can take place at that given moment. Using constraints means the designer can prevent or reduce the user from making mistakes or selecting incorrect options [28].

Consistency

The consistency principle is that the design should be consistent. This means that the designer should make sure that similar operations use the similar elements for achieving similar tasks. Having a consistent interface means that it will be easier to use and to learn[28].

Affordance

Affordance is the attribute of an object that lets the user know how to use it. The term affordance is often used when describing how interfaces should make it obvious what can be done. Examples of this can be buttons, links, and scrollbars when designing these; the designer should design so that it is intuitive for the user to know what to do. For example, it should be clear that a scrollbar is scrollable [28].

2.11 User experience

To design product while considering the user experience (UX) means to not only think about the functions and aesthetics of the product.

- UX deals with the questions surrounding context
- Aesthetic design deals with making sure that the interface is appealing, and buttons have tempting shape and texture.
- Functional design deals with making sure that the triggers are appropriate for the device.

The design of UX handles the context for the whole product, asking questions regarding size of buttons connected to important functions; is the placement appropriate when considering the controls the users could be employed at the same time [29]?

It is about how people feel about a product, their pleasure, and satisfaction when using it, looking at it, holding it and opening or closing it. It includes their overall impression of how good it is to use, right down to the sensual effect small details have on them, such as how smoothly a switch rotates or the sound of a click and the touch of a button when pressing it. An important aspect is the quality of the experience someone has, be it a quick one, such as topping up a mobile phone, or a leisurely one such as playing with an interactive toy or an integrated one such as visiting a museum. One cannot design a user experience but one can design *for* a user experience [30].

2.11.1 Usability goals

Usability means to ensure that the product designed is easy to learn, efficient, and enjoyable for the users. The interactions between users and the product should be optimized in a way that enables them to do their activities in their daily lives. Usability can be broken down into the Effectiveness, Efficiency, Safety, Utility, Learnability, Memorability [30]. The usability goals are usually in the format of questions; this is to give the interaction designer a more concrete way of assessing the aspects and usability of the system or product. By answering the questions, the designer will be able to notice potential issues in the design or conflicts that have not been considered. The

questions should be detailed as they can be turned into usability criteria that will enable the designer to assess the usability of the product and find out how it can be improved, or not [30].

Effectiveness

Effectiveness is a very general goal and tackles how good a product is at doing what it is supposed to do. How effective it is to use [30]. Example question: Is the product capable of allowing people to learn, carry out their work efficiently, access the information they need, or buy the goods they want [30, p.20]?

Efficiency

Refers to if the product supports the users in performing their tasks [30]. Example question: Once users have learned how to use a product to carry out their tasks, can they sustain a high level of productivity [30, p.20]?

Safety

Safety involves that the users should be protected from dangerous conditions and undesirable situations. The product should help the users avoid dangers associated with carrying out unwanted actions accidentally. Safety also refers to dangers the user feels that might occur if they make errors, and how this feeling impacts the user's behavior. The design principles consistency and constraints will help with making the design safer for the users. Error handling, undo possibility, and confirmation dialog boxes will also contribute [30]? Example question: What is the range of error that is possible using the product and what measures are there to permit users to recover easily from them [30, p.20]?

Utility

Does the product provide the right kind of functionality, so that the product supports users in what they need or want to achieve [30]? Example question:

Does the product provide an appropriate set of functions that will enable users to carry out all their tasks in the way they want to do them [30, p.20]?

Learnability

Refers to how easy the system is to learn to use. Does it require the users to spend a long time learning how to use it? Users rarely like spending a considerable amount of time learning a new system; they prefer to get started straight away and become competent at carrying out tasks without too much effort. This is particularly the case for systems or products designed to be used in everyday life. Users are willing to spend longer time learning complex systems if it has a broad range of functionality which is perceived as useful [30]. Example question: Is it possible for the user to work out how to use the product by exploring the interface and trying out certain actions? How hard will it be to learn the whole set of functions in this way [30, p.21]?

Memorability

How easy is it to remember how to use the product, once it is learned? This goal is crucial when it comes to interactive products that are not used every day. Ideally, the users should be able to remember or rapidly be reminded how to use it even after a few months or longer. The users should not have to relearn how to use a system [30]. Example question: What kind of interface support have been provided to help users remember how to carry out tasks, in particular for the products and operations they use infrequently? [30, p.22]

2.12 Data visualization

Data visualization is the graphical display of abstract information for two purposes: sense-making (also called data analysis) and communication. Important stories live in our data and data visualization offers a powerful means to discover and understand these stories, and then to present them to others. The information is abstract in that it describes things that are not physical. Statistical information is abstract. Whether it concerns sales, incidences of

disease, athletic performance, or anything else, even though it doesn't pertain to the physical world, we can still display it visually, but to do this, we must find a way to give form to that which has none. This translation of the abstract into physical attributes of vision (length, position, size, shape, and color, to name a few) can only succeed if we understand a bit about visual perception and cognition. In other words, to visualize data effectively, we must follow design principles that are derived from an understanding of human perception. But if we're looking for patterns, trends, or exceptions among these values, if we want a quick sense of the story contained in these numbers, or we need to compare whole sets of numbers rather than just two at a time, this table fails. Jacques Bertin laid the foundation for much of the progress that's been made during the last half a century with the publication in 1967 of the book Semiologie Graphique. His work was pivotal because he discovered that visual perception operated according to rules that could be followed to express information visually in ways that represented it intuitively, clearly, accurately, and efficiently. One should always judge a visualization's merits by the degree to which we can easily, efficiently, accurately, and meaningfully perceive the story that the information has to tell. To do this, one must understand the perceptual strengths and weakness of various graphical means for displaying particular stories [31].

2.13 Information visualization

Information visualization systems which generate diagrams representing discrete relational information must consider potential users if they are to be effective. Many algorithms which render an abstract graph structure as a diagram are valued for their conformance to aesthetic criteria (e.g. reducing the number of edge crossings, maximizing symmetry), or for computational efficiency. They are not usually judged on their ability to produce diagrams that maximize human performance. This paper presents the results of experiments investigating the relative worth (from an HCI point of view) of graph drawing aesthetics and algorithms using a single graph. The results indicate that while some individual aesthetics affect human performance, it is difficult to say that one algorithm is 'better' than another from a relational understanding point of view. Designers of automatic layout algorithms, and the systems which embody such algorithms, can benefit from this study and

this human centered approach, by adapting their methods to focus on user concerns, rather than computational ones [32].

Information visualization is about gaining insight into data through a visual representation. This data is often multivariate, and increasingly, the datasets are vast. To help us explore all this data, numerous visualization applications, both commercial and research prototypes, have been designed using a variety of techniques and algorithms. Whether they are dedicated to geospatial data or skewed hierarchical data, most of the visualizations need to adopt strategies for dealing with overcrowded displays, brought about by too much data to fit in a small display space. Ellis(2007) analyses a large number of these clutter reduction methods, classifying them both regarding how they deal with clutter reduction and more importantly, regarding the benefits and losses. The aim of the resulting taxonomy is to act as a guide to match techniques to problems where different criteria may have different importance, and more importantly as a means to critique and hence develop existing and new techniques [33].

The field of information visualization offers little methodological guidance to practitioners who seek to design novel systems. Though many sources describe the foundations of the domain, few discuss practical methods for solving visualization problems. One frequently cited guideline to design is the "Visual Information-Seeking Mantra," proposed by Shneiderman in 1996 [34]. Although often used to inform the design of information visualization systems, it is unclear what use this has been for visualization designers. We reviewed the current literature that references the Mantra, noting what authors have found useful about it and why they cite it. The results indicate a need for empirical validation of the Mantra and a method, such as design patterns, to inform a holistic approach to visualization design [35].

2.13.1 Mobile data visualization

We believe that mobile devices offer great, only partly realized, potential and that they will play an essential role in the future of information visualization interfaces. In the context of data visualization and exploration, today's mobile devices combine many advantages: they have become ubiquitous (famil-

iarity) and can be used almost anywhere and at any time (availability). Due to their broad success and availability in the consumer electronics market, they provide an ideal platform to bring information visualizations techniques to even inexperienced users (non-experts). Both, their physical and technical properties make them particularly suited for collaborative work: they can be integrated into existing environments or form their collaborative interface when multiple mobile devices are combined. Altogether, this creates a notion of the great potential which mobile devices can bring into the field of information visualization [36].

2.14 Data safety

In healthcare, the right information at the right time is a necessity to provide the best possible care for a patient. Patient information must also be protected from unauthorized access to protect patient privacy. It is also common for patients to visit more than one healthcare provider, which implies the need for crossborder healthcare and a focus on the patient process. Countries work differently with these issues [37].

2.15 Digitalization

Within health there is multiple ways digitalization can contribute to easing medical care and also providing care. Digitalization can be anything from digitizing forms to delivering digital care to rural places. Digitalization also offers challenges when it comes to acceptance from the users since it will be something new not everyone will be likely to adopt a new process including a new system. An example of digitizing is going from paper records to electronic record. Some hospitals in Norway have core patient record, patient record, letters, appointments and communication between physician/specialist and the patient through a web based system. Patients can also view some selected details as the online system promotes more openness in the record, and also add information to the core journal [38].

Digitalization of NEHRS (National Electronic Health Record Systems) Policymakers, politician, and some researchers claim that digitizing

health information will help eliminate inefficient paper-based systems and cut costs while facilitating the development of new better-coordinated models.Making electronic records available to citizens, proponents claim, will also encourage them to take more responsibility for their health. However, existing research suggests that although their visions are compelling, translating them into workable systems is highly problematic. As well as technical challenges of replacing or connecting diverse legacy systems, new forms of governance are needed to manage the potential risks associated with the wider distribution of potentially sensitive information. Garrety et al.(2014) argue that one reason NEHRS have been so difficult to implement is that policy makers have seriously underestimated the degree to which digitalization disrupts existing social moral and medico-legal order through which health care is governed and delivered. Often these disturbances are pushed to the background while the technical capabilities of NEHRS are foregrounds as "the solution" [39].

Changes in health care processes are implemented with the goal to improve care through better patient safety, reducing the costs and workload, and enhance communication. However, changes often trigger unintended consequences that may stress other health care system components, with the result sometimes being a failure. Changes done in one particular hospital does not mean it will succeed in another [40].

Chapter 3

Attitudes towards reporting

"The resistance by physicians towards quality assurance and quality improvement ef- forts are, to my knowledge, common across all countries and health systems." [41, p.6].

There are many reasons for the lack of reporting; the table below presents the main ones.

Individual	Organizational	Culture based
Fear	Workload	Inevitability of error
Motivation	Colleagues	Staffing level
Health staff reservation	Policies	Habits
	Procedures	Colleague bonds

The goal of safety reporting is to ensure patient safety. But to be able to identify areas where there is a need for other procedures or progress one needs reports. Information about what aspects regarding the individual, cultural or organizational factors allow the existence of barriers is important to be able to overcome these. This is essential information to be able to ensure and improve procedures related to patient safety [9].

Blame culture is something most medical staff fear. The reportee may feel that their competence might be questioned, and would lead to reprimands, poor references, or a ruined reputation as a medical professional. A fear that

senior staff would keep information about the incident and would use this at a later date was also suggested as a barrier. Waring also found that a small group of the participants, who were mainly senior medical representatives and/or clinical directors were positive, aware and supportive of the developments concerning patient safety. The incident reporting was regarded as an effective mechanism for encouraging quality. It was suggested that incident reports could be used to reinforce claims for organizational changes by demonstrating the need for more staff, equipment, or resources [42].

Medical practitioners accepted is that some mistakes were unavoidable and potentiality these were not possible to correct therefore reporting of these events would have no effect. Medical staff was also concerned that there would be an increased chance that staff with nonmedical training and management would engage in governing the medical quality [42].

To overcome barriers related to blame, one possibility is to make reports anonymous so that employees and "whistleblowers" will not fear reprisals and it could open up to learning situation instead. One of the most important factors to contribute to increasing reporting is to create a fair and reasonable culture to counteract the culture of blame [42].

Chapter 4

Norwegian reporting process

How to report?
The hospitals routines should be followed for adverse event reports. For many, this entails reporting through the electronic adverse event system. If there is no such system, a report should be submitted to Helsedirektoratet[43].Helsedirektoratet also provides more in-depth information about what specific laws and regulations count for the obligation to report adverse incidents[44].

Who should report?
All health institutions are covered by the specialist health service law; both private and public ought to send reports about the serious adverse event that lead to or could have has serious consequence for the patient. It is the medical staff in the health institution that has to report the incident through the internal electronic adverse event system [43].

What event should be reported?
As soon as an incident is discovered it has to be reported. As soon means at the latest 24 hours after discovery. However, this does not mean that reports older than 24 hours will be rejected.

Events with these criteria should be reported:

- That *could* have to lead to significant injury.
- That lead to significant injury.

The significance of the injury is assessed based on the consequence for the patient. It is classified as significant if it impacts the patients' disease or consequence is pain or reduced quality of life . Examples of significant injury are:

- Event that leads to death.
- Event where lifesaving procedures were necessary
- Event that lead to injury that lasted or probably will last longer than two weeks.
- Event that leads to prolonged or unexpected stay in intensive care or emergency ward,
- Event that leads to extended hospitalization.
- Event that leads to a need for extra treatment, rehabilitation or similar.
- Event that resulted in other physical or psychological damage that is considered serious or could have lead to serious injury.

An unwanted incident should also be reported if it occurs because of the following: lack of performance from health services, lack of prevention, guidance, diagnosis, donation, treatment, supervision, care and nursing

It is safe to report
The reports are anonymous, where the reports are collected directly from the system for anomalies. It is the separate institutions that decide if you can report anonymously in the internal system. Any data that can be linked to the patient or institution is removed before it gets stored at the Health Directorate. A report can not in itself be the foundation for a case against health personnel.

Chapter 5

Process

The process of reporting varies from hospital to hospital so pinning down how this is done is not an easy task. Ideally, any system should capture early reporting starting at the patient bedside. And connecting this information to the patient information system. This would be a way to combine information specifically for patient adverse events with the rest of the patient electronic record.

If the case is adjudicated as very serious, then it needs to be sent reported to the national regulatory authority.If it stays in the internal system, the reportee will get a reference number so that they can check what has been done to resolve the adverse event. It is important to ensure clarity and transparency of the reporting so that all the clinical staff involved in the reporting has the possibility to get feedback. This could provide confirmation that right choices were made to resolve safety issues.

This is important so that the reportee will feel that their time has been well spent writing the reporting and also. Some hospitals such as the Linkøping has dedicated personnel for the safety reporting. They fill a large amount of information through a web portal (see different forms in Appendix B). It seems to be useful to have dedicated staff which can provide feedback and data for different forms of reporting. This solution might not be affordable in each clinical environment.

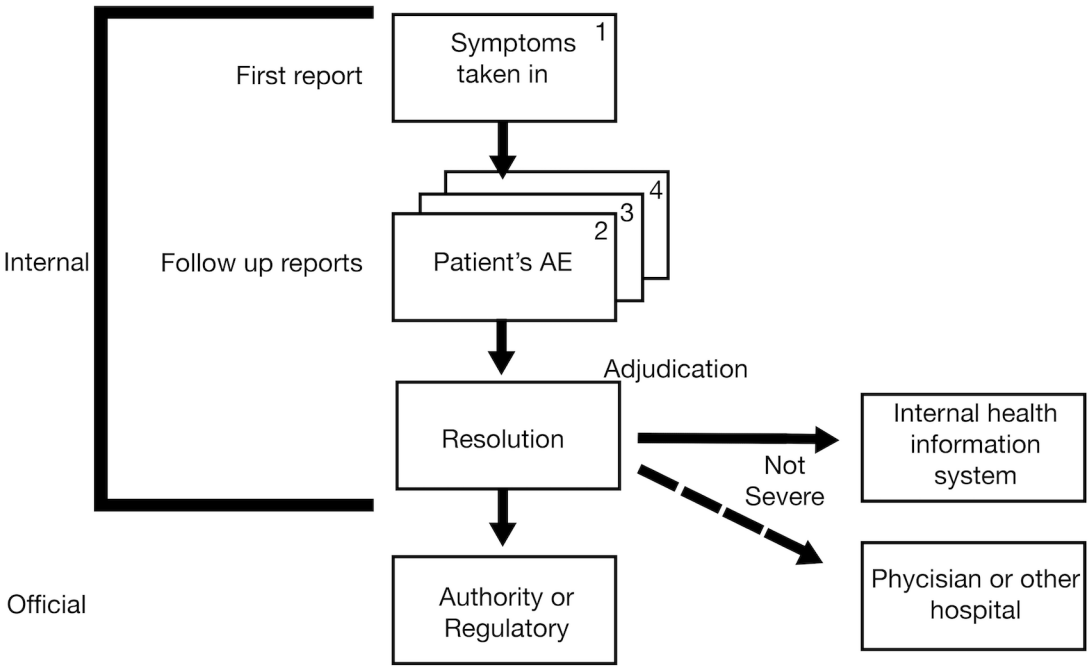


Figure 5.1: Adverse Event(AE) reporting procedure

Figure 5.1 shows how the process of reporting works in most places. The first step is to enter patient symptoms which initiates the reporting process. Next step will be following up the event and creating additional reports until the situation is resolved. During these steps, it is important to assess whether adverse event is severe and needs to be reported to the authorities. If not the report should remind in the internal hospital systems to be assessed by management, medical staff or hospital safety committee to decide what action needs to be taken to avoid similar events.

Mobile design could be considered as a way of supporting the process of reporting adverse events. Having a mobile device at hand and entering patient symptoms is simply done and can facilitate automatic data processing. Mobile technology can also be used in all follow up reports and to obtain final patient report regarding the adverse event. Mobile solutions can help sharing data among treating staff and help make information easily accessible. This way a report does not have a life of its own, outside of the system.

Chapter 6

Methods

6.1 Design Science Research

The defining feature of Design Science Research is learning through building. Design science research is primarily a type of research where design is used as a research method or technique. It is proposed in [45] that design science research should be distinguished from the regular routine design by the production of interesting new knowledge. Attempts using routine design can still, however, lead to design science research, as one may find missing knowledge in a new area. Using existing knowledge so that the researcher gets a better feel of what is needed to fill the knowledge gap.
.

Hevner proposes seven guidelines to use in Design Science Research. To assist researchers, reviewers, editors, and readers to understand the requirements for design science research [8].

> Guideline 1: Design an artifact
> Guideline 1: Suggests that an artifact must be produced. This is rarely a complete information system that is used in practice but can be a construct, model, method or instantiation [8].

Guideline 2: Problem relevance
The goal of the second guideline is to develop technology-based solutions for important and relevant problems [8].

Guideline 3: Design evaluation
The third guideline is that evaluation of utility, quality, and efficacy of the artifact is demonstrated by using well-executed evaluation methods. A crucial component of the research process is the evaluation step. To be able to properly evaluate a designed IT artifact appropriate metrics, gathering of data, and analysis is required [8].

Guideline 4: Research contributions
Effective design science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and design methodologies [8].

Guideline 5: Research rigor
Design science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact [8].

Guideline 6: Design as a search process
The 6th guideline focuses on that the search for an effective artifact requires utilizing the available resources to reach the desired end while still satisfying the laws in the problem space [8].

Guideline 7: Communication of research
The design science should be presented in an efficient way to both technology oriented, and management oriented audiences [8].

6.1.1 Design Science Checklist

Design Science Research checklist is proposed to be able to assess the progress in the thesis according to the guidelines from design science research, The

checklist Hevner suggests has been used, to make sure that the key aspects of design science research are addressed, which makes it easier for a novice researcher to understand hoe the research is going[7]. The checklist is shown in figure 6.1, underneath the text.

6.2 User Centered Design

Real users and their goals are the driving force behind the product development, not just technology. As a consequence, a well-designed system will make the most of human skill and engagement, will be directly relevant to the activity in hand and will support rather than constraint the user. This is less technique and more philosophy.

Gould and Lewis(1985) wrote down three principles they believed would lead to a useful and easy to use computer system.

The approach is to focus early on users and tasks. This means that first understanding of users will be by directly studying their cognitive behavioral, anthropomorphic and attitudinal characteristics. Users should be observed while doing their regular tasks, studying the nature of those tasks, and then involving users in the design process. Following are the principles.

1. Early focus on users and tasks.
   This can also be expanded by five more principles.
   (a) The driving force of the development is the user's tasks and goal, and how to provide better support for the user's goals.
   (b) Studying users behavior and context of use.
   (c) The characteristics of the user are captured and designed for.
   (d) Users partake during the whole process, from earliest phases to the last iteration. And their input is taken seriously.
   (e) All decisions made regarding design take into account the users context, work, and environment.
2. Empirical measurement
   Early in development, the reactions and performance of intended users

Questions	Answers
1. What is the research question (design requirements)?	
2. What is the artifact? How is the artifact represented?	
3. What design processes (search heuristics) will be used to build the artifact?	
4. How are the artifact and the design processes grounded by the knowledge base? What, if any, theories support the artifact design and the design process?	
5. What evaluations are performed during the internal design cycles? What design improvements are identified during each design cycle?	
6. How is the artifact introduced into the application environment and how is it field tested? What metrics are used to demonstrate artifact utility and improvement over previous artifacts?	
7. What new knowledge is added to the knowledge base and in what form (e.g., peer-reviewed literature, meta-artifacts, new theory, new method)?	
8. Has the research question been satisfactorily addressed?	

Figure 6.1: Design science research checklist [7, p.20]

to printed scenarios, manuals, etc. are observed and measured. Later on, users interact with simulations and prototypes, and their performance and reactions are observed, recorded and analyzed.

Here specific usability and user experience goals should be identified, clearly documented and shared upon. These may help designers to choose between alternative designs and to check on progress as the product is developed. Identifying specific goals up front means that the product can be empirically evaluated at regular stages as it is developed.

3. Iterative design
   When problems are found in user testing, they are fixed, and then more tests and observations are carried out to see results. This means that design and development is iterative, with cycles of design-test-measure-redesign being repeated as often as necessary.
   Doing design work in iterations allows models or designs to be refined based on feedback. As the users and designers engage with the domain and start discussing requirements, need, hopes, and aspirations, then different insights into what is required, what will help and what is achievable will emerge. This leads to a need for a new iteration, and for activities to inform each other and to be repeated. However exceptional the designers are and however clear the users may think their visions are of the required artifact, it will be necessary to alter ideas in light of feedback, several times [46].

These three principles has become accepted as the basis of user centered design [30].

6.3 Research methods

6.3.1 Interviews

To be able to collect detailed information interviews were used as a method of data gathering. This because the knowledge and information will gives possibility to ask more complex questions, and also use open ended questions

while also catering to the individuality of the people that will be interviewed. Especially since the order and logic of questions sometimes need to be different for the various interviewees and contexts. Using interview I will be able to explore more, and gain information that cannot be described via a questionnaire [47]

The most important thing for using the different interview types that collect as much data as possible, get new ideas, and include the interviewees in the design and gain a better understanding of the problem space.

6.3.2 Unstructured interview

Since unstructured interviews are more exploratory and more like a conversation around a chosen topic, the interviewer can go into more depth. All questions are open so that there are no expected answers. The interviewer should have a plan of the main themes and topics he or she wants to cover during the interview. It is not advisable to go into interviews without an agenda. When conducting an unstructured interview, it is important to get a balance between getting answers to a relevant question, while also being open minded to new ideas [30]. During an unstructured interview the role of the interviewer will be, to be as non intrusive as possible, while also introducing topics or themes. The researcher in these situations has less control than in other types of interviews [47]

6.3.3 Semi structured interviews

Since semi-structured interviews are a combination of structured and unstructured interviews and use open and closed questions, this type of interview will be useful to get answers to specific questions but also inquire in-depth information. Using semi-structured interviews, I can ask more specific questions related to my thesis, while also including open ended questions and being open to new ideas and topics I might not have thought about including or missed during the first round of interviews. It is important to create questions that are not leading to an expected answer; the goal is to get the interviewees answer not lead them to one specific [30]. Usually, the interviewer will have a list of themes to cover and questions to ask, but the

order is not important and will change depending on how the conversation flows. Adding additional questions if there are themes or issues that the interviewer is not prepared for, is not a problem when using semi-structured [47].

6.3.4 Group interviews

Group interviews are most practical since the interviewees tend be busy people. Normally between 3-6 people are together during a group interview. The idea is for the group to interact with the each other and develop a discussion which results in new insights that may not have been discussed or noticed if only talking to one individual. Some of the advantages of using group interviews are that they can generate more responses and also more variation in the responses collected because the participants might challenge or stimulate each other's ideas. Doing group interviews also means that the participants can brainstorm different themes that the researcher might find useful. One of the things that are important during group interviews is to remember that some people might dominate while other are quiet, so it is important for the interviewer to find a balance and guide the group [47].

6.4 Design

6.4.1 Conceptual model

To be able to gain an understanding of the problem space a literature review was conducted and discussion with medical staff in Sweden and Norway. To be able to explain the concept more properly there was included sketches of the intended system for the review and interviews with the professionals.

6.4.2 Graphical profile

To create consistency between proposed design and Helse Vests visual identity, visual elements were based on the design of the graphical profile from the Helse Vest hospitals. This will hopefully create a coherent feeling for the

users so that the reporting system feels incorporated into their workplace. This will also show that this system is for the hospital, many systems used in management for health does not consider the look and feel of the system. They are designed for function, and usually, there might not be any thought behind the overall design of the medical system.

The visual profile will be based on the graphical profile designed for all hospitals in Norway by the Ministry of Health and Care Services. The reasoning behind creating a common profile for the hospitals is to make the common identity and belonging visible. And at the same time, it will have information value for the patients, relatives and other collaborators and signalize a publicly owned, funded and cohesive health service [48]

The first round of profiling was in 2002 and was revised in 2012. The full profile for all hospitals in Norway can be found at the Ministry of health and care services web site [49]

6.4.3 Interface design

Interface design is about selecting and using the right elements for the task the user is trying to accomplish and also arrange them on the screen in a way that the user will easily understand and use them. The different tasks will often stretch across various screens, and each screen will contain a different set of the element for the user to contend with. If the user immediately notices the important content and interface is said to be successful. When designing for complex systems one of the biggest challenges is to decide which aspects does the user need and which are just simply reducing the visibility of the important stuff, and also which elements should be left out. Creating a big button, because it is more likely the user will find it and press it, is not a viable solution to every interface problem. A simple trick would be to think about default options selected when the interface is presented at first to the users. If based on your understanding of user goals and tasks makes you think they would prefer a detailed search, then the box that shows detailed search should be checked by default. Doing this would automatically make users more content with their search results, regardless of whether it was their choice or not. Another solution would be to have a system that remembers the users preferred options from the previous searches [29]

6.4.4 Wireframes

A wireframe is a depiction of all the components of a page and how they fit together and serves as a visual reference for visual design work and site implementation. There is variation in how much detail a Wireframe contains. The visual design does not have to match with the wireframes precisely. The wireframe is only to account for the relative importance and grouping of elements presented in the wireframe[29].

Figure 6.2: Wireframe made for iteration 1

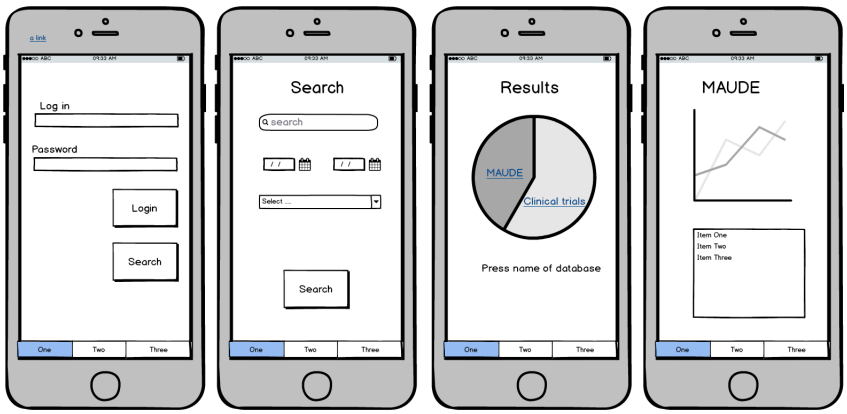


Figure 6.3: Wireframes made for iteration 3

Balsamiq was used to create the wireframes in the beginning of the iterations.

These were the basis together with sketches for further development of the visual design and prototypes (Chapter 8 and Appendix C, D and E).

6.5 Evaluation

Evaluation is an integral part to the design process. Evaluators collect information about users or potential users experiences when interacting with a prototype, app or product. The motivation for evaluation is to improve the design. It focuses on both the usability of the of the system (ease of use) and the user experience when using the system (how satisfying, enjoyable or motivation it is). When designing it is important not to avoid assumptions. And evaluation is one way to overcome these challenges because it enables the designer to check if their design s appropriate and acceptable for the wider user population [30].

6.6 Data interpretation issues

6.6.1 Reliability

How reliable or consistent a method is when it comes to reproducing the same results on separate occasions under same circumstances. If someone else uses the same method, they should be able to recreate the same results [30].

6.6.2 Validity

Validity is concerned with whter a chosen evaluation method measures what it is intended to measure. Both the method itself and the way it is implemented [30].

The prototype did not get the possibility to be tested in the environment, so it remains an open issue. But the concept has been proven through discussions, interviews, and evaluation including the primary user group and also the

wider population of users that might find this project interesting (care takers, doctors, nurse, people interested in learning more, students)

6.6.3 Ecological Validity

This is a particular kind of validity that concerns how the environment in which an evaluation is conducted influences or even distorts the results. That means the difference, in for example, evaluating in a natural setting vs. lab setting. The testers/evaluator will behave differently and be impacted by the environment based on the setting. Ecological validity is also impacted by the fact the people know they are being studied [30].

In this research the evaluations have little ecological value as participants are not at the patient's bedside. The evaluations done by other than medical staff have higher ecological validity as these were done at home/work/school where they would most likely use this app to look up information about the medical devices. One of the interviews/discussions were done in the busy hospital cafeteria this could emulate a busy day for medical staff where they cannot focus exactly on one thing when there is a lot of sounds surrounding you.

6.6.4 Bias

Bias is something that occurs when results are distorted. An example of this may be if an expert does a heuristic evaluation the expert might be sensitive to certain flaws more so than others, and this might be reflected in the results. Evaluators gathering data by observing might selectively gather data. Interviewers may influence responses from interviewees by their tone of voice, facial expressions, or by the way questions are phrased. So it is important to be sensitive to the possibility of bias[30]

6.6.5 Scope

The scope of an evaluation study refers to how much of its findings can be generalized. It is important to not over generalize the results [30].

6.7 System usability scale

System Usability Scale (SUS) has several attributes that make it a good choice for general usability practitioners. The main attribute is that the survey is technology agnostic, making it flexible enough to assess a wide range of interface technologies, from Interactive Voice Response systems (IVRs) and novel hardware platforms to the more traditional computer interfaces and Web sites. Secondly, the survey is relatively quick and easy to use by both study participants and administrators. Thirdly, the survey provides a single score on a scale that is easily understood by the wide range of people (from project managers to computer programmers) who are typically involved in the development of products and services and who may have little or no experience in human factors and usability. Finally, the survey is nonproprietary, making it a cost effective tool as well [50].

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.

6.7.1 Heuristic Evaluation

Is a usability inspection method that was developed by Nielsen and his colleagues and later modified by other researchers for evaluating specific types of systems. In heuristic evaluations experts, guided by a set of usability principles known as heuristics, to evaluate whether the user-interface elements such as dialog boxes, menus, navigation structure, online help and so on conform to tried and tested principles. These heuristics closely resemble high-level design principles [30].

Jakob Nielsen's ten heuristics are listed in the following text:

spacing

Visibility of system status The system should always inform users regarding what is going on, through the appropriate feedback within reasonable time.

Match between system and the real world The system should communicate with the users' natural language, using words, phrases, and concepts familiar, rather than system-oriented terms. The wording should Follow real-world conventions, making information appear in a natural and logical order.

Consistency and standards Users should not have to speculate whether different words, situations, or actions mean the same thing.Important to follow platform conventions.

Error prevention Better than decent error messages is a design which prevents problems from arising. A strategy is to eliminate error-prone conditions or check for them and give the user a confirmation option as feedback.

Recognition rather than recall The users should not have to memorize part of the system. One should rather make objects, actions, and options visible. Instructions for the use of the system should be visible or easily retrievable whenever appropriate.

Flexibility and efficiency of use Accelerators that are unseen by a novice user, and often speed up the interaction for the expert user. That way the system has the possibility to cater to both inexperienced

and experienced users. Allow users to tailor frequent actions.

Aesthetic and minimalist design Information that is not relevant should be avoided, and all dialogues should not contain any irrelevant or rarely needed information.

Help users recognize, diagnose, and recover from errors Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution

Help and documentation Even though it is better to have a system that can be used without documentation, sometimes is a necessity to have support and documentation available for the user.

To use three to five evaluators is recommended since one does not gain that much additional information by using larger numbers of participants.It is not necessarily true that the same person will be the best evaluator every time. Second, some of the hardest-to-find usability problems are found by evaluators who do not otherwise find many usability problems. Therefore, it is recommended to involve multiple reviewers in any heuristic evaluation. The Heuristic evaluation is performed by having each evaluator inspect and explore the interface alone. Only after all evaluations have been completed the reviewers are allowed to communicate and have their findings aggregated. This procedure is necessary to make sure that evaluators are not impacted by each other.The assessment can be recorded either as written reports from each evaluator or by having the evaluators talk out loud to the observer. Using Written reports one will have the advantage of presenting a formal record of the evaluation [51].

6.8 Prototype

To be able to show design ideas and create a discussion around them, and also evaluate them with others, a prototype will be needed. Prototyping is an effective way for a designer to explore different ideas, the building of a prototype encourages reflection around the design itself. A prototype can help answer questions and help with choosing between the various alternatives. The prototype can serve a variety of different purposes: to test out technical feasibility, clarify requirements, be used during user testing, evaluation of

design or usability. The decision of which kind of prototype to use will be guided by the purpose. Paper prototypes may work well for investigating scenarios, or to decide if buttons, images and labels are appropriate. But to be able to test response time, or sound levels one must use a higher fidelity prototype which allows for such output [30].

6.8.1 Low fidelity

Starting off with a low fidelity prototype might be useful as this kind of prototype is simple, cheap, and quick to produce. This also means that low fidelity prototypes are simple, fast and also easier to modify should it be necessary. Prototyping this way supports exploration of different ideas and designs which are critical during the early stages of development. Low fidelity prototypes are not meant to be kept and integrated into the final project but rather to be used for exploration [30].

6.8.2 High fidelity

A high fidelity prototype looks more like the final product and or provides more functionality than a low fidelity prototype. High fidelity prototyping is useful for convincing someone of ideas and for testing out technical issues. High fidelity prototypes can be developed by modifying and integrating existing components – Hardware and software [30].

6.9 Overview of tools

Axure
Axure is a prototyping tool mainly for web and desktop application. But is also used for mobile and smartwatches, there exist different templates and libraries that one can use when prototyping. Axure gives nonprogrammers the possibility of prototyping highly functioning, rich prototypes with animations and conditional logic so it can seem like a functioning system. It is also an option to share the prototype with others via a link[52]. Axure was used to create the prototypes which were used during evaluations done in

iteration 1 and 2.

Adobe XD
Adobe experience design is also a prototyping tool, where one can create interactive prototypes. But without the same advanced functionality as Axure. One can preview the work in real time, share and collaborate on the screens [**?**]. XD was used to create mock-ups before moving the design to Axure to add more functionality than Adobe XD allows.

Adobe photoshop
Photoshop is a powerful application that is used in many different setting and professionals. Users vary from students, graphical designers, and professional photographers [53]. The application can be used for almost any type of image editing or create. In the thesis, Photoshop was used to create sketches, models, and figures.

Xtensio
Xtensio is a toolbox that offers presentation tools but also interactive templates that could be useful during research, brainstorming, planning and strategy phases of a company [54]. From the toolbox that Xtensio has the persona template was used to create the personas used in the thesis.

Trello
Trello contains lists of lists with A Trello board contains a list of lists, which is filled with cards and can be used by oneself or team[55]. Trello has everything to organize projects no matter the team size. An example could of personalized Kanban board seen in figure 6.4.

Balsamiq
Is a rapid wireframing tool, the interface is drag-and-drop which speeds ut the process of creating mock ups and wireframes. [56]

6.10 Kanban

Kanban was used for the thesis research and design stages to easily keep track of the progress. The Kanban approach can be defined as a set of concepts, principles, practices, techniques and tools for managing the development

process with an emphasis on continuously delivering value to customers while promoting learning and continuous improvements. Specifically, a Kanban board, which is similar to Scrum boards for visualization of the work that needs to be done. Work in Progress (WIP) is used to manage the workflow with a set maximum of task that can be done instead of the time set for iterations like in Scrum [12].

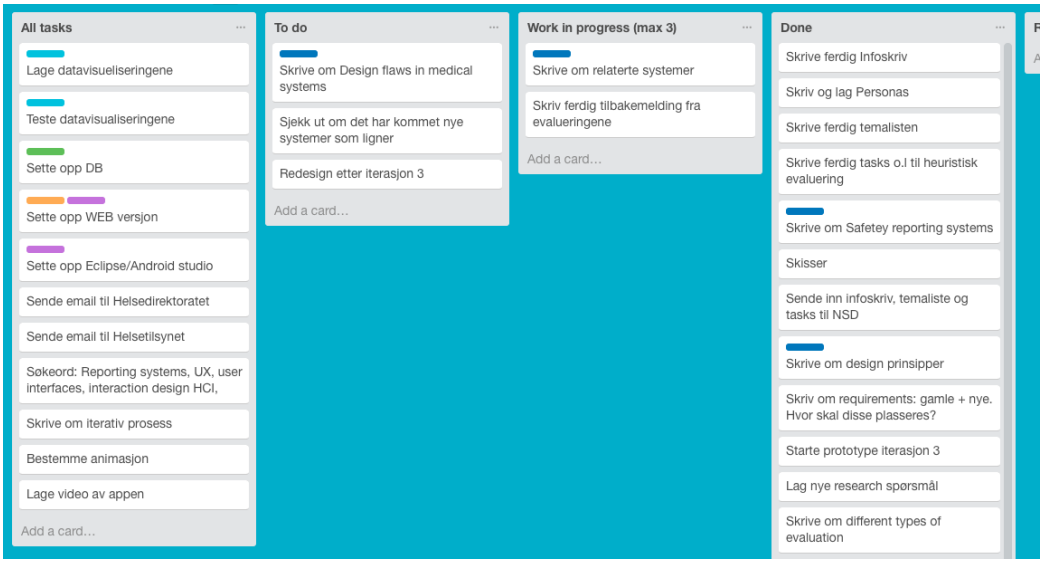


Figure 6.4: Personal kanban board used for designing and writing thesis

Since the primary focus of the project was to design, the kanban approach was adapted to the tasks that were going to be performed during the process. Tasks were mainly focused on design, research and writing activities. Some tasks were also focused on further development if it was to be programmed into a fully functioning system. Figure 6.4 is an example of how a kanban board with added task list could look like and is also the one used in the project.

Chapter 7

Requirements

User requirements are one of the driving forces behind development and design. This chapter overviews the formulation of requirements starting with the conceptual model, overview of the process of gathering of the requirements and target audience.

7.1 Conceptual model

Is a high-level description of how a system operates and is organized. And also an abstraction outlining what people can do with an artifact and what concepts are needed to understand how to interact with it. It also enables designers to straighten out their thinking before they start laying out their artifacts.[57]. In a nutshell, a conceptual model provides a working strategy and a framework of general concepts and their interrelations. The core components are:

- metaphors and analogies that are to convey to people what functions the product has, what it is and how to use it.
- The relationships between the concepts (whether one object contains another, the relative importance of actions to others, and whether an object is part of another object).
- The mappings between the concepts and the user experience the prod-

uct is designed to support or invoke (one can revisit through looking at a list of visited sites, most frequently visited or saved websites) [30].

concepts are short descriptions because of the limited real life data at the beginning of the project.

This research will consider two principal concepts which are in the field of arthroplasty:

Concept 1: A mobile application, to ease the input of data for adverse event reporting. With the option for already starting at the patient bedside.

Concept 2: Mobile pharmacovigilance system, for searching data about explanted medical devices.

7.2 Data Gathering

Bots concepts were further developed by studying literature, interviews, and observations.The gathered data was used to generate different design iterations. All feedback and discussions collected from these activities were made anonymous in the thesis in the thesis. This is because of barriers existing within the medical field towards safety reporting and also, to increase openness about the problems and processes without the fear of reprimand. I appendix B is a collection of example forms that experts have shared during interviews or as a suggestion to base requirements and design on.

7.3 Content requirements

The aim of this step is to understand to gain insight into the users, their activities and the context of that activity so that the system under development can support them in achieving their goals. The second aim is to produce a set of stable requirements as a basis for design. This does not require a comprehensive documentation or a set of rigid prescriptions. In practice requirements evolve and develop as the stakeholders interact with designs and

see what possibilities there are and how to utilize certain facilities. [30]A requirement is a statement about an intended product that specifies what it should do or how it should perform. The aim of the requirement activity is to make the requirements as precise, unambiguous, and clear as possible. Requirements come in many different forms and at many different levels of abstraction, but we need not make sure that the requirements are as clear as possible and that we understand how to tell when they have been fulfilled.

7.3.1 Requirements in the design iterations

Requirements for all iterations

1. The system should be
2. Intuitive
3. Easy to use
4. Contribute to the workflow
5. Increase efficiency compared to paper reports
6. Compatible with hospital software and hardware
7. Input by text
8. Text input should auto suggest
9. Least number of clicks as possible
10. Let the user choose date
11. Accommodate experienced users

Iteration 1

Users should be provided with support to collect, evaluate and write reports about adverse events. They should experience ease of navigation, adjusted data for mobile devices, and the report should available internally within the hospital and if serious should be reported to the correct authorities.

Iteration 2

Should enable pharmacovigilance by enabling retrieval of wanted data, response time should be quick, and the information adjusted to mobile device format. The solution should connect to original data sources.

iteration 3

Users should be able to save and share the articles and reports they find interesting. A possibility of customization of preferred keywords, databases, brands or device manufacturers should be available.

Iteration 4

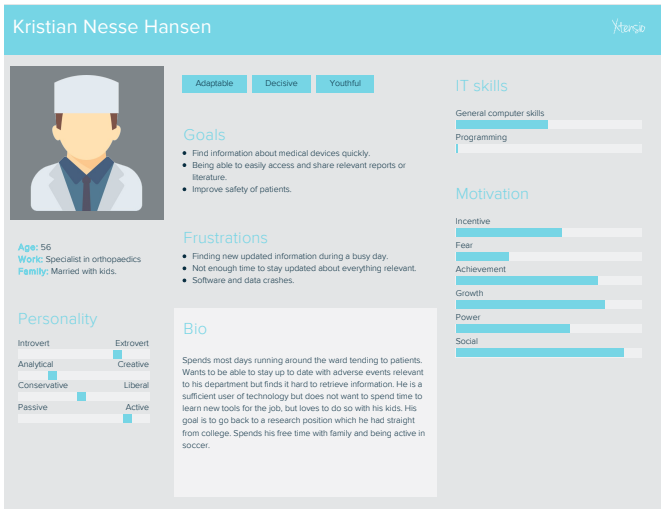
The data should be manipulated using voice, and some other functionalities could be added such as interactive graphs and for example. And additional digitalization. These requirements can be seen as nonfunctional since they require additional memory and graphical features that this thesis has not developed.

7.4 Target audience

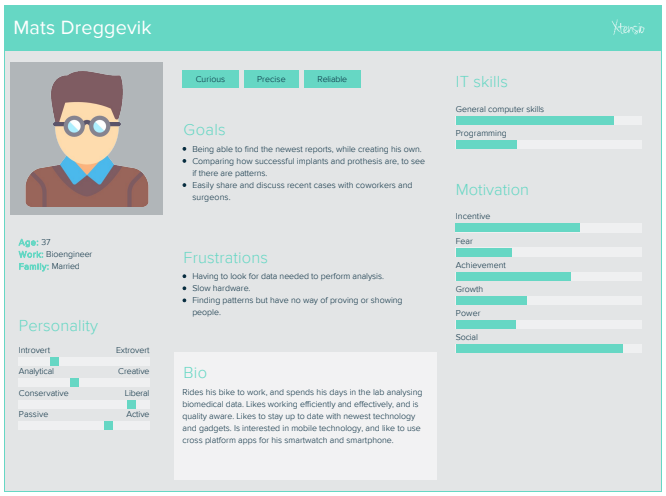
The main target audience for the application will be medical staff working within the field of arthroplasty and also the biomedical engineers which get the failed implants. This application could also be interesting for other researchers interested dealing with implants and prosthesis in arthroplasty, their interest could be data mining of the database. One example would be to find patterns of failures regarding the implants. The other example could be using the data for decision support when deciding upon a device for patients. The language in the application is expected to be medical but clear and simple enough by using key terms for search. It would allow even a patient to search for information regarding treatment.

7.5 Personas

Fictional characters that are created using research done into target group. And serves as example cases used during the user experience development. Personas represent the real people behind the statistics and express the needs of the whole group [29]. Personas are used by designers during development so that the focus is on the user. These rich descriptions are not real people but are realistic more so than idealistic. Each persona has a unique set of goals, related to the product under development. Personas usually contain a description of the user‘s skills, tasks, attitudes, and environment. All of these are written in some detail so that it is not just a description. Each persona will usually have a name, a picture and some personal trait that will guide the designers as to seeing the personas as real users. A small set of personas is what is normal to have a product, and it might be helpful to choose one primary to represent the larger section of the user group. Personas are also a powerful way of communicating user goals and characteristics to designers and developers. How the persona is styled varies from project to project [30]. There are different kinds of personas, goal directed, role directed, engaging personas and fictional personas. All of these types of personas are useful in a variety of ways [58].



(a) Persona: Specialist in orthopedics



(b) Persona: Bioengineer

Figure 7.1: Personas developed during the project

Two primary personas were created fromr the target group that could be main stakeholders. Two personas are chosen *surgeon/researcher* as the most relevant and realistic personas for their goals and roles.

Chapter 8

Results

This chapter presents the results of the design there are several iterations. Through which design was created, prototyped, and evaluated. Detailed results will be presented in the evaluation (chapter 9). Sketches can be found in appendix A, and more images of the prototypes in Appendix C,D and E.

8.1 Design Iteration 1: Adverse event reporting concept

8.1.1 Concept

Concept for iteration one was the original concept where the idea was to use a mobile device for input of patient information starting at bedside. This could provide health care staff an opportunity to start early and collect information using mobile technology. Instead of doing everything in one bulk, the reportee would take in as much as possible in the application and finish up the report on desktop. This is due to the fact that a user cannot be expected to input a large amount of a text on a mobile device. But could use it to efficiently start the process. Once all information is gathered it can be edited and finalized on a desktop. Mobile devices are suitable for adding

information that is possible via touch and minimal input. Which is already great help in real clinical environments.

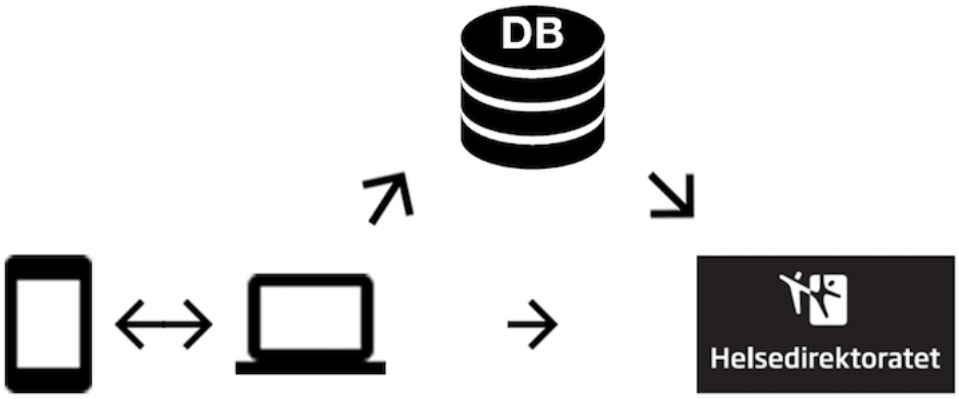
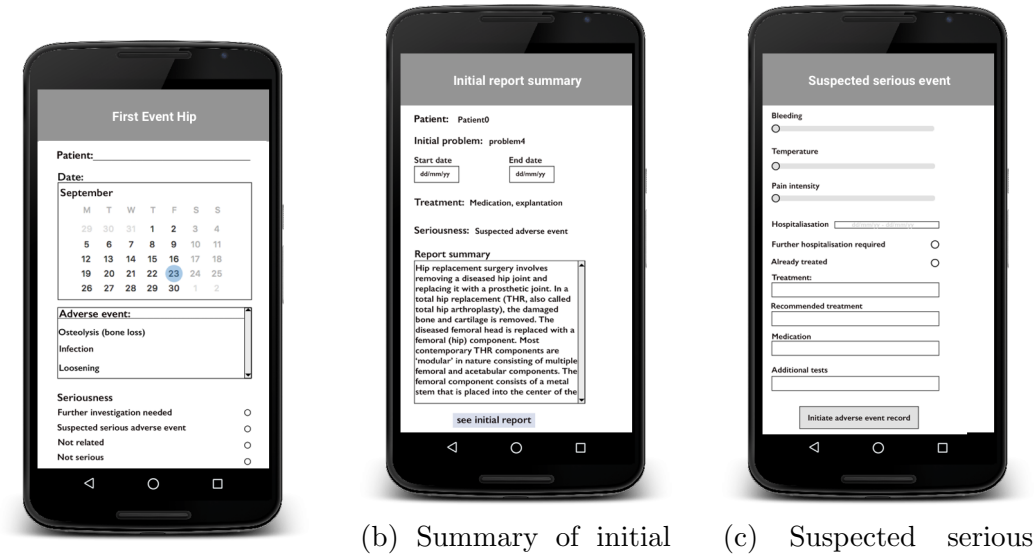


Figure 8.1: Iteration 1, Data flow in proposed mobile system

Figure 8.1 shows how the data collected should flow between mobile and desktop. And to the local internal system database and if judged as a serious case the report should be sent to the right authority. In Norway this would be helsedirektoratet. All the adverse events should be stored in local (hospital) databases as evidence and potentially learning material.

The reason it is important to also store everything in the local database and the internal system is to be able to learn from the mistakes that are done locally aswell as internationally.

The safety reporting consists of several steps prompted by an adverse reaction of event not anticipated with the usage of medical devices or treatment. The follow up entails one or several steps during which patient is checked and treated for the reaction. At each step, a report is created to detail a patient status and assessment of severity of the event. The result can be a final report with the resolved safety issue or a formal report to the regulatory authorities



(a) Input for first event (b) Summary of initial report (c) Suspected serious event

Figure 8.2: Screenshots from first iteration low fidelity prototype

in cases when the event is adjudicated as severe or serious. The mobile application is designed to start recording ad-verse events at the patient bedside thus allowing a quick and easy data entry. It should also enable a user to keep in touch with the whole hospital information system via a web-based system. The Figure 8.1 illustrates an IT platform with safety reporting as its integral part. Besides reporting of the safety reporting includes web-based reporting and patient reporting. The latter could be done using the same mobile design only adjusted to patient self- reporting that would include intensity and location of the patient's pain. An interactive design is going is being developed especially for patients. In addition, a web-mobile system will make complete reports available via a link and allow access to other related patient data. This part of development is dependent on the decisions and strategy of the Haukeland University Hospital in Bergen; the system should be a part of the hospital information system and its management.

Figure 8.2.a shows the first screen where the user starts with inputting data, 8.2.b is a screen of how the first initial report might look like, and 8.2.c is representing the input screen for when an adverse event is deemed serious.The design allows additional functionalities to be implemented. The application could further connect to desktop where the user will be able to add more

details.Resulting from the literature studies is a set of demands regarding the elements and structure of adverse event reporting. It starts with an initial report, which is followed-up with one, or several sequential follow-up reports that often include the adjudication of the event severity before the final report is generated. A mobile platform would be useful for collecting details at the ward, while on rounds and seeing patients in diverse ambulatory settings. This would simplify the reporting process, which may request notifying a regulatory body in case of severe adverse events. Mobile reporting would secure a faster and simpler report generating. Another advantage could be achieved by combining mobile and web-based technology. Safety reporting data could be combined with other patient data collected in electronic patient records and safety reports. Figure 1 suggests a platform integrating various data resources and enables a set of functionalities utilizing them.The safety reporting consists of several steps prompted by an adverse reaction of event not anticipated with the usage of medical devices or treatment. The follow up entails one or several steps during which patient is checked and treated for the reaction. At each step, a report is created to detail a patient status and assessment of severity of the event. The result can be a final report with the resolved safety issue or a formal report to the regulatory authorities in cases when the event is adjudicated as severe or serious.

8.1.2 Summary of feedback

There were some mixed responses to the concept and prototype. While most of them could se the benfit in using such a system. One surgeon commented that since there is not a large number of adverse event in each department it might be better and more useful to have a system for near misses and complications. The surgeon expressed a doubt regarding such a system: most medical staff would not like to do more reports than they already need to do. They may also not be happy with learning one more system. The feedback from bioengineers was different, they could see a huge need for such technology, they also mentioned the benefit of reducing cost when using systems like these. It was also pointed out that it was important to find out who collects data, and when. Especially since this might not be standardized so it might vary from hospital to hospital, vary between different nurses, doctors, countries, and states. Laws will also vary according to country and, or state. Another valid point mentioned was that when trying to interview medical

staff one must tread carefully and be forthcoming with information, this is because people in general might be afraid of change. And might not give information if they sense that there is a possibility of change.

Suggested questions and considerations to improve system concept: Questions to ask:

1. Does a GP refer the patient to the specialist or did they come in as an emergency? (what data do they collect and on what system)
2. What does the specialist do then. Collect basic data (or does a nurse to this)?
3. What diagnostic tests are done e.g. if the patient is sent to a radiologist, or a sample is sent to a histologist.
4. If there is an operation, who collects what information (perhaps the surgeon does some and a nurse the rest)
5. Is it different from the journal system the doctors are already using? Will there be overlap?
6. Is there difference in your system and the regular one is that in your system contains the more unusual ones, this must be defined better. E.g. is it the ones that require you to do a re-operation?
7. Is there a difference between treatment and recommended treatment? Or is it a recommendation for the doctor/surgeon based on national recommendation or hospital routines (called method book)?
8. Is it possible to have a connection to the journaling system? Are there any security issues?

Summary of iteration

The main knowledge that can be extracted from iteration 1 is that there is a need for these types of data and systems. The reason why it is so difficult to implement is because of the reluctance from intended users. This confirms the findings from literature regarding barriers and attitudes towards safety reporting.Feedback from intended users was straight forward and useful, but

has also suggested a need for alternative ways of looking for safety information. One suggested that a natural shift of the concept would be towards pharmacovigilance.

8.1.3 Evaluation of concept

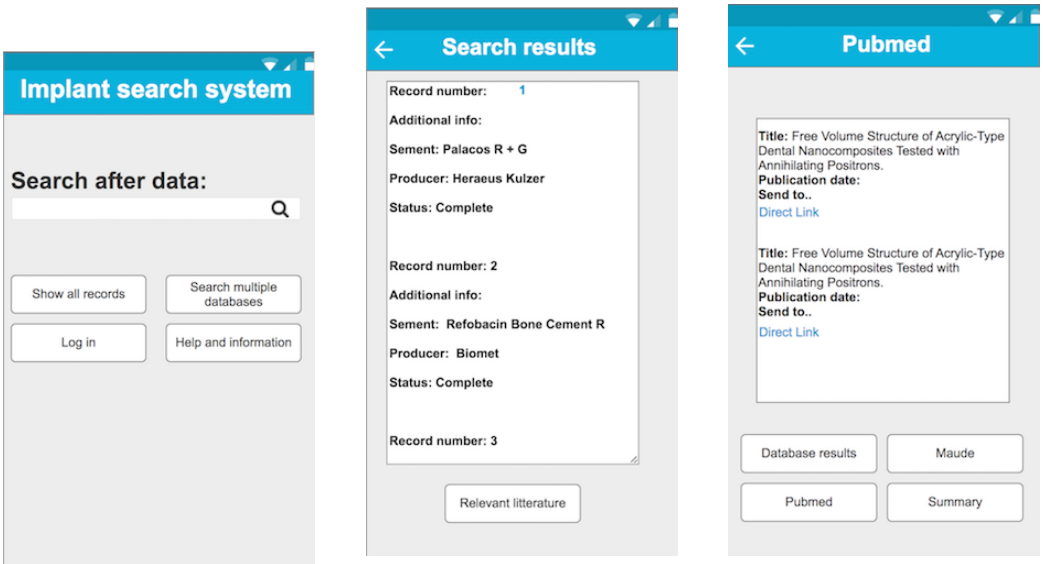
To evaluate the concept experts were given a description of the concept along with a low fidelity paper prototype to illustrate the system. They were also given instructions where they were encouraged to comment and draw on the illustrations and give feedback when appropriate.

8.2 Design Iteration 2: Pharmacovigilance system concept

In recent years pharmacovigilance has increasingly incorporated information and communication technologies. Researchers have explored possibilities of sharing data online and using internet search engines[59]. A rise of web based systems has inspired development of system called weBBiss[60] That has been developed by the medical informatics group at the university of Bergen. To extend the usability of the webBISS a mobile design was designed. The intention was to gather safety information at the minimal inconvenience of using the mainframe(Webiss) but to make it convenient and simple. This iteration will describe adjustment of interface from webBBiss to mISS. This iteration is therefore seen as transitional.

8.2.1 Pharmacovigilance concept 1

Concept The concept changed from input to output, the intention here is to create a suggestion for a cross-platform app, where the users can search for failed implants and articles related to prosthesis. It will be based on WebBiss site which is already initiated but limited to the focus on the back-end side of the system. The central pharmacovigilance concept was adopted after webBiss[60]. The new suggestions regarded the interface, UX, and interaction design for a mobile version. This prototype was evaluated by two



(a) Search screen

(b) How results could look

(c) Suggestion for literature results

Figure 8.3: Three screenshot from iteration two

experts in the field of HCI and interaction designto reflect on usability and content. The prototype was of mixed fidelity.

8.2.2 Design Expert Feedback

One of the experts pointed out that for such a small screen there is a lot of text. A suggestion given was to add visualizations on smaller screens so that user can spend less time reading and increase the effectiveness and efficiency of using the app. Another valid point the experts had was to add some awareness to the app. This was to let the user know where they are in the app, give the users choice to what they want to see and also ease navigation and increase learnability. Another expert gave a practical suggestion to give users the possibility to save articles of interest. This would give the user opportunity not lose valuable information and to read articles on convince. Such as a bigger screen or at home.

8.2.3 Evaluation

The design was already developed and easier to redesign when basing on an already suggested solution. But the system needed adaptation and more focus on usability.

8.3 Design Iteration 3

The feedback from iteration two has suggested using visualizations as this would help users make faster choices and enable them to spend less time using the app and more time on interpreting retrieved information. Ideally, the visualization will let the user retrieve information quicker and more efficient than scrolling trough a large number of text. Results should be to the point instead of some screens scroll. The design that allows smaller well-defined steps are beneficial; one more step could mean gain instead of losing information through scrolling. In other words visualized and well presented information is better than just text rolling up and down the screen. Visualization helps with growing body of the information as it returns a well defined clear data and helps to keep the overview.

(a) Search screen (b) Clinical trial results (c) First suggestion for settings

Figure 8.4: Three screens from iteration three

8.3.1 Concept

Since you cannot assume that mobile users are sitting still, it is important to consider how to choose the different databases in the app, and keep in mind that the user will most likely be a bit distracted if they are on the go. Therefore allowing the user a larger area to select the wanted prototype is a smart idea.

Also based on feedback in iteration two a decision to add visualization as this will help the users make faster choices and be able to spend less time using the app and more time on using the information that they find. Ideally, the visualization should increase the speed to which the user finds what they are looking for instead of just scrolling page after page. The mistake that was made in previous iterations was thinking that adding one more step in the selection process would slow down and irritate the users when this actually

might be opposite. Adding an extra step that allows the user to quickly choose where to go next compared to scrolling just text would, in theory, be more pleasurable and visually pleasing than the traditional text.

8.3.2 Design

The design is presented as a set of screenshots in Appendix E; here there is also screens from the changes made after the first round of evaluation(Chapter 9). Figure 8.4.a shows the proposed search screen where keywords will trigger a search through MAUDE [61], PubMed [62], clinical trial database [63] and local database. One can also navigate by using the bar at the bottom of the screens.

8.3.3 Feedback

The feedback from participants this round was positive to the design. They managed all the tasks fine. It is however not easy to evaluate prototypes which are not finished as all the functions are not done. So an expected low score on error handling and pop up messages was expected. The high fidelity prototype suggested all the functionalities that would exist in the finalized app, but some not fully functioning. That seems to make it intuitive and easy to use.More detailed feedback and comments can be found in the evaluation (Chapter 9).

8.3.4 Evaluation

The system still needed some tweaking for mobile devices, because of small screen size changes were needed.

Chapter 9

Evaluation

This chapter is organized around the design iterations. It is based on evaluation method done at the end of each iteration. Expert evaluation, Nielsen heuristic and System usability scale.

9.0.1 Evaluation summary of iteration 1

Before any real world application can be implemented, it is important to think about safety issues and barriers. Another practical issue is compatibility of safety reporting systems and existing hospital software and hardware systems.Some norwegian physicians are currently using dictaphone for input which can be a factor in designing at a later stage. The content should be created concerning the complexity of medical language. Users must be aware, clear meaning examples such as a difference between *fever* and *temperature*. Another important example is the difference between *treatment* and *recommended treatment*. It is important to know if it is a recommendation from surgeon or guideline for treatment. The initial report could be problematic as this could be too similar to patient record, this could have implication for the safety and privacy of data. Another concern is that the system could overlap with current patient record system. That would mean that design should be detailed and well thought of. Regardless of the reluctance of the reporting the design should be relevant and capture well clinical processes. It must be clear that this design concerns adverse events in the first hand.

And inspiration for the design could also be the paper form used by the national registry(appendix). There is also an issue of standardization; different surgeons, nurses, and hospitals do things in a slightly different way. And may have opinions on how things should be done. This requires as many surgeons as possible to elicit competent and detailed understanding of their expectations. One of the major issues is to understand the pathway from start to finish.

9.1 Evaluation summary of iteration 2

Iteration 2 is based on the webBiss system. The issued is how to browse and use a moderately large information volume on a small screen, being restricted to touch input and soft keyboard. It is recommended to analyze data and think about mobile first data visualization of moderate size data set as a separate task, independent of the interaction design of the source system(webBiss). Another solution would be to filter the amount of information available through mobile access to a few top ranked hits. In this case, more text oriented approach would be sufficient otherwise data visualization is the option to explore. Dealing also with the moderate size databases could be simplified by using "my library" to store interesting articles. Otherwise, it is recommended to simplify tasks and have a list of pointer to the original website. For the safety and privacy reasons, it might be good to have a log in option.

9.2 Evaluation summary and results of iteration 3

9.2.1 Evaluation summary

Expert opinions were in general positive, and main functionalities were clear and easy to connect with the flow of adverse events. It would be a good idea to come with several visual representations of results. The next thing would be to design a filter that would allow a quick and precise search. For example, the event type is the most important, then perhaps device brand

to search with. Some additional things could be added to the database, but that would demand more work with users. Regarding the local bioengineering database, it would be ideal to show some x-rays and reasons for removal of the device. There might be some confusion the heart icon for "liking" button whose functions is to mark a favorite article or report. Another expert has also emphasized the need to filter specialized databases to enable as precise as possible retrieval. Users could choose from a list of different brands of medical devices. That way it would be possible to get more information about the safety of particular medical devices.

Three experts were chosen for the first heuristic evaluation and system usability scale. The reason was, in addition, to conduct a semi-structured interview and allow evaluators to respond in depth. These had a background in human computer interaction. In the second round, six evaluators contributed. The observer was present mainly to answer questions as no in depth interview was planned.

The heuristic evaluation found that most of the participants were satisfied with the visibility of the system, the match between real world and system, consistency of the system, easiness of navigation and icons used, according to the evaluators.

The heuristics with the lowest score was related to error prevention, help and documentation. Lower scores were expected since these functions were not implemented yet in the prototype. There also seems to be a problem of understanding the medical terminology by non-medically trained participants; some words were hard to comprehend, and it was equally demanding to grasp the content of different databases. This could be easily fixed in the future by generating an 'About' or 'Help' page. There were also some cases where most participants gave a high score, and one participant gave a very low score. This might be due to a misunderstanding, but the participant opted not to ask for help during or additional during the evaluation. All participants were told that they could spend as much time they wanted/needed and that they could ask questions at any point.

the choice was made to start with three users for the first heuristic evaluation and system usability scale. This would create an opportunity to have a discussion, and get more in depth with the first participants. These were experts in HCI and medical field.

The second round of heuristic evaluations and SUS used 6 participants who gave their feedback, but no interview was planned. The observer was available for questions if they needed to ask, or wanted explanations for functionalities or concept.

Heuristics

Was performed using Nielsen 10 heuristics, this is because of these already established heuristics for interfaces. System usability scale was used after performing five tasks linked to the heuristic evaluation. The participants first received information, then they did the tasks, answered the heuristics, and after that, the final assessment was the system usability scale.

Tasks All of the rounds of the heuristic evaluation got the same tasks:

1. Go to search page
2. Type inn keyword "knee" and choose Biomet as manufacturer
3. Select one of the databases from the results.
4. Favorite or try and email one of the results.
5. Explore and try and get familiar with the application before answering and commenting.

Number 5 in the table was added to make sure evaluators explore the functionalities of the design/prototype. The idea was also to see if they can make it without having additional information given. The evaluation was performed with only a single participant at the time to avoid an information cascade. The participants were also asked to score the heuristics from 1-10 and leave a comment if necessary.

9.2.2 Results from iteration 3

All graphs presented are the average Scores from heuristics and the average SUS scores.

Heuristic evaluation

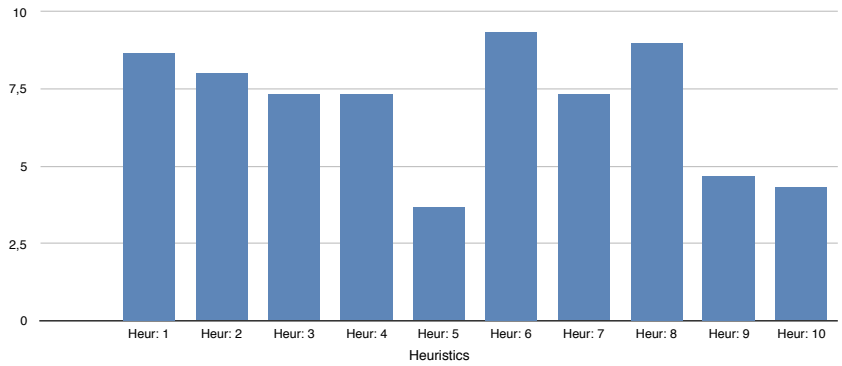


Figure 9.1: Results from heuristic evaluation with interview

Comments from Evaluators first round

- Emergency exit would be preferred, even though you can navigate back.
- Home option should take the user to either search or login screen.
- Buttons are too small; several items in the user interface should increase in size.
- *As an experienced user I would like to set my preferred database and manufacturer so that I do not have to reselect them all the time.*
- There are no error messages.
- More information needed about the databases and what they are and what can be done in the application.
- More feedback required for action regarding functionality(for example: set favorite article or report).
- Being able to erase data easier.
- Having help on each page to explain options and specific information linked to that site.
- The color of the selected page in navigation does not go well with the others, maybe another hue same as the rest of the app would be suitable.

System Usability Scale

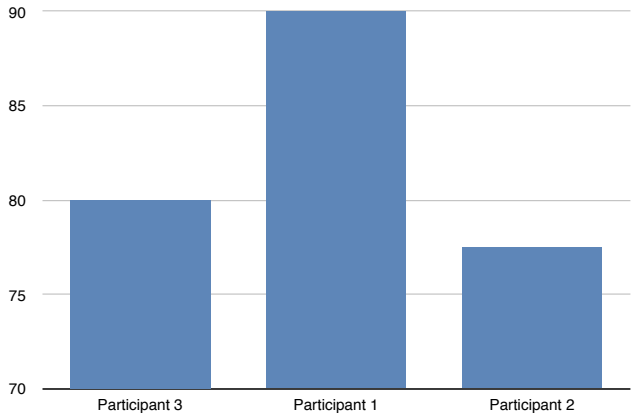


Figure 9.2: Results from SUS with interview

9.2.3 Results from evaluation without interview

Heuristic evaluation

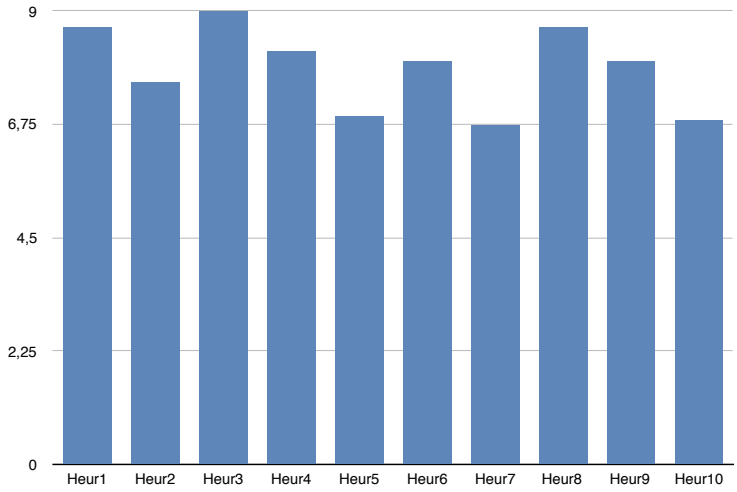


Figure 9.3: Heuristic evaluation without interview

Comments from Evaluators second round

- Language is probably easy for the target group, but for me it is not clear what information resides.
- Good match between system and the real world as the intended user will know the terminology.
- Bottom of page(navigation) gives the impression that this is part of search function.
- No problems navigating back and forth
- Suggesting a redo button
- Does one need to log in?
- There should be feedback about the amount of reports and literature that matches the search term.
- Choose to view graphs or textual representation.
- Error messages where appropriate did only get one when no search term was entered.
- Consider different systems (Android, Google, Apple) smartphones use different icons for the menu. All are understandable but should be customized.

System Usability Scale

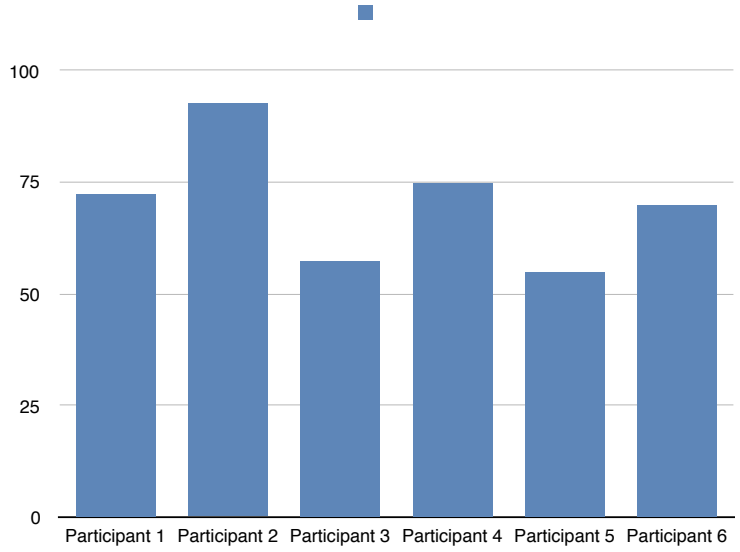


Figure 9.4: Results from SUS without interview

The heuristic evaluation found that most of the participants were satisfied with the visibility of the system, the match between real world and system, consistency of the system, easiness of navigation and icons used.

9.3 Summary of iteration 3

Lowest scored heuristics:
Heuristic 5: *Error prevention* got a very low score with the first three evaluators, but higher when there were more participants.
Heuristic 7: *Flexibility and efficiency of use*received a lower score when more evaluators were involved.
Heuristic: 9: *Help users recognize, diagnose and recover from errors* had the lowest score in heuristics with the interview. This suggests that the small changes made between heuristic evaluation with interview and heuristic evaluation without interview were successful.
Heuristic 10: *Help and documentation* received low score in both heuristic

evaluations

Some of the evaluators chose to answers N/A on these heuristics which might have impacted the result. They chose to do this because they felt it did not apply to their experience of the system and also had no opinion or comment they wanted to make. There was also a huge variety in the System Usability scores; this is also because the text is open to interpretation. So some took the text literally, and some imagined being medical staff for example. This is information received during the interviews and comments made during evaluation by some participants.

The design principles supports the usability goals which again can be measured by Nielsen heuristics. In my case the usability goals that were not satisfied were safety and utility this is because error prevention, help and documentation and several wanted functionalities were not implemented in the prototype when evaluation was done.

Chapter 10

Discussion

In this chapter, the main aspects of the research and development will be reflected on. Methods used, prototypes, answers to the research questions are discussed in detail. Design Science Research approach was utilized as the guiding principle throughout the master thesis project. Following the guidelines by Hevner et al[8] was instrumental in securing the holistic structure of the research. Two separate designs were developed and tested for reporting of adverse reports after arthroplasty. One was a mobile solution for safety reporting starting from the patient bedside and the second one was done for pharmacovigilance. Both of them are intended to contribute to patient safety, although in different ways. Only one of the design solutions (pharmacovigilance) had appealed to the medical staff with the reason being not the design, but rather the clinical routines and attitude towards the safety reporting.

10.1 Methods

Several methods were used to acquire requirements, create designs and involve potential user groups to elicit knowledge and evaluate the design solutions (artifacts).

Literature overview has been utilized very well and helped assemble the information requirements for the first safety reporting design (Chapter 8, 9).

Due to the well known facts, and needs for the safety reporting as a part of patient safety, surprisingly many details are available. The process of reporting could be delineated in general terms which were useful to create a design to which clinical staff could easily relate and suggest changes and comments.

Unstructured and semi structured interviews were used to elicit expert knowledge from the human computer interaction experts and the clinical staff regarding their current clinical routines and the need for safety reporting (Chapter 7, 9). This has been an excellent approach especially regarding the design concept and evaluation to which both the experts and clinical staff responded. When it comes to extracting the knowledge from clinical staff the most cooperative and constructive was the participants from the Biomedical Laboratory at the Haukeland University Hospital in Bergen (Chapter 7, 9). They deal with safety reporting daily and would benefit from a fully functioning safety reporting system.

Design Science framework was used for designing and assessing user experience. It was flexible enough to secure the purpose driven creation of two artifacts as a solution for the relevant problem (safety reporting and pharmacovigilance) using research cycles (Chapter 5, 6, 7, 8, 9, 10, 11). User experience was central to the artifacts (Chapter 8) since they are intended for end users who already feel reluctant to use such a system.

Observation was used only during the evaluation so that the observer was present to answer possible questions and observe if there were difficulties using the high-fidelity prototype.

10.2 HCI methods

Interaction design and UX methods were applied aided in the design process. The design iterations consisted of sketches, mock-ups, requirements and evaluation before repeating for the next step. Involving stakeholders at an even earlier point than this research would be reasonable and create an even better design and requirements. Also, a larger number of evaluators would be a good choice. Based on the literature and my experiences I would start the next project with research and data gathering involving users at the earliest possible step, then create requirements based on the data and

information generated. The last two steps should be creating a prototype and testing or evaluating the prototype based on if it is low or high fidelity. Another tip would be to create heuristic specifically for the product that one is developing as this can also be done, but off course Nielsen heuristics for the web are equally as good to follow. The evaluation showed that not all usability goals were reached after iteration three. So there is still work that could be done to increase the likelihood of user satisfaction.

Starting from a low fidelity prototype and continuing up to a high fidelity prototype creates a solid design basis to base choices on and also get concrete feedback from evaluators. Prototyping is necessary to avoid spending a significant amount of time and money on developing something that users either don't like or find too hard to use, so they abandon it or find something else.

Development methodology was mainly a personal Kanban[12] that was instrumental in keeping the control over the work and timelines. This straightforward and easy to follow method was efficient and recommendable for a single project developer. More complicated Agile methods would demand the presence of the stakeholders, and potential users which would be hard to secure on the permanent basis in a master thesis type of project. This has not excluded experts who were present in the and evaluation work (Chapter 8,9).

10.3 Answering Research Questions

Research Question 1 How could mobile technology design support adverse event reporting?

Within the thesis work, two main approaches were applied to support safety reporting. Both of them were based on mobile platforms to make it as quick and easy as possible for the user to send and retrieve data. Each of them was understandable and with clearly defined functions, but with a very different appeal to potential users.

The reason seems to be additional work that adverse event reporting (first artifact) would cause. This reluctance to report had also consequence for this research; the first design was appealing and clear as the design but

would mean additional work burden. The second solution (artifact) was developed to support a much more accepted practice of pharmacovigilance. A web-based system WebBISS (ref) was used as a starting point that allows searching for information on explanted knee and hip prostheses. Users seemed to appreciate a mobile solution as an addition to the already existing web-based solution (WeBBIS); the mobile platform meant more flexibility and easier interaction with the information resources using a smartphone.

Design wise both the solutions have the same features and should, in theory, have the same kind of appeal to the user for the purpose of online reporting. Both designs have been tested by users and experts at differing points in the iterative process. It was interesting to notice that the first has reminded physicians of the mandatory forms that health authorities usually demand of them. This could be of credit to the design solution, as it had suggested professional finalization. The fact that literature could provide a solid basis for the first design speaks about the relevance of the problem. With refinements from users, it would be possible to tailor solutions that would fit into various hospital information system; both of the developed mobile solutions are flexible and resourceful to enable that.

Research Question 2 How can interaction design support building sustainable and appealing solutions for adverse event reporting?

The straight answer would be to design solutions with the functionality that is clear and easy to follow and that can make the reporting as simple and agreeable as possible. To this end, user centered design has been utilized. Users were involved to contribute through their knowledge and requirements and to critique the concept and test prototypes. Evaluations have been done using informal interviews, discussion around the concept, heuristic evaluation, and system usability scale. Every evaluation done is valuable for the next iteration as this gives me information about what works and what does not work. It had been especially important to get feedback from medically trained staff since I have been designing for a domain which was at the start very new to me.

The results from all the iterations have shown that the design could be accepted and used if not for the barriers encountered. It has also shown that unwanted functionality may lead to rejecting artifacts. For a system to be implemented and accepted by its users, it should fit in naturally in the workflow and not disrupt as this could lead to negative connotations towards the

system. Design in this current form should be able to undergo more changes to satisfy more user groups. In the current state, there are two different user groups: surgeons and biomedical engineers. The first group would appreciate a simple design, while the other group would like more details because they need to produce more comprehensive reports. Visits to two different university hospitals, Bergen Haukeland and Linköping hospital, showed that there were different procedures established for safety reporting. Safety reporting is organized to fit the particular organizations, and this seems to be the case with other hospitals. This is of consequence to the design because different processes and stakeholders have different expectations and standard operating procedures. Interaction design has means of incorporating different practices and especially using mobile technology by developing design variations according to user specifications.

Attitude towards the safety reporting Safety reporting is a complicated process that is crucial for all involved in healthcare, medical and pharmaceutical industry. The ever-growing number of devices, medicines and related treatments is ever high. Monitoring and reporting adverse events is of vital importance. The ways of reporting are not often continent, well designed or transparent. The attitude toward reporting is defined by several key moments: information, willingness, accountability, feasibility, and learning (ref). This research as also identified a few additional moments that can impact the clinical reporting: the work burden, professional reputation, and continence of reporting. In this research, we were not dealing with the attitudes but rather tried to come with a design that would be acceptable. The clinical processes are too complex to interfere with. Another major issue with a project like this is getting enough time with medical staff. Some of the junior staff and newly graduated were unsure and did not know about the adverse event reporting. More senior staff knew what to do, but felt they were not as compliant with the reporting as they could be. During the interviews, it was revealed that the first reason for this was the work burden. Whatever the reason, the design should not be imposed on anybody as the means of changing the attitude.

Chapter 11

Conclusion

This research regarding safety reporting is backed up by literature and the interviews with medical professionals who all agree about the importance of the reporting of adverse events. The challenge of the clinical work makes them avoid any added labor, and that is also the case with reporting. Introducing a new system or ways of safety reporting would be positive, but it will come with a cost of maintenance and further work. The primary motivation being patient safety should make the medical staff consider new solutions. In this research, mobile technology was examined and should be integrated with existing hospital information systems. Aided by good design, based on the human computer interaction, it would be expected propose reasonable solutions in support of safety reporting.

The design of the first artifact for safety reporting was evident and brought up the sense of demand to report adverse safety events in a way that health authorities request it, the information and processes resemble the official ways of safety reporting. This understanding of the design also came with a question if it could be adjusted to general reporting which in turn would require additional user groups to participate in design process. There is still work to be done on attitudes towards reporting and lack of motivation for it; medical staff tends to comply with it in cases where it is made mandatory by the government. The second artifact was designed to retrieve information regarding patient safety in the form of a mobile pharmacovigilance tool. All the functionalities are designed to take the user straightforward to the public databases and retrieve safety information in a secure manner. This

artifact is an alternative to the first artifact since adverse event reporting is in some cases hindered by workload, work culture, or a fear of reprimand. The pharmacovigilance tool was evaluated using low and high fidelity prototypes which gave good critique and suggestions for next design iteration(s) and future work.

The evaluation has pointed out several ways in which mobile artifacts could be utilized. In design iteration 1, it was clear that serious events which need to be reported are not always reported. Therefore, it is important to avoid having the app feel like it is just a transformation of a paper form to the screen, it is essential to come with an intuitive design solution that enables simple, intuitive data entry. Starting the reporting process at the patient bedside would be a good step towards assembling a safety report. The data collection and the reporting process would be initialized using a smartphone. The rest of the data would be collected during the follow up and eventually the report would be assembled using the collected data and other vital information from the patient electronic health record. This solution would allow information sharing and transparency of the process among treating physicians.

The results and evaluation also suggest that there is more that could be done. One logical step would be improving the design solutions, but also work on the attitude towards reporting. In relation, this it would be wise to focus on one hospital to develop and make the best possible design. The next step would be to generalize a system of reporting which also cater to near misses and other non-serious events. Mobile solutions could be utilized to connect to the existing hospital information systems and other relevant sources of the safety data. National guidelines would standardize safety reporting procedures which would probably make the reporting not only serious adverse events mandatory but also other cases. The gain would be a national safety knowledge database, similar to the MAUDE system [61], which could be an open national system. This should ideally be connected to a worldwide database so international and national patterns could be identified and further researched. The Artifacts were developed for the field of arthroplasty, but are so general that they could easily be adjustable to other the fields.

Chapter 12

Future work

The first step for the future work would be to fully implement the artifacts and test them in a real clinical environment. It would be interesting to see whether this could make the first artifact for reporting of adverse event accepted into the clinical environment. The fact is that this kind of reporting is well established in many clinical environments which speak for it. The data and knowledge are of advantage when analyzing not only patient risks but also medical treatments.

Another value of collecting the safety data is its potential to improve current practices and create an e-learning environment. The latter could be of use even for students and patients.

The field of Medical Informatics offers lots of methods and technologies that could be utilized. Mobile solutions are most often compatible with the data security and privacy standards and data formats used in electronic patient records. That enables development of other mobile and web technology solutions; examples are following in the text.

- Further develop 1st prototype
  Include the option of reporting so that it would be a fully functioning input/output system for reports. This would require employees not just for the system but also for looking at the reports. So it would have to be decided if the system should be internal/external and who would be responsible for not only maintaining machines but also who would be responsible for the reports sent in.

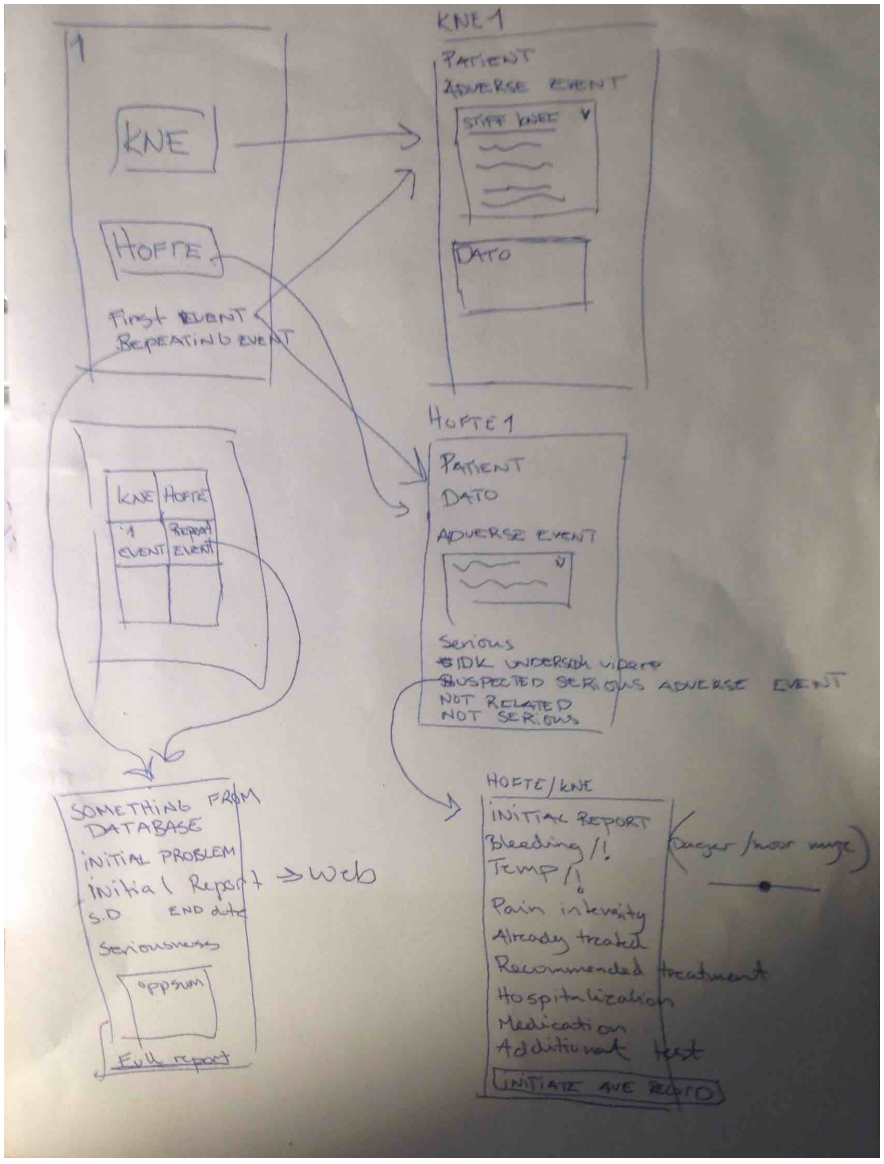
- Mobile system for patients
  Connecting a patient input system with my proposed system can generate patient data that surgeons and doctors may find valuable.
- Learning options for student/patient
  An automatic option for students to view the data in a learning effective way. So it could be used during education or when in the ward.
- generalized
  A generalized version where the first page would be where you choose between the medical discipline you want to view reports from. Not just orthopedics. Having an all-round system could be useful. Especially if patients have been in different wards with various issues. Another function would be to have an internal version that will handle near misses, adverse events and not just the serious events that happen during a procedure or related to medical devices.
- Cross platform
  Ideally, the application should work on different platforms and also over different brands so that it can be used by everyone not depending on which brand of electronics the hospital chose to buy.
- International/national
  Ideally, an application such as the one proposed should be used on a national level and maybe even a function to get international reports as well. This way there would be larger dataset collected in one application and not scattered all over. This could connect and link vital information that one otherwise would have to search multiple sources to find.
- Application for smartwatches
  A possibility in the future could also be including an application for smartwatches where the user could get notifications when a relevant report of literature is published. The user would have to set this in the setting menu and connect with the mobile application on desktop.
- Decision Support System (DSS)
  Ideally, this would be a system that could be generalized for every department and also include drug safety so that medical staff and researchers could look up reports concerning their interest in one app on either a mobile phone, tablet or desktop. Ideally, it should be inte-

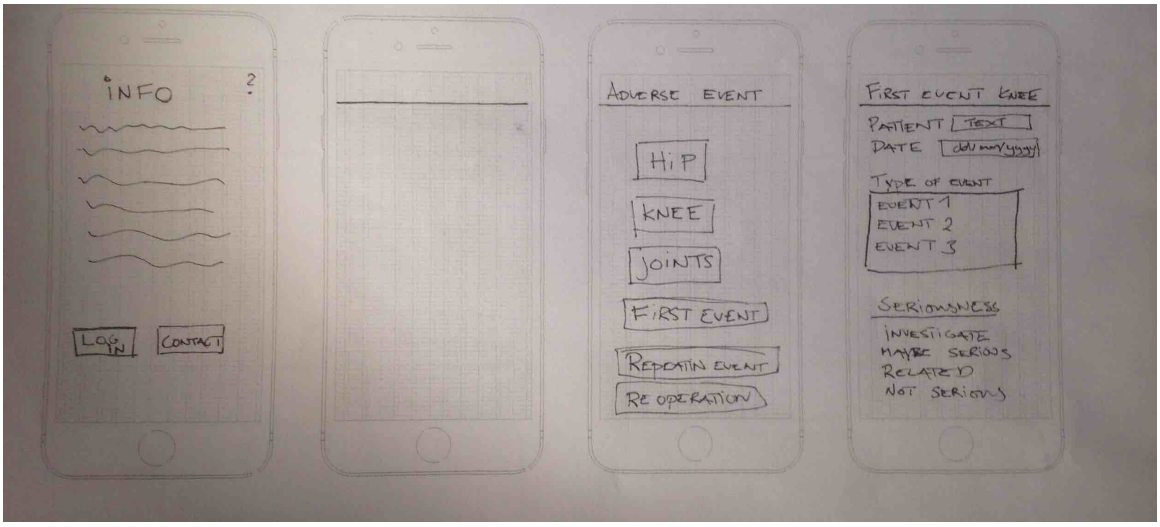
grated with a decision support system so that the DSS would gain data from the reports. This would especially help when making a decision about rare diseases or reaction to medical devices.

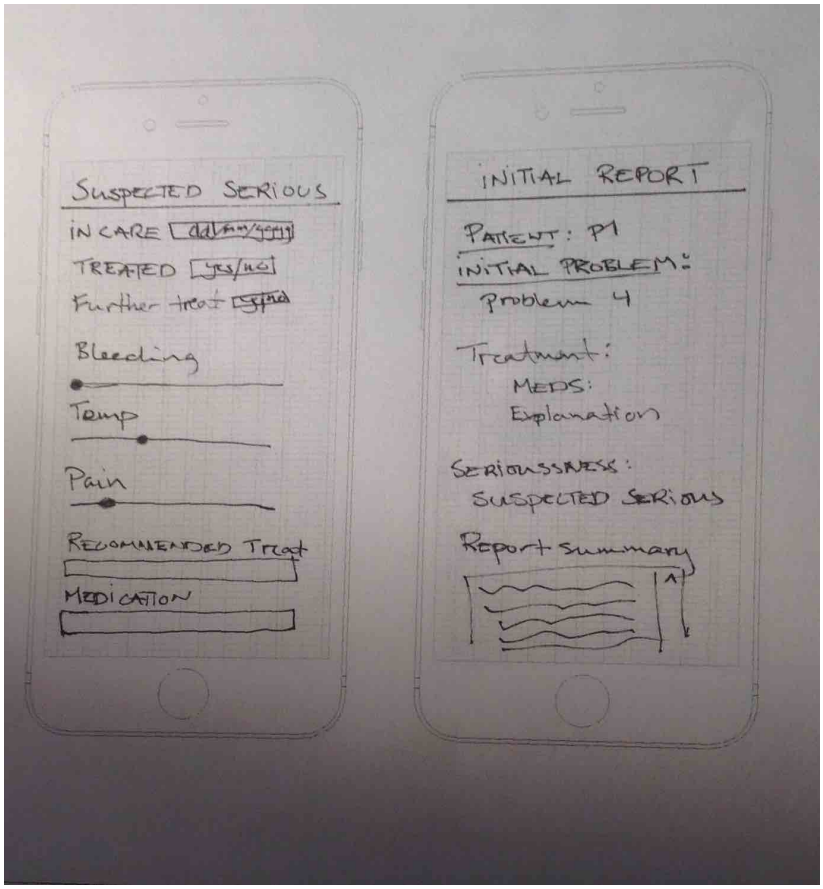
Social/work environment To be able to really fully implement and further develop applications presented in this research, attitudes towards the reporting need to change to a positive note. More work is needed in the clinical environments and even with patients who had already shown interest in safety reporting.

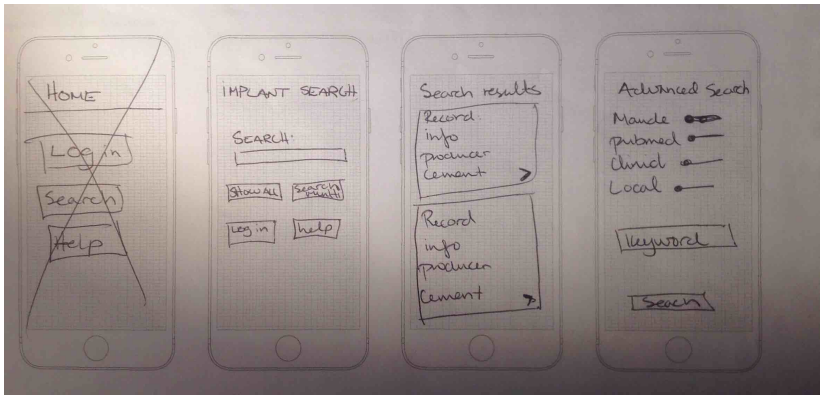
Appendix A

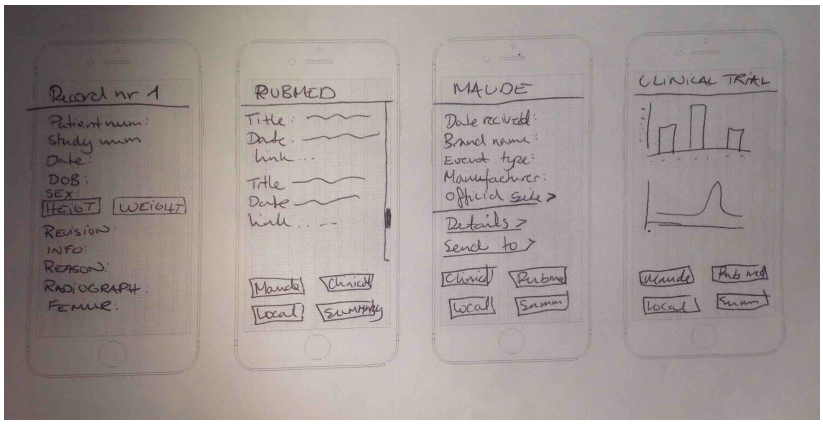
Sketches

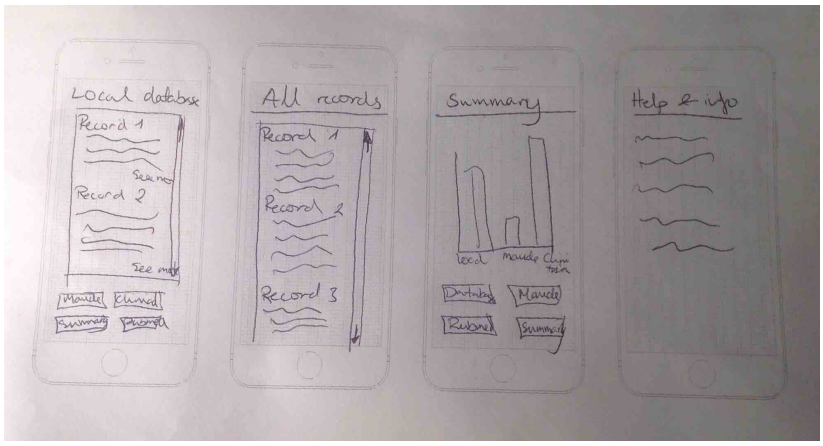

1
KNE
HOFTE
First EVENT
REPEATING EVENT
KNE 1
PATIENT
ADVERSE EVENT
STIFF KNEE
DATO
KNE
HOFTE
1 EVENT
REPEAT EVENT
HOFTE 1
PATIENT
DATO
ADVERSE EVENT
Serious
SUSPECTED SERIOUS ADVERSE EVENT
NOT RELATED
NOT SERIOUS
SOMETHING FROM DATABASE
INITIAL PROBLEM
Initial Report → web
S.D END date
Seriousness
Epp sum
Full report
HOFTE/KNE
INITIAL REPORT
Bleeding /!
Temp /!
Pain intensity
Already treated
Recommended treatment
Hospitalization
Medication
Additional test
INITIATE AVE REPORT

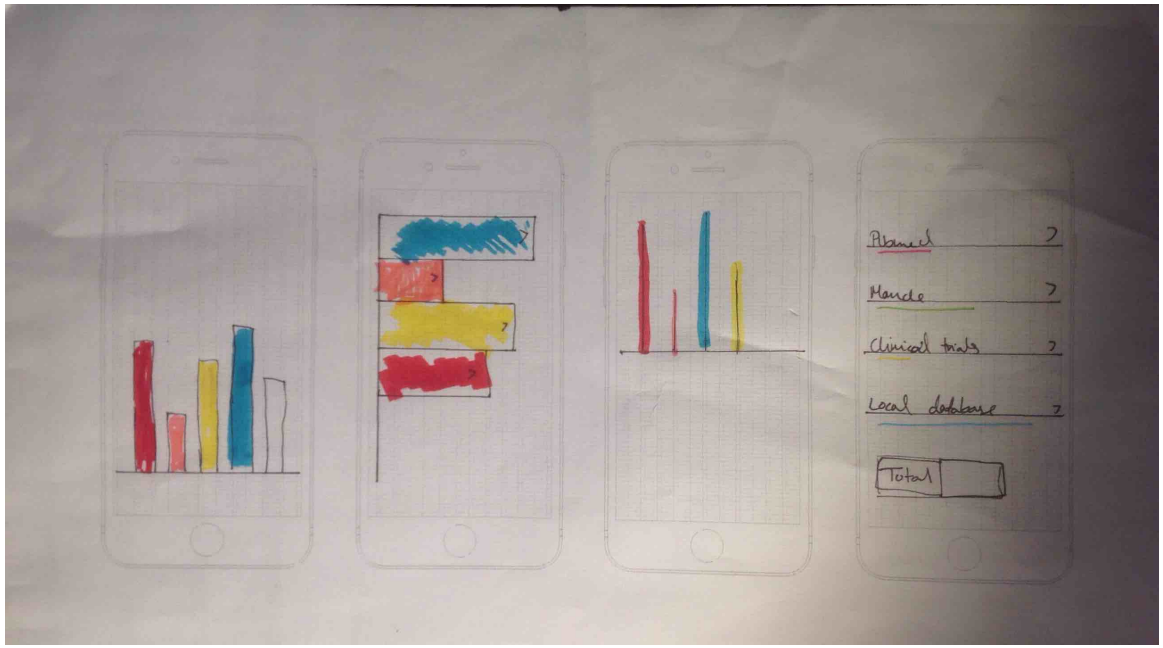

INFO
?
LOG IN
CONTACT
ADVERSE EVENT
HIP
KNEE
JOINTS
FIRST EVENT
REPEATN EVENT
RE OPERATION
FIRST EVENT KNEE
PATIENT
TEXT
DATE
dd/mm/yyyy
TYPE OF EVENT
EVENT 1
EVENT 2
EVENT 3
SERIOUSNESS
INVESTIGATE
MAYBE SERIOUS
RELATED
NOT SERIOUS

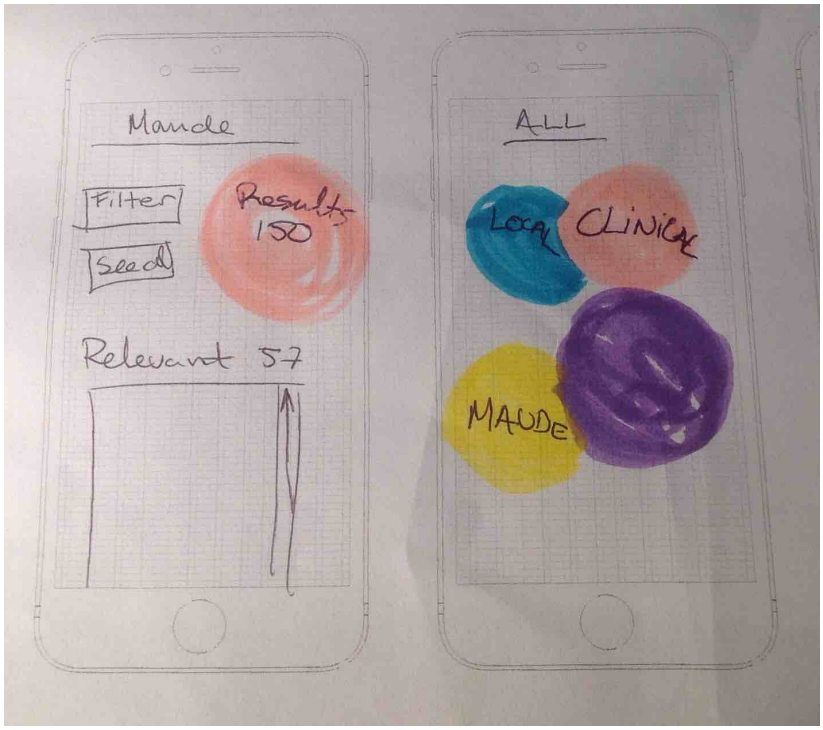

SUSPECTED SERIOUS
IN CARE [yes/no]
TREATED [yes/no]
Further treat [yes/no]
Bleeding
Temp
Pain
RECOMMENDED Treat
MEDICATION
INITIAL REPORT
PATIENT: P1
INITIAL PROBLEM:
Problem 4
Treatment:
MEDS:
Explanation
SERIOUSSNESS:
SUSPECTED SERIOUS
Report summary


HOME
Log in
Search
Help
IMPLANT SEARCH
SEARCH:
Show All
Search Results
Log in
help
Search results
Record
info
producer
Cement
Record
info
producer
Cement
Advanced Search
Mandle
pubmed
Clinical
Local
Keyword
Search


Record nr 1
Patient num:
Study num
Date:
DOB:
SEX
HEIGT
WEIGHT
REVISION
INFO
REASON:
RADIOGRAPH:
FEMUR:
PUBMED
Title:
Date:
link...
Title
Date
link...
Manual
Clinical
Local
Summary
MAUDE
Date received:
Brand name:
Event type:
Manufacturer:
Official Site >
Details >
Send to >
Clinical
Pubmed
Local
Summ
CLINICAL TRIAL
Manual
Pub med
Local
Summ


Local database
Record 1
Record 2
All records
Record 1
Record 2
Record 3
Summary
Help & info


Patient
Monde
Clinical trials
Local database
Total


Maude
Filter
Search
Results 150
Relevant 57
ALL
LOCAL
CLINICAL
MAUDE

Appendix B

Collection of reporting forms

NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland universitetssjukehus
Møllendalsbakken 11
5021 BERGEN
Tlf: 55976452

F.nr. (11 sifre).....

Navn:.....

(Skriv tydelig ev. pasientklistrelapp – **spesifiser sykehus**.)

Sykehus:.....

HOFTEBRUDD

PRIMÆRE OPERASJONER PÅ BRUDD I PROKSIMALE FEMURENDE og ALLE REOPERASJONER, inkludert lukket reponering av hemiproteser. Ved primæroperasjon med totalprotese og ved reoperasjon til totalprotese brukes kun hofteproteseskjema. Alle produktklistrelapper settes i merket felt på baksiden av skjemaet.

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

SIDE (ett kryss) (Bilateral opr.= 2 skjema)
☐1 Høyre ☐2 Venstre

OPR TIDSPUNKT (dd.mm.åå) |__|__|__|__|__|__| kl |__|__|

BRUDD TIDSPUNKT (dd.mm.åå) |__|__|__|__|__|__| kl |__|__|
Dersom det er usikkerhet om bruddtidspunkt, fyll ut neste punkt.

TID FRA BRUDD TIL OPERASJON I TIMER
☐1 0-6 ☐2 >6-12 ☐3 >12-24 ☐4 >24-48 ☐5 >48

KOGNITIV SVIKT
☐0 Nei ☐1 Ja (Se test på baksiden) ☐2 Usikker

ASA-KLASSE (se bakside av skjema for definisjon)
☐1 Frisk
☐2 Asymptomatisk tilstand som gir økt risiko
☐3 Symptomatisk sykdom
☐4 Livstruende sykdom
☐5 Moribund

TYPE PRIMÆRBRUDD (ÅRSAK TIL PRIMÆROPERASJON) (Kun ett kryss)
Se baksiden for klassifikasjon
☐1 Lårhalsbrudd udislokert (Garden 1 og 2)
☐2 Lårhalsbrudd dislokert (Garden 3 og 4)
☐3 Lateralt lårhalsbrudd
☐4 Pertrokantært tofragment (AO klassifikasjon A1)
☐5 Pertrokantært flerfragment (AO klassifikasjon A2)
☐9 Intertrokantært (AO klassifikasjon A3)
☐6 Subtrokantært
☐7 Annet, spesifiser.....

TYPE PRIMÆROPERASJON (Kun ett kryss)
(Fylles ut bare ved primæroperasjon - eget skjema for totalproteser)
(Fest produktklistrelapp på baksiden eller spesifiser nøyaktig produkt)
☐1 To skruer eller pinner
☐2 Tre skruer eller pinner
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Glideskrue og plate
☐6 Glideskrue og plate med trokantær støtteplate
☐7 Vinkelplate
☐8 Kort margnagle uten distal sperre
☐9 Kort margnagle med distal sperre
☐10 Lang margnagle uten distal sperre
☐11 Lang margnagle med distal sperre
☐12 Annet, spesifiser.....

Navn / størrelse og katalognummer.....

ÅRSAK TIL REOPERASJON (Flere enn ett kryss kan brukes)
☐1 Osteosyntesesvikt/havari
☐2 Ikke tilhelet brudd (non-union/pseudartrose)
☐3 Caputnekrose (segmentalt kollaps)
☐4 Lokal smerte pga prominerende osteosyntesemateriale
☐5 Brudd tilhelet med feilstilling
☐6 Sårinfeksjon – overfladisk
☐7 Sårinfeksjon – dyp
☐8 Hematom
☐9 Luksasjon av hemiprotese
☐10 Osteosyntesematerialet skåret gjennom caput
☐11 Nytt brudd rundt implantat
☐12 Løsning av hemiprotese
☐13 Annet, spesifiser.....

TYPE REOPERASJON (Flere enn ett kryss kan brukes)
(Fest produktklistrelapp på baksiden eller spesifiser nøyaktig produkt)
☐1 Fjerning av implantat (Brukes når dette er eneste prosedyre)
☐2 Girdlestone (= fjerning av implantat og caput)
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Re-osteosyntese
☐6 Debridement for infeksjon
☐7 Lukket reposisjon av luksert hemiprotese
☐8 Åpen reposisjon av luksert hemiprotese
☐9 Annet, spesifiser.....

Navn / størrelse og katalognummer.....

FIKSASJON AV HEMIPROTESE
(For totalprotese sendes eget skjema til hofteproteseregisteret)
☐1 Usementert ☐1 med HA ☐2 uten HA
☐2 Sement med antibiotika Navn.....
☐3 Sement uten antibiotika Navn.....

PATOLOGISK BRUDD (Annen patologi enn osteoporose)
☐0 Nei ☐1 Ja, type.....

TILGANG TIL HOFTELEDDET VED HEMIPROTESE (Kun ett kryss)
☐1 Fremre (mellom sartorius og tensor)
☐2 Anterolateral (mellom gluteus medius og tensor)
☐3 Direkte lateral (transgluteal)
☐4 Bakre (bak gluteus medius)
☐5 Annet, spesifiser.....

ANESTESITYPE
☐1 Narkose ☐2 Spinal ☐3 Annet, spesifiser.....

PEROPERATIVE KOMPLIKASJONER
☐0 Nei ☐1 Ja, hvilke(n).....

OPERASJONSTID (hud til hud).....minutter.

ANTIBIOTIKAPROFYLAKSE ☐0 Nei ☐1 Ja

	Navn	Dosering	Varighet i timer
Medikament 1	.....	.....	.....timer
Medikament 2	.....	.....	.....timer
Medikament 3	.....	.....	.....timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja: Første dose ☐1 Preoperativt ☐2 Postoperativt

Medikament 1 ..... Dosering opr.dag.....
Dosering videre ..... Varighet ..... døgn
Medikament 2 ..... Dosering ..... Varighet ..... døgn

FAST TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, type: .....

FIBRINOLYSEHEMMER
☐0 Nei ☐1 Ja, medikament : ..... Dosering .....

OPERATØRERFARING
Har en av operatørene mer enn 3 års erfaring i hoftebruddkirurgi? ☐0 Nei ☐1 Ja

Lege.....
Legen som har fylt ut skjemaet (navnet registreres ikke i databasen).

NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland universitetssjukehus
Møllendalsbakken 11
5021 BERGEN
Tlf: 55976452

F.nr. (11 sifre).....

Navn:.....

(Skriv tydelig ev. pasientklistrelapp – **spesifiser sykehus**.)

Sykehus:.....

HOFTEBRUDD

PRIMÆRE OPERASJONER PÅ BRUDD I PROKSIMALE FEMURENDE og ALLE REOPERASJONER, inkludert lukket reponering av hemiproteser. Ved primæroperasjon med totalprotese og ved reoperasjon til totalprotese brukes kun hofteproteseskjema. Alle produktklistrelapper settes i merket felt på baksiden av skjemaet.

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

SIDE (ett kryss) (Bilateral opr.= 2 skjema)
☐1 Høyre ☐2 Venstre

OPR TIDSPUNKT (dd.mm.åå) |__|__|__|__|__|__| kl |__|__|

BRUDD TIDSPUNKT (dd.mm.åå) |__|__|__|__|__|__| kl |__|__|
Dersom det er usikkerhet om bruddtidspunkt, fyll ut neste punkt.

TID FRA BRUDD TIL OPERASJON I TIMER
☐1 0-6 ☐2 >6-12 ☐3 >12-24 ☐4 >24-48 ☐5 >48

KOGNITIV SVIKT
☐0 Nei ☐1 Ja (Se test på baksiden) ☐2 Usikker

ASA-KLASSE (se bakside av skjema for definisjon)
☐1 Frisk
☐2 Asymptomatisk tilstand som gir økt risiko
☐3 Symptomatisk sykdom
☐4 Livstruende sykdom
☐5 Moribund

TYPE PRIMÆRBRUDD (ÅRSAK TIL PRIMÆROPERASJON) (Kun ett kryss)
Se baksiden for klassifikasjon
☐1 Lårhalsbrudd udislokert (Garden 1 og 2)
☐2 Lårhalsbrudd dislokert (Garden 3 og 4)
☐3 Lateralt lårhalsbrudd
☐4 Pertrokantært tofragment (AO klassifikasjon A1)
☐5 Pertrokantært flerfragment (AO klassifikasjon A2)
☐9 Intertrokantært (AO klassifikasjon A3)
☐6 Subtrokantært
☐7 Annet, spesifiser.....

TYPE PRIMÆROPERASJON (Kun ett kryss)
(Fylles ut bare ved primæroperasjon - eget skjema for totalproteser)
(Fest produktklistrelapp på baksiden eller spesifiser nøyaktig produkt)
☐1 To skruer eller pinner
☐2 Tre skruer eller pinner
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Glideskrue og plate
☐6 Glideskrue og plate med trokantær støtteplate
☐7 Vinkelplate
☐8 Kort margnagle uten distal sperre
☐9 Kort margnagle med distal sperre
☐10 Lang margnagle uten distal sperre
☐11 Lang margnagle med distal sperre
☐12 Annet, spesifiser.....

Navn / størrelse og katalognummer.....

ÅRSAK TIL REOPERASJON (Flere enn ett kryss kan brukes)
☐1 Osteosyntesesvikt/havari
☐2 Ikke tilhelet brudd (non-union/pseudartrose)
☐3 Caputnekrose (segmentalt kollaps)
☐4 Lokal smerte pga prominerende osteosyntesemateriale
☐5 Brudd tilhelet med feilstilling
☐6 Sårinfeksjon – overfladisk
☐7 Sårinfeksjon – dyp
☐8 Hematom
☐9 Luksasjon av hemiprotese
☐10 Osteosyntesematerialet skåret gjennom caput
☐11 Nytt brudd rundt implantat
☐12 Løsning av hemiprotese
☐13 Annet, spesifiser.....

TYPE REOPERASJON (Flere enn ett kryss kan brukes)
(Fest produktklistrelapp på baksiden eller spesifiser nøyaktig produkt)
☐1 Fjerning av implantat (Brukes når dette er eneste prosedyre)
☐2 Girdlestone (= fjerning av implantat og caput)
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Re-osteosyntese
☐6 Debridement for infeksjon
☐7 Lukket reposisjon av luksert hemiprotese
☐8 Åpen reposisjon av luksert hemiprotese
☐9 Annet, spesifiser.....

Navn / størrelse og katalognummer.....

FIKSASJON AV HEMIPROTESE
(For totalprotese sendes eget skjema til hofteproteseregisteret)
☐1 Usementert ☐1 med HA ☐2 uten HA
☐2 Sement med antibiotika Navn.....
☐3 Sement uten antibiotika Navn.....

PATOLOGISK BRUDD (Annen patologi enn osteoporose)
☐0 Nei ☐1 Ja, type.....

TILGANG TIL HOFTELEDDET VED HEMIPROTESE (Kun ett kryss)
☐1 Fremre (mellom sartorius og tensor)
☐2 Anterolateral (mellom gluteus medius og tensor)
☐3 Direkte lateral (transgluteal)
☐4 Bakre (bak gluteus medius)
☐5 Annet, spesifiser.....

ANESTESITYPE
☐1 Narkose ☐2 Spinal ☐3 Annet, spesifiser.....

PEROPERATIVE KOMPLIKASJONER
☐0 Nei ☐1 Ja, hvilke(n).....

OPERASJONSTID (hud til hud).....minutter.

ANTIBIOTIKAPROFYLAKSE ☐0 Nei ☐1 Ja

	Navn	Dosering	Varighet i timer
Medikament 1	.....	.....	.....timer
Medikament 2	.....	.....	.....timer
Medikament 3	.....	.....	.....timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja: Første dose ☐1 Preoperativt ☐2 Postoperativt

Medikament 1 ..... Dosering opr.dag.....
Dosering videre ..... Varighet ..... døgn

Medikament 2 ..... Dosering ..... Varighet ..... døgn

FAST TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, type: .....

FIBRINOLYSEHEMMER
☐0 Nei ☐1 Ja, medikament : ..... Dosering .....

OPERATØRERFARING
Har en av operatørene mer enn 3 års erfaring i hoftebruddkirurgi? ☐0 Nei ☐1 Ja

Lege.....
Legen som har fylt ut skjemaet (navnet registreres ikke i databasen).

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority	

Date of this report

Reference number assigned by the manufacturer

Reference number assigned by NCA

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ○ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ○ All other reportable incidents

Identify to what other NCA's this report was also sent

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer Information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

4 Authorised Representative Information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

5 Submitter's Information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

6 Medical device information | new

Class

- AIMD Active implants
- MDD Class III
- MDD Class IIb
- MDD Class IIa
- MDD Class I
- IVD Annex II List A
- IVD Annex II List B
- IVD Devices for self-testing
- IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	

Nomenclature text

Commercial name/ brand name / make

Model number	Catalogue number

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)

Software version number (if applicable)

Device Mfr Date	Expiry date

Implant date (For implants only)	Explant date (For implants only)

Duration of implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number

7 Incident Information

Date the incident occurred

Incident description narrative

User facility report reference number, if applicable

Manufacturer's awareness date

Number of patients involved (if known)	Number of medical devices involved (if known)

Medical device current location/disposition (if known)

Operator of the medical device at the time of incident (select one)

- ◯ Healthcare Professional
- ◯ Patient
- ◯ Other

Usage of the medical device (select from list below)

- ◯ initial use
- ◯ reuse of a single use medical device
- ◯ reuse of a reusable medical device
- ◯ re-serviced/refurbished
- ◯ other
- ◯ problem noted prior use

8 Patient information

Patient outcome

Remedial action taken by the healthcare facility relevant to the care of the patient

Gender, if applicable

◯ Female ◯ Male

Age of the patient at the time of incident, if applicable	**units** ◯ Years ◯ months ◯ days

Weight in kilograms, if applicable

9 Healthcare facility information new

Name of the healthcare facility

Contact person within the facility

Name of the

Address

Postcode	**City**
Phone	**Fax**
E-mail	**Country**

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

Initial corrective actions/preventive actions implemented by the manufacturer

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ○ No

Number of similar incidents

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☐ DE	☐ DK
☐ EE	☐ ES	☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE
☐ IS	☐ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☐ NL
☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI	☐ SK	☐ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

Region Östergötland

(Händelserubrik)

Ärendetyp * Avvikelse - Negativ händelse/Olycka (Ändra)

Avvikelsesamordning * Region Östergötland - HMC - Thorax-Kärlkliniken US - THIVA (Ändra)

Status * ○ Registrerat ○ Under behandling ○ Godkänt ○ Avslutat

Planerat slutdatum (Lägg till)

☐ Särskild sekretess

☐ Visa/lägg till mottagare av e-postmeddelande innan du sparar

☐ Fortsätta att redigera ärende efter att ha sparat

Spara ärende Ta bort ärende

Expandera alla Minimera alla

– Var och vad

Händelsedatum *

Händelserubrik

Händelseförlopp *

Möjliga orsaker och konsekvenser noterat av rapportören

Direkt vidtagen åtgärd

Händelsekategorisering *

Rapporterad av enhet * Region Östergötland - HMC - Thorax-Kärlkliniken US - THIVA

Rapporterad av kommun/entreprenör

Ansvarig enhet * Region Östergötland - HMC - Thorax-Kärlkliniken US - THIVA

Ansvarig kommun/entreprenör

Plats

Kommentar till plats

Uppgiftslämnare Kuzminski Caroline

Yrkeskategori Sjuksköterska

– Involverade personer 0

Inga involverade personer har lagts till
Lägg till involverad person

− Generell klassificering

Arbetsprocess

LID- eller tappningsnummer

Involverade system

Involverad utrustning

Involverat(d) ämne/ kemikalie

Involverad kommun/entreprenör

Involverade enheter

Referenser Inga referenser har lagts till
Lägg till referens

− Konsekvens

Kommentarer

Inga konsekvenser har lagts till
Lägg till uppgift om faktisk konsekvens

+ Riskbedömning

− Orsaker 0

Kommentarer

Valda orsaker

− Åtgärd 0 0

Inga åtgärder har lagts till
Lägg till åtgärd

Adverse events 0.20

Section: Adverse event**Page:** 1
Instructions: Report all adverse events (max. 40 events/form) and specify date of onset and resolution (if resolved). Partial dates are allowed.

1. Adverse Event(s)

Repeat: 1

Adverse event	Description	Related to	Medication / Other
☐ Unproportional pain ☐ Infection ☐ Unproportional inflammatory reaction ☐ Corneal scarring ☐ Perforation ☐ Ectasia ☐ Glaucoma ☐ Defect epithelization ☐ Other (specify)		☐ Unrelated ☐ Bandage lens ☐ Amniotic membrane ☐ Sutures ☐ Graft transplantation ☐ Topical steroids ☐ Topical antibiotics ☐ Other (specify) ☐ Unknown	
Date of onset	**Date of resolution**	**Treatment**	**Treatment details**
		☐ None ☐ Medication ☐ Hospitalization ☐ Surgery ☐ Unknown	

Adverse event report 0.27

SECTION: Adverse event

Adverse event: Date:

Event description:

First report: ☐ Yes ☐ No Date:

Follow up: ☐ Yes ☐ No Date:

Final report: ☐ Yes ☐ No Date:

Reported to authorities: ☐ Yes ☐ No Date:

Statens legemiddelverk

RELIS

folkehelseinstituttet

Melding om mistenkte bivirkninger ved bruk av legemiddel (inkl. naturlegemiddel)

Skjemaet er på to (2) sider. Utfylt skjema skal sendes til RELIS i din helseregion.
Melding vedrørende vaksiner sendes til Folkehelseinstituttet.
Se baksiden for adresser.

PASIENTOPPLYSNINGER

Unntatt offentlighet jf. Offl. §13 første ledd, jf. Fvl. §13 første ledd nr.1

Navn:

Kjønn:

Født:

☐ **Pasienten eller pårørende har samtykket til å melde bivirkningen(e)** (se bakside).

Vedlegg: ☐ Epikrise ☐ Obduksjonsrapport ☐ Labjournal ☐ Annet ☐ Journalnotat

Bakgrunn for meldingen:

- ☐ Resulterte i død
- ☐ Livstruende
- ☐ Sykehusinnleggelse/forlenget opphold
- ☐ Vedvarende uførhet/nedsatt funksjonsevne
- ☐ Anomali/fødselsdefekt
- ☐ Ikke beskrevet i preparatomtalen
- ☐ Bivirkning(er) ved generisk bytte
- ☐ Bivirkning(er) ved bruk av reseptfritt legemiddel/naturlegemiddel
- ☐ Merket med svart trekant ▼ (Bivirkning(er) av legemidler under særlig overvåking, se www.legemiddelverket.no)
- ☐ Annet:

Konsekvenser for pasienten:

- ☐ Restituert uten ettervirkninger
- ☐ I bedring, men ikke fullstendig restituert
- ☐ Restituert, men med ettervirkninger
- ☐ Ingen bedring
- ☐ Død

LEGEMIDLER

Navn, styrke, legemiddelform, produsent	Dosering	Indikasjon	Startdato – Stoppdato (evt varighet av behandlingen)	Seponert (ja/nei)
Mistenkte legemidler*: Legemiddel er kjøpt på internett ☐				
Andre legemidler: ☐ Nei ☐ Ja (fyll ut hvilke):				

Mistanke om interaksjon ☐ Hvilke legemidler? :

Reeksponering av mistenkte legemidler ☐ ja ☐ nei Evt resultat:

BIVIRKNINGER

Bivirkningsdiagnose(r) evt. symptomer:	Startdato – Stoppdato (evt. varighet av bivirkning)

*For biologiske produkter og vaksiner bør batchnr/lotnr oppgis

Snu →

RELEVANTE OPPLYSNINGER (KAN ERSTATTES AV VEDLEGG)

Beskrivelse av forløpet:

Pasientens sykehistorie:

Resultater av tester:

OPPLYSNINGER OM MELDER

Navn:

Adr:

Tlf:

E-post:

☐ Lege ☐ Tannlege

☐ Farmasøyt ☐ Annet helsepersonell

Melders dato:

Melders underskrift:

Utfylt skjema sendes per post til RELIS i din region:

Helseregion Sør-Øst (Oslo, Akershus, Østfold, Vestfold, Vest-Agder, Aust-Agder, Telemark, Buskerud, Oppland og Hedmark): **RELIS Sør-Øst** Oslo universitetssykehus HF, Rikshospitalet Postboks 4950 Nydalen 0424 OSLO Tlf. 23 07 55 00 relis@ous-hf.no	**Helseregion Midt-Norge (Møre og Romsdal, Sør-Trøndelag og Nord-Trøndelag):** **RELIS Midt-Norge** Avdeling for klinisk farmakologi St. Olavs Hospital HF 7006 Trondheim Tlf. 72 82 91 00 relis@legemidler.no	**Regionalt legemiddelinformasjonssenter** (RELIS) – felles vevside www.relis.no
Helseregion Nord (Nordland, Troms og Finnmark): **RELIS Nord-Norge** Universitetssykehuset i Nord-Norge HF Postboks 79 9038 Tromsø Tlf. 77 75 59 98 relis@unn.no	**Helseregion Vest (Rogaland, Hordaland og Sogn og Fjordane):** **RELIS Vest** Haukeland universitetssjukehus 5021 Bergen Tlf. 55 97 53 60 relis@helse-bergen.no	**Bivirkningsmeldinger som vedrører *vaksiner* sendes til:** **Folkehelseinstituttet** Postboks 4404 Nydalen 0403 OSLO Tlf. 21 07 70 00 **Merk konvolutten «Mistenkt bivirkning etter vaksinasjon»**

Hva skal meldes?

Følgende bivirkninger er meldepliktige:

- **Dødelige og livstruende bivirkninger**
- **Bivirkninger som har gitt varige alvorlige følger**
- **Nye eller uventede bivirkninger**

Statens legemiddelverk anser det også som nyttig å få meldinger om**:**

- **Alle bivirkninger av nye legemidler**
- **Alle bivirkninger av legemidler under særlig overvåking ▼ (se www.legemiddelverket.no)**
- **Problemer ved seponering av legemidler**
- **Reaksjoner på grunn av overdosering eller feilbruk av reseptfrie legemidler**
- **Bivirkninger av naturlegemidler og uventede bivirkninger ved generisk bytte**

Andre nyttige adresser:

Statens legemiddelverk
Postboks 6167 Etterstad, 0602 Oslo
0901 Oslo
Tlf. 22 89 77 00
www.legemiddelverket.no

Skjema kan bestilles fra de enkelte RELIS, Statens legemiddelverk eller hentes på www.relis.no/bivirkninger eller www.legemiddelverket.no/bivirkninger

Mistanke om bivirkning er tilstrekkelig for å melde. Meldinger blir lagt inn i den nasjonale databasen for at opplysningene skal kunne formidles videre til Verdens helseorganisasjon (WHO) og de europeiske legemiddelmyndighetene, samt brukes senere. Klassifiseringen innebærer ikke at årsakssammenhengen er bevist. Vedlegg av epikriser, journalnotater eller obduksjonsrapporter gir oss verdifull tilleggsinformasjon.

Hvem skal melde?

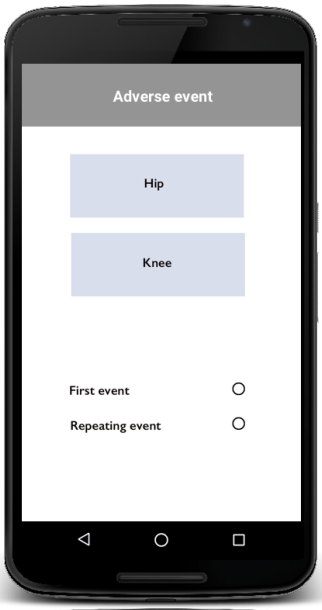
Blir pasienten lagt inn på sykehus, bør meldingen skrives av den sykehuslege som har behandlet eller utredet pasienten. Utenfor sykehus bør meldingen sendes av legen/tannlegen som diagnostiserer reaksjonen. Apotekfarmasøyter med pasientkontakt oppfordres til å melde bivirkninger de får kunnskap om gjennom sitt arbeid.

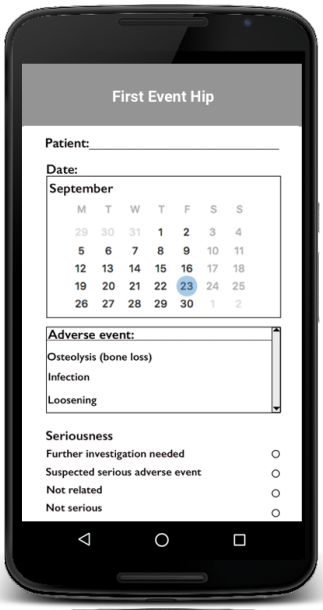
Personvern og samtykke

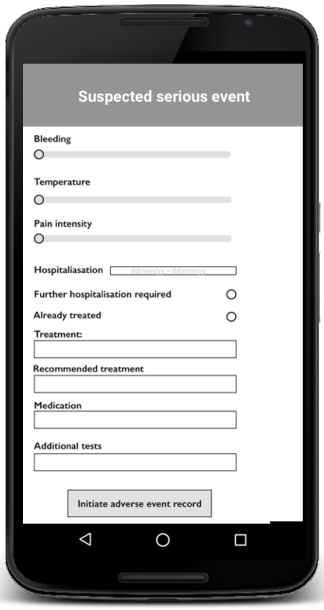
Alle pasientopplysninger blir behandlet strengt konfidensielt. Alle persondata blir anonymisert ved innleggelse i bivirkningsdatabasen. Identifiserbare data blir ikke gitt videre i noe tilfelle. Dersom meldingen inneholder personidentifiserbare data må pasient eller nærmeste pårørende gi sitt samtykke til at bivirkningen meldes. Meldinger som kun inneholder opplysninger i form av kjønn, alder, fødselsdato og initialer krever ikke samtykke. Det er ikke krav til samtykke for vaksinemeldinger.

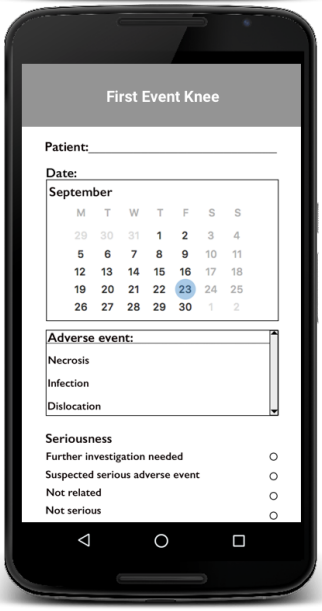
Appendix C

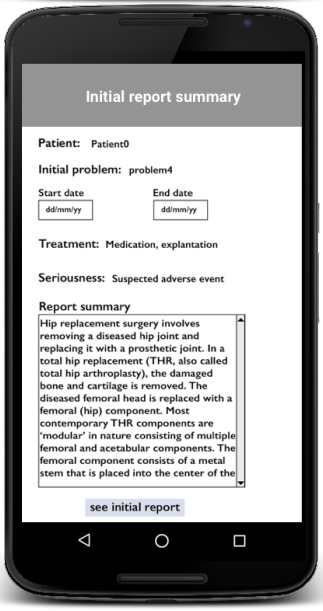
Prototype: Iteration 1


Adverse event
Hip
Knee
First event
Repeating event


First Event Hip
Patient:
Date:
September
M T W T F S S
29 30 31 1 2 3 4
5 6 7 8 9 10 11
12 13 14 15 16 17 18
19 20 21 22 23 24 25
26 27 28 29 30 1 2
Adverse event:
Osteolysis (bone loss)
Infection
Loosening
Seriousness
Further investigation needed
Suspected serious adverse event
Not related
Not serious

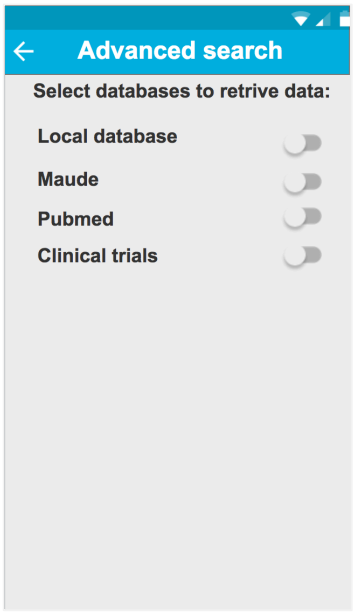

Suspected serious event
Bleeding
Temperature
Pain intensity
Hospitaliasation
Further hospitalisation required
Already treated
Treatment:
Recommended treatment
Medication
Additional tests
Initiate adverse event record

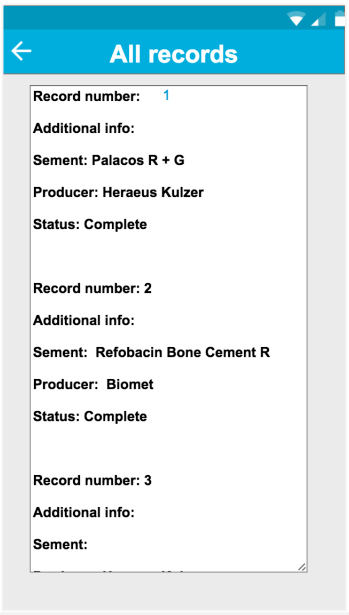

First Event Knee
Patient:
Date:
September
M T W T F S S
29 30 31 1 2 3 4
5 6 7 8 9 10 11
12 13 14 15 16 17 18
19 20 21 22 23 24 25
26 27 28 29 30 1 2
Adverse event:
Necrosis
Infection
Dislocation
Seriousness
Further investigation needed
Suspected serious adverse event
Not related
Not serious

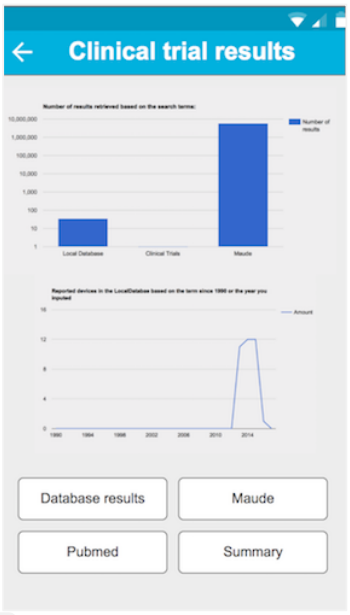

Initial report summary
Patient: Patient0
Initial problem: problem4
Start date
dd/mm/yy
End date
dd/mm/yy
Treatment: Medication, explantation
Seriousness: Suspected adverse event
Report summary
Hip replacement surgery involves removing a diseased hip joint and replacing it with a prosthetic joint. In a total hip replacement (THR, also called total hip arthroplasty), the damaged bone and cartilage is removed. The diseased femoral head is replaced with a femoral (hip) component. Most contemporary THR components are 'modular' in nature consisting of multiple femoral and acetabular components. The femoral component consists of a metal stem that is placed into the center of the
see initial report

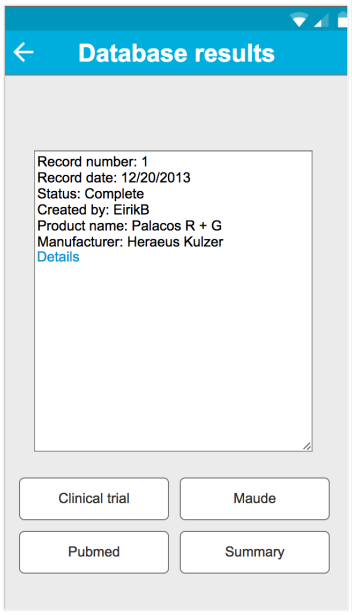
Appendix D

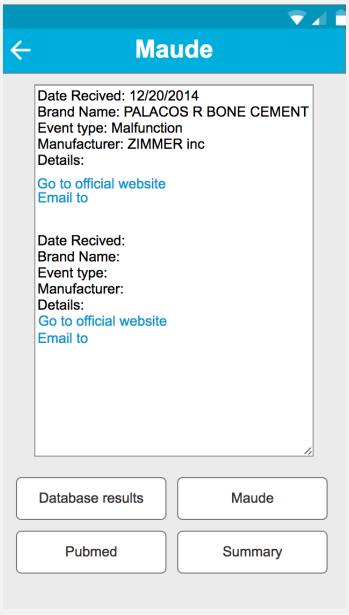
Prototype: Iteration 2

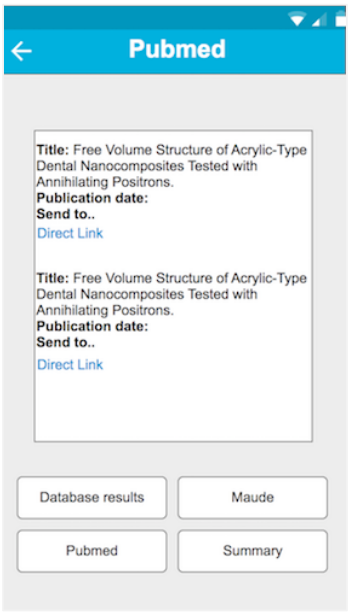

Advanced search
Select databases to retrive data:
Local database
Maude
Pubmed
Clinical trials

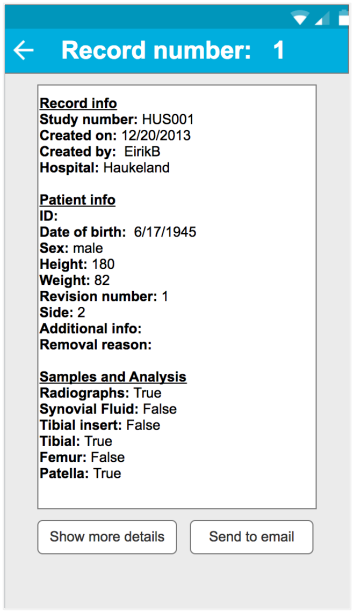

All records
Record number: 1
Additional info:
Sement: Palacos R + G
Producer: Heraeus Kulzer
Status: Complete
Record number: 2
Additional info:
Sement: Refobacin Bone Cement R
Producer: Biomet
Status: Complete
Record number: 3
Additional info:
Sement:

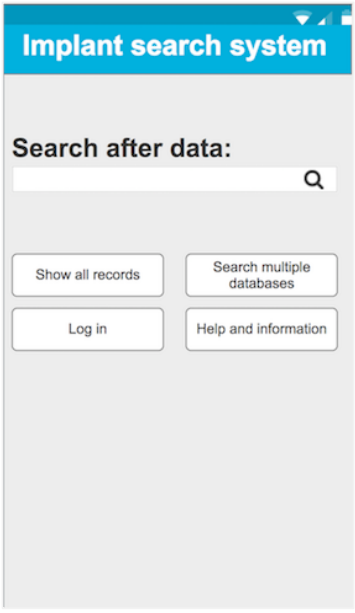

Clinical trial results
Database results
Maude
Pubmed
Summary

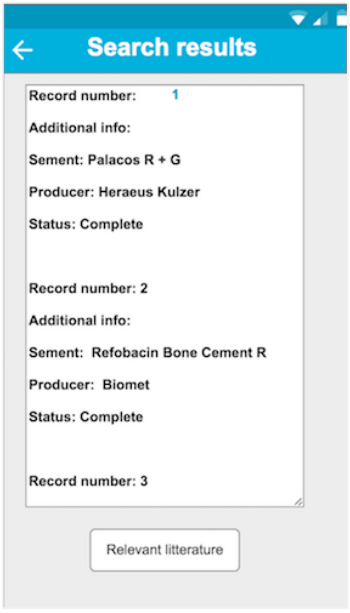

Database results
Record number: 1
Record date: 12/20/2013
Status: Complete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Heraeus Kulzer
Details
Clinical trial
Maude
Pubmed
Summary

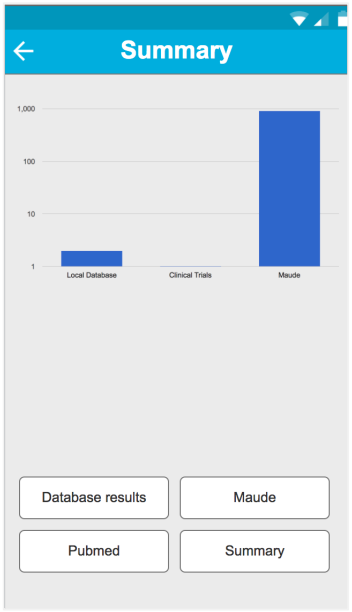

Maude
Date Recived: 12/20/2014
Brand Name: PALACOS R BONE CEMENT
Event type: Malfunction
Manufacturer: ZIMMER inc
Details:
Go to official website
Email to
Date Recived:
Brand Name:
Event type:
Manufacturer:
Details:
Go to official website
Email to
Database results
Maude
Pubmed
Summary


Pubmed
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date:
Send to..
Direct Link
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date:
Send to..
Direct Link
Database results
Maude
Pubmed
Summary


Record number: 1
Record info
Study number: HUS001
Created on: 12/20/2013
Created by: EirikB
Hospital: Haukeland
Patient info
ID:
Date of birth: 6/17/1945
Sex: male
Height: 180
Weight: 82
Revision number: 1
Side: 2
Additional info:
Removal reason:
Samples and Analysis
Radiographs: True
Synovial Fluid: False
Tibial insert: False
Tibial: True
Femur: False
Patella: True
Show more details
Send to email


Implant search system
Search after data:
Show all records
Search multiple databases
Log in
Help and information


Search results
Record number: 1
Additional info:
Sement: Palacos R + G
Producer: Heraeus Kulzer
Status: Complete
Record number: 2
Additional info:
Sement: Refobacin Bone Cement R
Producer: Biomet
Status: Complete
Record number: 3
Relevant litterature

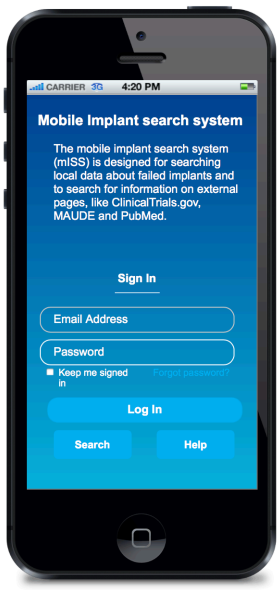

Summary
1,000
100
10
1
Local Database
Clinical Trials
Maude
Database results
Maude
Pubmed
Summary

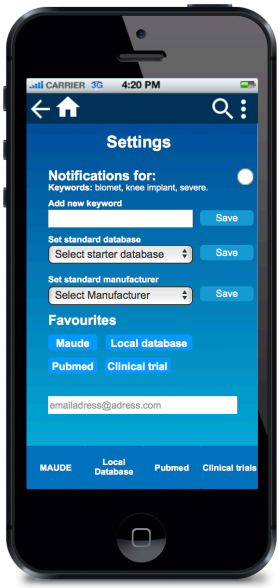
Appendix E

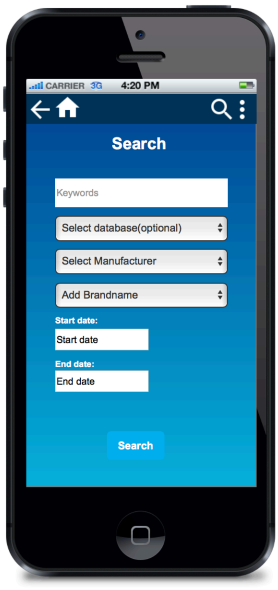
Prototype: Iteration 3

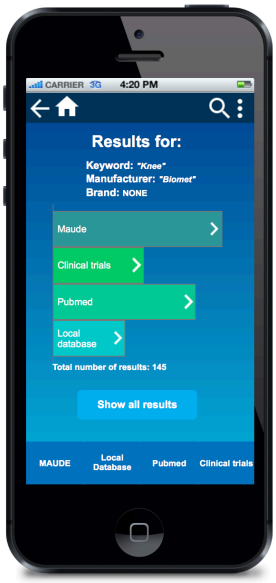

CARRIER 3G 4:20 PM
Mobile Implant search system
The implant search system (ISS) is designed for searching local data about failed implants and to search for information on external pages, like ClinicalTrials.gov, MAUDE and PubMed.
Sign In
Email Address
Password
Keep me signed in
Forgot password?
Enter email above
Log In
Search
Help
Settings
Notifications for:
Keywords: biomet, knee implant, severe.
Manage notification
Favourites
Maude
Local database
Pubmed
Clinical trial
E-mail
you@youremail.com
Home MAUDE Local Databas e Pubme d Clinical trials Search
Search
Keywords
Select Manufacturer
Select brand name
Start Date:
End Date:
Show all records
Search
Relevant literature
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date: 03/03/2017
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date: 1/5/2016
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date: 03/03/2017
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons.
Publication date: 03/03/2017
Local database
Record number: 1497
Record date: 12/20/2013
Status: Complete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Details
Record number: 1342
Record date: 12/20/2013
Status: incomplete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Details
Maude
Number of results retrieved based on the search terms:
Date Recived: 12/20/2014
Brand Name: PALACOS R BONE CEMENT
Event type: Malfunction
Manufacturer: Biomet
Summar y
Go to official site
Date Recived: 12/22/2014
Brand Name: PALACOS R BONE CEMENT
Event type: Malfunction
Manufacturer: Biomet
Summar y
Go to official site


CARRIER 3G
4:20 PM
Clinical trial
Total results: 12
Record number: 1342
Record date: 12/20/2013
Status: Incomplete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Record number: 1342
Record date: 12/20/2013
Status: Incomplete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Home
MAUDE
Local Databas
Pubme d
Clinical trials
Search
CARRIER 3G
4:20 PM
All results
Record number: 1497
Additional info:
Cement: Palacos R + G
Producer: Biomet
Status: Complete
Details
Record number: 2245
Additional info:
Cement: Refobacin Bone Cement R
Producer: Biomet
Status: Complete
Details
Record number: 1397
Additional info:
Cement:
Producer: Biomet
Status: Incomplete
Details
Home
MAUDE
Local Databas
Pubme d
Clinical trials
Search


CARRIER 3G 4:20 PM
Mobile Implant search system
The mobile implant search system (mISS) is designed for searching local data about failed implants and to search for information on external pages, like ClinicalTrials.gov, MAUDE and PubMed.
Sign In
Email Address
Password
Keep me signed in
Forgot password?
Log In
Search
Help


CARRIER 3G 4:20 PM
Settings
Notifications for:
Keywords: biomet, knee implant, severe.
Add new keyword
Save
Set standard database
Select starter database
Save
Set standard manufacturer
Select Manufacturer
Save
Favourites
Maude
Local database
Pubmed
Clinical trial
emailadress@adress.com
MAUDE
Local Database
Pubmed
Clinical trials


CARRIER 3G 4:20 PM
Search
Keywords
Select database(optional)
Select Manufacturer
Add Brandname
Start date:
Start date
End date:
End date
Search


CARRIER 3G 4:20 PM
Results for:
Keyword: "Knee"
Manufacturer: "Biomet"
Brand: NONE
Maude
Clinical trials
Pubmed
Local database
Total number of results: 145
Show all results
MAUDE
Local Database
Pubmed
Clinical trials


CARRIER 3G 4:20 PM
Local database
10
8
6
4
2
Year 2007 2010 2013 2016
Record number: 1497
Record date: 12/20/2013
Status: Complete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Details
Record number: 1342
Record date: 12/20/2013
Status: incomplete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Details
MAUDE
Local Database
Pubmed
Clinical trials


CARRIER 3G 4:20 PM
Maude
100
80
60
40
20
10
Year 2007 2010 2013 2016
Date Recived: 12/20/2014
Brand Name: PALACOS R BONE CEMENT
Event type: Malfunction
Manufacturer: Biomet
Summary
Go to official site
Date Recived: 12/22/2014
Brand Name: PALACOS R BONE CEMENT
Event type: Malfunction
Manufacturer: Biomet
Summary
Go to official site
MAUDE
Local Database
Pubmed
Clinical trials


CARRIER 3G 4:20 PM
Pubmed
Relevant literature
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons. Publication date: 03/03/2017
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons. Publication date: 1/5/2016
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons. Publication date: 03/03/2017
Title: Free Volume Structure of Acrylic-Type Dental Nanocomposites Tested with Annihilating Positrons. Publication date: 03/03/2017
MAUDE
Local Database
Pubmed
Clinical trials
CARRIER 3G 4:20 PM
Clinical trial
Total results: 12
Record number: 1342
Record date: 12/20/2013
Status: incomplete
Created by: EirikB
Product name: Palacos R + G
Manufacturer: Biomet
Record number: 1342
Record date: 12/20/2013
Status: incomplete
Created by: EirikB
Product name: Palacos R + G
MAUDE
Local Database
Pubmed
Clinical trials
CARRIER 3G 4:20 PM
Help and Information
Maude
MAUDE web search feature is limited to adverse event reports within the past 10 years. Contains FDA reported cases aswell as voluntary reports.
Local database
Contain local entries for internal systems. And will in the future contain reports made in this system.
Pubmed
Biomedical literature from MEDLINE, life science journals, and online books.
Clinical trials
Is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. https://clinicaltrials.gov
MAUDE
Local Database
Pubmed
Clinical trials

Appendix F

User consent

Forespørsel om deltakelse i forskningsprosjektet

"HCI and design for clinical safetey reporting"

Dette prosjektet er en del av mastergradsoppgave i informasjonsvitenskap ved Universitetet i Bergen. Temaet for prosjektet er HCI og design relatert til rapportering av uheldige hendelser innen helsesektoren. Formålet er å få svar på om teori og metoder fra feltene HCI og interaksjon design kan bidra til å forbedre prosessen og skape en mer positiv opplevelse av innrapportering av uheldige hendelser relatert til kne og hofte proteser.

For å få svar på dette og komme frem til et forslag ønsker jeg å ha gruppeintervjuer som er semi-strukturerte med personer som har fagbakgrunn innen ortopedi og har jobbet med dette. Spørsmålene her vil handle om prosessen rundt rapportering, meninger om prosessen, plattform og datasystemer. Det vil bli gjort opptak under intervjuene, og det vil også bli tatt skriftlige notater underveis.

Alle personopplysninger vil bli behandlet konfidensielt. All informasjon vil være utilgjengelig for en tredjepart, den eneste utenom studenten som skal ha tilgang er veileder. I eventuelle publikasjoner av masteroppgaven vil ingen personopplysninger være inkludert og alt vil være anonymisert. Alle personopplysninger vil bli slettet ved prosjekt slutt 1.juni 2017.

Har du spørsmål til studien, kan du ta kontakt med
Student: Hanne Åserød, 95 86 51 50, Hanne.Aserod@student.uib.no
Veileder: Ankica Babic, 55 58 91 39, Ankica.Babic@uib.no

Studien er meldt til Personvernombudet for forskning, NSD - Norsk senter for forskningsdata AS.

Samtykke til deltakelse i studien

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

---

(Signert av prosjektdeltaker, dato)

Appendix G

Approval from NSD

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

Vår dato: 18.10.2016 Vår ref: 50127 / 3 / AGL Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 21.09.2016. Meldingen gjelder prosjektet:

50127	*HCI and design for clinical safetey reporting system*
Behandlingsansvarlig	*Universitetet i Bergen, ved institusjonens øverste leder*
Daglig ansvarlig	*Ankica Babic*
Student	*Hanne Åserød*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering 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.

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

Vår dato: 18.10.2016 Vår ref: 50127 / 3 / AGL Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 21.09.2016. Meldingen gjelder prosjektet:

50127	*HCI and design for clinical safetey reporting system*
Behandlingsansvarlig	*Universitetet i Bergen, ved institusjonens øverste leder*
Daglig ansvarlig	*Ankica Babic*
Student	*Hanne Åserød*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering 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

Katrine Utaaker Segadal

Audun Løvlie

Kontaktperson: Audun Løvlie tlf: 55 58 23 07
Vedlegg: Prosjektvurdering

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

NSD – Norsk senter for forskningsdata AS Harald Hårfagres gate 29 Tel: +47-55 58 21 17 nsd@nsd.no Org.nr. 985 321 884
NSD – Norwegian Centre for Research Data NO-5007 Bergen, NORWAY Faks: +47-55 58 96 50 www.nsd.no

Appendix H

Poster accepted for conference

The European Federation for Medical Informatics Association (EFMI). Informatics for Health, Manchester.

Designing a bedside application for adverse event reporting

Hanne Aserod and Ankica Babic, *Dept. for Information Science and Media Studies, University of Bergen, Norway, Bergen*

Introduction We present a mobile software application development for safety reporting within the field of angioplasty. The application aims at supporting physicians with capturing and retaining data regarding safety events. A combination of Interaction design and User experience techniques was used to inspire usability[1] and create useful, intuitive interface. The consequence of not considering the user experience could be user frustration and the user looking for an alternative solutions to data capture. If forced upon users, an application usage could increase the likelihood of mistakes increases, and reduce effectiveness.[2]

Method To collect data and define system requirements a literature review and a field study were conducted which resulted in both quantitative and qualitative data. The data was analyzed to understand the data flow and clinical processes all with a purpose to enable a user keeping in touch with the whole hospital information system. To be able to utilize the users' skills and experiences within their domain, it was important to include them in the participatory design process. To get feedback on the concept, medical staff was given the screens together with explanation of the concept based on several levels of functionality.

Results Proposed user interface enables entry of data specific for adverse events of the knee and hip implants. Besides the patient data, the system allows entry of the event classification (serious, non-serious) and treatment, as well as the connection of the database maintained within the Helse Bergen hospital system. Reports could be initiated and retrieved if there are previous adverse event instances. Expert evaluation of the first design solution was performed using low fidelity prototype. It has shown that design was relevant, straightforward, done in a way that official reporting would commence. A question was also asked if the system could be adjusted to general reporting.

Discussion The design was met with enthusiasm by the healthcare professionals. However, it has been clear that there are reservations exist for reporting adverse events in general. The main reason seems to be a heavy work burden. There were also concerns about being viewed negatively by other medical staff. Attitudes towards reporting were not entirely negative, for example, the biomedical engineer lab that evaluates explanted medical devices would appreciate such a bed side reporting. Interviewed physicians accepted this point of view and did not entirely rule out their participation. Therefore, more work needs to be done to address attitudes towards reporting and lack of motivation for it.

Conclusion The development is directed towards the high-fidelity prototype and further web-based system development that will enable more detailed reports. Those will be fit into the hospital information system and provide basis for other functionalities such as e-learning and other general reporting.

References

1. N. Kellingley, "What is the difference between Interaction Design and UX Design?" [Online]. Available: https://www.interaction-design.org/ literature/article/what-is-the-difference-between- interaction-design-and-ux-design. [Accessed: 07-May-2016].

2. O. Mival and D. Benyon, "Requirements Engineering for Digital Health," A. S. Fricker, C. Thümmler, and A. Gavras, Eds. Cham: Springer International Publishing, 2015, pp. 117–131

Appendix I

Paper Submisson to Conference

Joint conference of the European Medical and Biological Engineering Conference (EMBEC) and the Nordic-Baltic Conference on Biomedical Engineering and Medical Physics (NBC), in Tampere, Finland.

Designing a mobile system for safety reporting of arthroplasty adverse events

Hanne Åserød, B. Sc[1], and Ankica Babic, PhD[1,2]

[1] Department of Information Science and Media Studies, University of Bergen, Norway
[2]Department of Biomedical Engineering, Linköping University, Sweden

Abstract — **This paper presents a mobile software application development for safety reporting of adverse events within the field of arthroplasty. Proposed user interface enables entry of data specific for adverse events of the knee and hip implants. Besides the patient data, the system supports entry of the event, its classification (serious, non-serious), its follow up, as well as a connection to the database maintained within the Helse Bergen hospital information system. Safety reports can be initiated and retrieved on request and depending on the adjudication of the event; suspected severe events should be followed up until their resolution. Expert evaluation of the first design solution was performed using low fidelity prototype. It has shown that design was relevant, straightforward, done in a way that official reporting would commence. Some users were positive to the reporting, some felt it would demand more work. A comprehensive evaluation with different potential user groups is planned to meet their needs and understand their views.**

Keywords -- **Safety reporting, mobile application, HCI, low fidelity porotype evaluation**

I. Introduction

A prototype of adverse events system has been developed as an alternative to traditional reporting methods. Handling adverse events is putting significant burden onto the staff so it could be anticipated that simplifying and making the system enjoyable will help overcoming barriers towards safety reporting. To improve patient care in health organizations it is important to understand what is hindering reporting. Specifically, barriers like extra time, additional workload, badly designed report forms are possible to handle with redesign. But attitudes like trust issues, fear of harming professional reputation, inability to recognize errors, insufficient feedback after reporting are things that must be worked on by the organizations themselves [1], [2]. Patient safety will most likely always be a topic of concern in healthcare all over the world. It is the patients' safety, which is the main reason for reporting incidents, so that we will be able to learn from them [3]. Reporting of adverse events is an important step for securing patient safety and for preventing potential medical issues in the future. It is vital to understand, document and properly report severe adverse events. In Norway, all severe adverse events should be reported to Helsedirektoratet (Ministry of Health), but this requirement is not always met in practice. Due to underreporting, much information is lost and many Norwegian, as well as European physicians use a Web-based system MAUDE (Manufacturer And User Facility Device Experience) [4]. There is where they get the information about adverse events related to the devices they are using. The MAUDE database is publicly available for anyone to access. This study is motivated by the need to create a flexible, easy to use design for reporting adverse events. It looks at designing a mobile application that would support various user groups.

II. Materials

The study material comes from the literature and the interviews with the representatives of two major potential user groups at the Haukeland University Hospital in Bergen.

III. Methods

To collect data and define system requirements a literature review and a field study were conducted. The resulting design sketches were created in Photoshop whilst adobe preview was used to present them on mobile devices.
To open a dialogue with potential users a concept evaluation was done using concept judgement and a preliminary user participatory design session.
A combination of Interaction design and User experience techniques were used for designing solutions that consider different data sources, workflows, and multiple user groups. Application of the both methodologies should help creating a useful, intuitive interface that could inspire usability [4]. The consequence of a system that has not considered the user experience and how engaging it could be, can result in users either will not use the system or find a replacement for it. In addition, if a system is forced upon them it can lead to a higher likelihood of mistakes, wrong usage and reducing effectiveness [6].

.

IV. Results

Resulting from the literature studies is a set of demands regarding the elements and structure of adverse event reporting. It starts with an initial report, which is followed with one, or several sequential follow-up reports that often include the adjudication of the event severity before the final report is generated. A mobile platform would be useful for collecting details at the ward, while on rounds and seeing patients in diverse ambulatory settings. This would simplify the reporting process, which may request notifying a regulatory body in case of severe adverse events. Mobile reporting would secure a faster and simpler report generating. Another advantage could be achieved by combining mobile and web based technology. Safety reporting data could be combined with other patient data collected in electronic patient records and safety reports. Figure 1 suggests a platform integrating various data resources and enables a set of functionalities utilizing them.
The safety reporting consists of several steps prompted by an adverse reaction of event not anticipated with the usage of medical devices or treatment. The follow up entails one or several steps during which patient is checked and treated for the reaction. At each step, a report is created to detail a patient status and assessment of severity of the event. The result can be a final report with the resolved safety issue or a formal report to the regulatory authorities in cases when the event is adjudicated as severe or serious.

The mobile application is designed to start recording adverse events at the patient bedside thus allowing a quick and easy data entry. It should also enable a user to keep in touch with the whole hospital information system via a web based system. The Figure 1 illustrates an IT platform with safety reporting as its integral part. Besides reporting of the safety reporting includes web based reporting and patient reporting. The latter could be done using the same mobile design only adjusted to patient self-reporting that would include intensity and location of the patient's pain. An interactive design is going is being developed especially for patients. In addition, a web mobile system will make complete reports available via a link and allow access to other related patient data. This part of development is dependent on the decisions and strategy of the Haukeland University Hospital in Bergen; the system should be a part of the hospital information system and its management.

Figure 1. The IT platform integrating safety reporting and learning functionalities utilizing several databases including patient data.

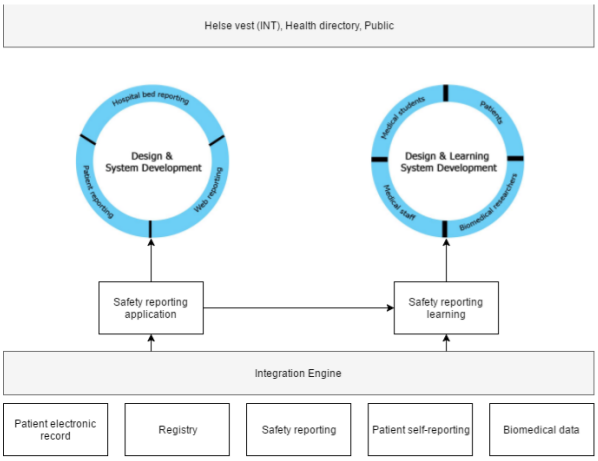


Figure 1. The IT platform integrating safety reporting and learning functionalities utilizing several databases including patient data.

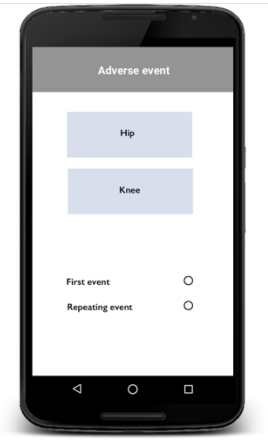


Fig 1: First screen

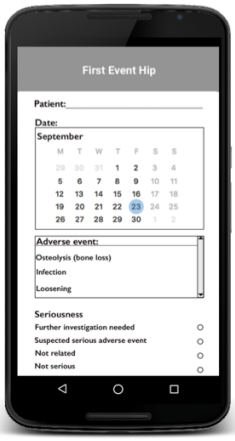


Fig 2:Hip related event

Figure 2 shows the first step after the user has logged in, where two choices must be made: *Hip* or *knee* and *First event or Repeating event.* Figure 3 shows the choices if *Hip* and *First event* is chosen. Here, the user will be able to start a new report.

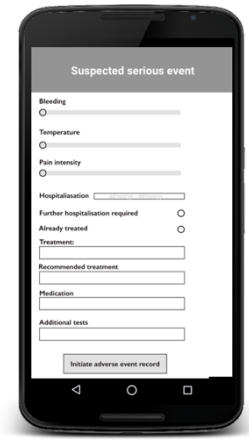


Fig 3: Serious event

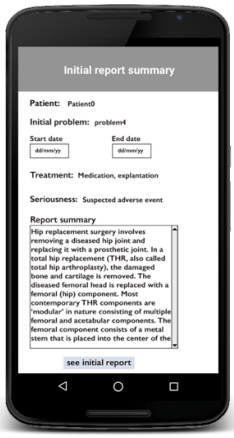


Fig 4: Summary of report

Figure 4 shows some of the content that must be entered into the report in case of a suspected serious event. Figure 5 is an example of a safety report summary. The design allows additional functionalities could be implemented. The application could further connect to desktop where the user will be able to add more details.

V. Discussion

Many efforts are made to improve patient safety. Medical devices are designed with high safety standards in mind and with capabilities to report errors. Many efforts concern also human engineering and their capacity to recognize, adjudicate and report safety issues. In this study, we have research possibilities of designing a safety reporting system utilizing Internet and mobile technologies to suit the clinical environment in which surgeons and biomedical engineers share the arthroplasty data on explanted devices. Even though they share the same goals, they have different expectation on how manage the data. To be able to utilize the users' skills and experiences within their domain, it was important to include them in the participatory process so that they could be able to affect the outcome. The experience shows that early into the design process, a selected user group could be a part of analysis, and evaluation of this step of the development process [7]. We have presented the design of safety reporting to the representative of both these groups and they responded with enthusiasm. One surgeon has immediately recognized the reporting process as the one typically required by regulatory authorities. As much as he appreciated the concept, he wondered if it could burden. Also mentioned was the outcome of submitting a report, the concern that other medical staff would view it negatively and that it would affect the status, feedback, and cause additional workload. Such barriers will decrease the likelihood of a reporting system being successful. However, attitudes towards reporting are not always negative. The biomedical engineers that evaluated the designs and concept agreed that there is a need for such systems; they have recognized potential of safety reporting systems to decrease costs and improve patient outcome. When it comes to the design, the feedback was that the design contained almost everything needed. Nevertheless, some details should be added depending on whom the report is intended for. Different departments may appreciate specific information.

VI. Conclussions

The design was very clear and brought up the sense of the demand to report adverse safety events in a way that health authorities request it, the information and processes resemble the official ways of safety reporting. This understanding of the design, and such a reacting to it, came also with a question if this could be adjusted to general reporting. Therefore, the next step will be to study, understand and design for different user groups and levels of hospital care system involved in safety reporting. It would be recommended to carry out a comprehensive evaluation of different design solutions that would meet different expectations.
There is still work to be done on attitudes towards reporting and lack of motivation for it; medical staff tends to comply with it in cases when it is made mandatory by government.
The development is directed towards the high-fidelity prototype and further web based system development to enable reports that are more detailed.

Acknowledgment

We wish to express our sincere thanks to the participants in the research for their time, insight and expertise. We are very grateful for all opinions and input given.

Conflict of interest

The authors declare that they have no conflict of interest to declare.

References

[1] J. R. Brubacher, G. S. Hunte, L. Hamilton, and A. Taylor, “Barriers to and incentives for safety event reporting in emergency departments.” *Healthc. Q.*, vol. 14, no. 3, pp. 57–65, 2011.

[2] N. Hartnell, N. MacKinnon, I. Sketris, and M. Fleming, “Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study,” *BMJ Qual. Saf.*, vol. 21, no. 5, pp. 361–368, 2012.

[3] R. P. Mahajan, “Critical incident reporting and learning.” *Br. J. Anaesth.*, vol. 105, no. 1, pp. 69–75, Jul. 2010.

[4] MAUDE - Manufacturer And User Facility Device Experience". *Accessdata.fda.gov*. N.p., 2017. Web. 21 Apr. 2017

[5] N. Kellingley, “What is the difference between Inter-action Design and UX Design?” [Online]. Available: https://www.interaction-design.org/literature/article/what-is-the-difference-between-interaction-design-and-ux-design. [Ac-cessed: 07-May-2016].

[6] O. Mival and D. Benyon, “Requirements Engineering for Digital Health,” A. S. Fricker, C. Thümmler, and A. Gavras, Eds. Cham: Springer International Publishing, 2015, pp. 117–131.

[7] F. Kensing and J. Blomberg, “Participatory Design: Issues and Concerns,” *CSCW J. Collab. Comput.*, vol. 7, no. 3–4, pp. 167–185, 1998.

Corresponding Author: Hanne Åserød
Institute: Information Science and Media Studies (INFOMEDIA)
Street: Fosswinckels gate 6
City: 5007 Bergen
Country: Norway
Email: hanneaaseroed@gmail.com

Appendix J

Paper Submisson to Conference

International Conference on Informatics, Management and Technology in Healthcare, Athens, Greece.

Pharmacovigilance Mobile Tool Design in the Field of Arhroplasty

Hanne Åserød[a,1] and Ankica BABIC[a,b]
[a] *Department of Information Science and Media Studies, University of Bergen, Norway*
[b] *Department of Biomedical Engineering, Linköping University, Sweden*

Abstract. Pharmacovigilance is an important part of the patient safety and it has a great appeal to physicians. It is concerned with the safety of medical devices and treatments in the light of understanding the risks and dangers based on the already reported safety issues. Internet resources such as the Manufacturer And User Facility Device Experience (MAUDE) web-site are often retrieved due to the lack of internal, local safety databases. The research looked at how Human Computer Interaction could improve user experience. We have designed data entry for safety reporting and pharmacovigilance based on the web-bases system called WebBISS *(Web-based implant search system)*[1]**.** The expectation is not only to improve usability, but also to stimulate physicians to enter their safety data and become also contributors, and not only users of information. The expert evaluation has been generally positive and encouraged stronger help and error reporting functions. The high fidelity design has given a good impression of the future mobile solution.

Keywords. HCI design, high fidelity porotype, safety reporting, pharmacovigilance, arthroplasty

Introduction

The reporting of adverse events is an important step to secure patient safety and to prevent potential medical issues in the future. It is important to understand the reasons behind adverse events so that medical staff can recognize situations of high risk for patients and identify medical devices which might endanger patients' health. In Norway severe adverse events should be reported to Helsedirektoratet to alert about the risks of either medical devices or procedures. Helsedirektoratet publishes annual reports, but offers currently no online support. Therefore many clinicians and researchers turn to the systems like MAUDE (Manufacturer And User Facility Device Experience), which is a web-based system [9], that collects and provides information about adverse events. It is available for surgeons, doctors and general public. The Federal Drug Administration (FDA) uses MAUDE to monitor medical devices and collect information about performance or warning signs regarding the patient safety.

The World health organization defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse events. They have also widened the definition to include herbals, traditional and complementary medicines, blood products, biological, medical devices, and vaccines. Pharmacovigilance's goal is to improve patient care and safety in relation to the use of

[1] Corresponding Author. Hanne Åserød, E-mail: hanneaaseroed@gmail.com

medicines and all medical and paramedical interventions with aim to improve health and safety. It also contributes to assessment of benefit, harm, effectiveness and risk of medicines, encourages safe and rationale use of medicines and devices, promotes understanding, education and training in pharmacovigilance and effectively communicates with the public.

It is essential that adverse events are reported, analyzed and communicated [2] to improve patient safety and lower health care costs in the process [3]. Pharmacovigilance is important in ensuring that doctors and patients have enough information to make a decision regarding a treatment [4].

We have explored possibilities of improving pharmacovigilance in the field of arthroplasty. There is a great number of surgical procedures performed and systematically documented even within the Norwegian national arthroplasty registry [14], but there is no automatic system to retrieve pharmacovigilance information. To improve that we have first developed a web-based system called WebBISS *(Web-based implant search system)*[1] and now designed a mobile solution by combining Interaction design and User experience techniques.

1. Method and material

We have used Interaction design to create a high fidelity porotype trough three design iterations. The first iteration dealt with concepts of safety reporting, the second and third were directed towards designing a pharmacovigilance mobile tool. The design has combined knowledge of technological possibilities, systems, aesthetic judgment and empirical facts about users [5]. There are four possible user groups identified: biomedical engineers, clinicians, students and researchers. Evaluation considered three different prototypes ranging from the low to high fidelity prototypes; the low fidelity prototype was evaluated by two Human Computer (HCI) experts, the final high fidelity prototype was evaluated by one HCI expert.

We have followed five design principles: visibility, feedback, constraints, consistency, and affordance [6]. Those were evaluated according to the Nielsen's heuristics [7] and the System Usability Scale (SUS) [8] using a set of predefined tasks (‘*go to you user page’, ‘search for given key words’, ‘chose a database’,* and ‘*inspect the results’*). A total of 7 evaluators performed the tasks.

2. Results

Mobile design solutions are presents as a set of screenshots. The user starts by entering key words (Figure 1) which triggers search through the MAUDE [9], Clinical trials database [10], PubMed [11], and the internal local database proved by the biomedical engineers at the Haukeland University Hospital in Bergen. Results of the retrieval are available through the interaction of the graft (Figure 2). The interaction is also possible via navigation bar. Results of the MAUDE database (Figure 3) and the BIOMED database (Figure 4) provide detailed records in their original data format. The BIOMED database is managed by the Biomedical Engineering Laboratory as a part of the routine clinical work done on the explanted medical devices.

The screenshots belong to the last design iteration (a high fidelity) [12].

The heuristic evaluation found that most of the participants were satisfied with the *visibility of the system, the match between real world and system, consistency of the system, easiness of navigation and icons used*, according to the evaluators.

The heuristics with the lowest score was related to *error prevention*, *help and documentation*. Lower scores were expected since these functions were not implemented yet in the prototype. There also seems to be a problem of understanding the medical terminology by non-medically trained participants; some words were hard to understand and it was equally demanding to grasp the content of different databases. This could be easily fixed in the future by generating an '*About'* or '*Help'* page. There were also some cases where most participants gave a high score, and one participant gave a very low score. This might be due to a misunderstanding, but the participant opted not to ask for help during or additional during the evaluation. All participants were told that they could spend as much time they wanted/needed and that they could ask questions at any point.

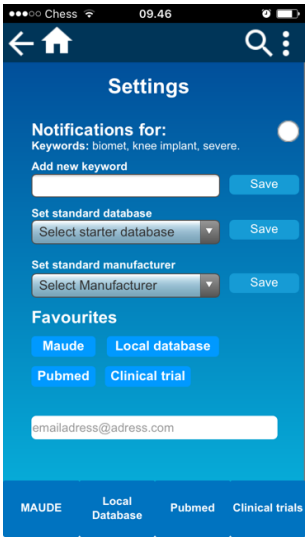


Figure 1. Initial user page (Screenshot).

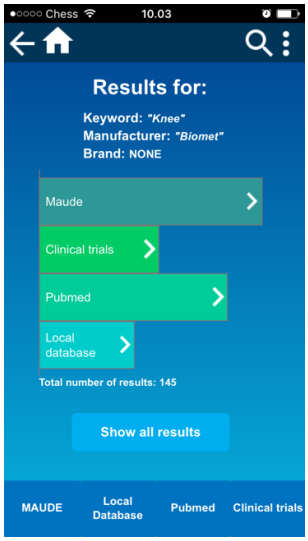


Figure 2. Navigation through the databases for given key words (Biomet).

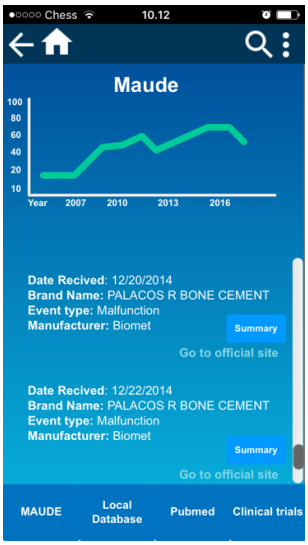


Figure 3. Results retrieved in the MAUDE database (Screenshot).

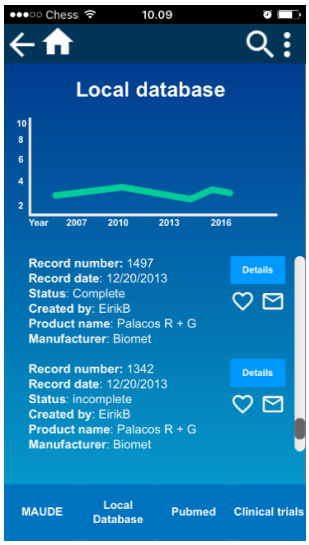


Figure 4. Results retrieved from local database (Screenshot).

The SUS scores vary from 57 to 75 and thus showing a need for improvement. Some evaluators commented that it was very intuitive to use the tool and the only help they would have liked would be an introduction to the specific databases and their content.

Some of the evaluators had again issues with the medical language, which they found hard due to their background in HCI, so that they gave a low score regarding the usability.

3. Conclusions

To enable retrieval of information regarding patient safety we have proposed and designed a pharmacovigilance mobile solution. It combines different databases via one single search window. All the functionalities are designed to take the user straightforward to the public databases and retrieve safety information in an easy manner. The results suggest that the design was a good step supporting pharmacovigilance. The main reasons for hindering a prompt safety reporting seem to be a workload, work culture, a fear of reprimand [13]. Therefore a better and easier pharmacovigilance could be considered as one reliable way of enabling patient safety.

The mobile tool was evaluated using the low and high fidelity prototypes which gave good critique and suggestions that will be used in the next design iteration(s).

References

[1] Ø. Ertkjern, "Postmarket Surveillance of Orthopaedic Implants using Web-technologies," 2015.

[2] G. Jeetu and G. Anusha, "Pharmacovigilance: A worldwide master key for drug safety monitoring," *J. Young Pharm.*, vol. 2, no. 3, pp. 315–320, 2010.

[3] J. Sultana, P. Cutroneo, and G. Trifirò, "Clinical and economic burden of adverse drug reactions," *J. Pharmacol. Pharmacother.*, vol. 4, no. Suppl1, pp. S73–S77, Dec. 2013.

[4] L. Härmark and A. Grootheest, "Pharmacovigilance: methods, recent developments and future perspectives," *Eur. J. Clin. Pharmacol.*, vol. 64, no. 8, pp. 743–752, 2008.

[5] E. Goodman, E. Stolterman, and R. Wakkary, "Understanding interaction design practices," *CHI '11*. ACM, pp. 1061–1070, 2011.

[6] J. Preece, Y. Rogers, and H. Sharp, *Interaction design : beyond human-computer interaction*, 4th ed. Chichester: Wiley, 2015.

[7] J. Nielsen, "Heuristic Evaluation: How-To: Article by Jakob Nielsen," 1995. [Online]. Available: https://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/. [Accessed: 12-May-2017].

[8] A. Bangor, P. T. Kortum, and J. T. Miller, "An Empirical Evaluation of the System Usability Scale," *Int. J. Hum. Comput. Interact.*, vol. 24, no. March 2015, pp. 574–594, 2008.

[9] "MAUDE - Manufacturer and User Facility Device Experience."

[10] "ClinicalTrials.gov." [Online]. Available: https://clinicaltrials.gov/. [Accessed: 15-May-2017].

[11] "PubMed - NCBI." [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/. [Accessed: 15-May-2017].

[12] "Prototypes, Specifications, and Diagrams in One Tool | Axure Software." [Online]. Available: https://www.axure.com/. [Accessed: 11-May-2017].

[13] H. Åserød and A. Babic, "Designing a mobile system for safety reporting of arthroplasty adverse events," 2017.

[14] http://nrlweb.ihelse.net/eng/

Bibliography

[1] "Safety Occurrence Reporting - SKYbrary Aviation Safety." [Online]. Available: http://www.skybrary.aero/index.php/Safety{_}Occurrence{_}Reporting

[2] "Total Hip Replacement-OrthoInfo - AAOS." [Online]. Available: http://orthoinfo.aaos.org/topic.cfm?topic=a00377

[3] "Total Knee Replacement-OrthoInfo - AAOS." [Online]. Available: http://orthoinfo.aaos.org/topic.cfm?topic=A00389

[4] O. Mival and D. Benyon, "Requirements Engineering for Digital Health," A. S. Fricker, C. Thümmler, and A. Gavras, Eds. Cham: Springer International Publishing, 2015, ch. User Exper, pp. 117–131. [Online]. Available: http://link.springer.com/chapter/10.1007{%}2F978-3-319-09798-5{_}6

[5] C. Acharya, H. Thimbleby, and P. Oladimeji, "Human Computer Interaction and Medical Devices," in *Proceedings of the 24th BCS Interaction Specialist Group Conference*, ser. BCS '10. Swinton, UK, UK: British Computer Society, 2010, pp. 168–176. [Online]. Available: http://dl.acm.org/citation.cfm?id=2146303.2146329

[6] "Mobile Apps — WEB-RADR." [Online]. Available: https://web-radr.eu/mobile-applications-for-adr-submission/

[7] A. Hevner and S. Chatterjee, "Design Research in Information Systems: Theory and Practice." Boston, MA: Springer US, 2010, ch. Design Sci, pp. 9–22. [Online]. Available: http://dx.doi.org/10.1007/978-1-4419-5653-8{_}2

[8] A. Hevner, S. March, J. Park, and S. Ram, "DESIGN SCIENCE IN INFORMATION SYSTEMS RESEARCH1," *MIS Quarterly*, vol. 28, no. 1, pp. 75–105, 2004.

[9] N. Hartnell, N. MacKinnon, I. Sketris, and M. Fleming, "Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study," *BMJ Quality & Safety*, vol. 21, no. 5, pp. 361–368, 2012.

[10] S. M. Evans, J. G. Berry, B. J. Smith, A. Esterman, P. Selim, J. O'Shaughnessy, and M. DeWit, "Attitudes and barriers to incident reporting: a collaborative hospital study." *Quality & safety in health care*, vol. 15, no. 1, pp. 39–43, 2006. [Online]. Available: http://qualitysafety.bmj.com.iclibezp1.cc.ic.ac.uk/content/15/1/39.full

[11] J. Firth-Cozens, "Barriers to incident reporting." *Quality & safety in health care*, vol. 11, no. 1, p. 7, mar 2002. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/12120590http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC1743555

[12] O. Al-Baik and J. Miller, "The kanban approach, between agility and leanness: a systematic review," *An International Journal*, vol. 20, no. 6, pp. 1861–1897, 2015.

[13] J. C. Wyatt and J. L. Y. Liu, "Basic concepts in medical informatics," *Journal of Epidemiology and Community Health*, vol. 56, no. 11, p. 808, 2002.

[14] W. R. Hersh, "Medical informatics: improving health care through information.(Contempo Updates: Linking Evidence and Experience)," *JAMA, The Journal of the American Medical Association*, vol. 288, no. 16, p. 1955, 2002.

[15] World Health Organization, "The Importance of Pharmacovigilance - Safety Monitoring of medicinal products," *Who*, pp. 1–52, 2002. [Online]. Available: http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

[16] G. Jeetu and G. Anusha, "Pharmacovigilance: A worldwide master key for drug safety monitoring," *Journal of Young Pharmacists*, vol. 2, no. 3, pp. 315–320, 2010.

[17] J. Sultana, P. Cutroneo, and G. Trifirò, "Clinical and economic burden of adverse drug reactions," *Journal of Pharmacology & Pharmacotherapeutics*, vol. 4, no. Suppl1, pp. S73–S77, dec 2013. [Online]. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853675/

[18] L. Härmark and A. Grootheest, "Pharmacovigilance: methods, recent developments and future perspectives," *European Journal of Clinical Pharmacology*, vol. 64, no. 8, pp. 743–752, 2008.

[19] I. Mitchell, A. Schuster, K. Smith, P. Pronovost, and A. Wu, "Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'," *BMJ Quality & Safety*, vol. 25, no. 2, pp. 92 LP – 99, jan 2016. [Online]. Available: http://qualitysafety.bmj.com/content/25/2/92.abstract

[20] "Arthroplasty - procedure, recovery, blood, pain, complications, adults, time, infection." [Online]. Available: http://www.surgeryencyclopedia.com/A-Ce/Arthroplasty.html

[21] "Arthroplasty Definition — Back Pain and Neck Pain Medical Glossary." [Online]. Available: http://www.spine-health.com/glossary/arthroplasty

[22] M. J. Carroll, "Human computer interaction - Brief intro," in *The encyclopedia of Human-Computer Interaction*, 2nd ed., M. Soegaard and R. F. Dam, Eds., ch. 2. [Online]. Available: https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/human-computer-interaction-brief-intro

[23] M. Dunlop and S. Brewster, "The challenges of mobile devices for human computer interaction (editorial for special edition)," *Personal and Ubiquitous Computing*, vol. 6, no. 4, pp. 235–236, 2002. [Online]. Available: http://strathprints.strath.ac.uk/2574/

[24] "About Us — WEB-RADR." [Online]. Available: https://web-radr.eu/about-us/

[25] "WEB-RADR." [Online]. Available: https://web-radr.eu/

[26] E. Goodman, E. Stolterman, and R. Wakkary, "Understanding interaction design practices," pp. 1061–1070, 2011.

[27] N. Kellingley, "What is the difference between Interaction Design and UX Design?" [Online]. Available: https://www.interaction-design.org/literature/article/what-is-the-difference-between-interaction-design-and-ux-design

[28] J. Preece, Y. Rogers, and H. Sharp, "Interaction Design: Beyond Human-Computer Interaction," *Design*, vol. 18, no. 1, pp. 68–68, 2002. [Online]. Available: http://linkinghub.elsevier.com/retrieve/pii/S0010448586800215

[29] J. J. Garrett, *The elements of user experience : user-centered design for the web and beyond*, 2nd ed., ser. Voices that matters. Berkeley, Calif: New Riders, 2011.

[30] J. Preece, Y. Rogers, and H. Sharp, *Interaction design : beyond human-computer interaction*, 4th ed. Chichester: Wiley, 2015.

[31] S. Few, "Data Visualization for Human Perception: The Encyclopedia of Human-Computer Interaction, 2nd Ed. — Interaction Design Foundation." [Online]. Available: https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/data-visualization-for-human-perception

[32] H. Purchase, "Effective information visualisation: a study of graph drawing aesthetics and algorithms," *Interacting with Computers*, vol. 13, no. 2, pp. 147–162, 2000. [Online]. Available: http://www.sciencedirect.com/science/article/pii/S0953543800000321

[33] G. Ellis and A. Dix, "A taxonomy of clutter reduction for information visualisation," *IEEE Transactions on Visualization and Computer Graphics*, vol. 13, no. 6, pp. 1216–1223, 2007.

[34] B. Shneiderman and B. Shneiderman, "The Eyes Have It : A Task by Data Type Taxonomy The Eyes Have It : A Task by Data Type Taxonomy for Information Visualizations," 1996.

[35] B. Craft and P. Cairns, "Beyond guidelines: What can we learn from the visual information seeking mantra?" *Proceedings of the International Conference on Information Visualisation*, vol. 2005, pp. 110–118, 2005.

[36] R. Langner, T. Horak, and R. Dachselt, "Information Visualizations with Mobile Devices: Three Promising Aspects," *Proceedings of the Workshop on Data Exploration for Interactive Surfaces (DEXIS 2015)*, pp. 20–23, 2015.

[37] R.-M. Åhlfeldt and E. Söderström, "Information Security Problems and Needs in a Distributed Healthcare Domain- A Case Study," no. August 2016, 2007.

[38] "Min helse - helsenorge.no." [Online]. Available: https://helsenorge.no/min-helse

[39] K. Garrety, I. McLoughlin, R. Wilson, G. Zelle, and M. Martin, "National electronic health records and the digital disruption of moral orders," *Social Science and Medicine*, vol. 101, pp. 70–77, 2014. [Online]. Available: http://dx.doi.org/10.1016/j.socscimed.2013.11.029

[40] W. H. Drummond, J. M. Ferranti, C. U. Lehmann, and D. E. Lighter, "Complexity in healthcare information technology systems," *Pediatric Informatics*, pp. 83–117, 2009. [Online]. Available: http://www.springerlink.com.proxy.lib.umich.edu/content/hlt18428h3749420/fulltext.pdf

[41] P. G. Shekelle, "Why don't physicians enthusiastically support quality improvement programmes?" *Quality & safety in health care*, vol. 11, no. 1, p. 6, 2002.

[42] J. J. Waring, "Beyond blame: cultural barriers to medical incident reporting," *Social Science & Medicine*, vol. 60, no. 9, pp. 1927–1935, 2005.

[43] "Meldeordningen etter §3-3 i spesialisthelsetjenesteloven." [Online]. Available: https://helsedirektoratet.no/meld-uonsket-hendelse/meldeordningen-etter-3-3-i-spesialisthelsetjenesteloven{#}om-meldeordningen

[44] "Reporting of adverse incidents involving medical devices." [Online]. Available: https://helsedirektoratet.no/english/medical-devices/

reporting-of-adverse-incidents-involving-medical-devices{#}
legal-requirements-for-the-obligation-to-report-adverse-incidents.-

[45] V. Vaishnavi and B. Kuechler, "Design Science Research in Information Systems," 2004. [Online]. Available: https://miside.uib.no/dotlrn/classes/det-samfunnsvitenskapelige-fakultet/infomevi300/infomevi300-2016v/file-storage/download/144060944/design-science-research-in-information-systems.pdf

[46] J. D. Gould and C. Lewis, "Designing for usability—key principles and what designers think," *Proceedings of the SIGCHI conference on Human Factors in Computing Systems - CHI '83*, vol. 28, no. 3, pp. 50–53, 1985. [Online]. Available: http://portal.acm.org/citation.cfm?doid=800045.801579

[47] B. J. Oates, *Researching information systems and computing*. London: Sage Publications, 2006.

[48] G. Tunge, "Profilprogram for helse stavanger HF," 2012. [Online]. Available: http://www.helse-stavanger.no/no/OmOss/Avdelinger/kommunikasjonsavdelingen/Documents/Profilmanual010612.pdf

[49] H. og Omsorgsdepartementet, "Nasjonalt profilprogram for helseforetakene," sep 2014. [Online]. Available: https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/styringsdokumenter1/nasjonalt-profilprogram-for-helseforetak/id650208/

[50] A. Bangor, P. T. Kortum, and J. T. Miller, "An Empirical Evaluation of the System Usability Scale," *International Journal of Human-Computer Interaction*, vol. 24, no. March 2015, pp. 574–594, 2008.

[51] J. Nielsen, "Heuristic Evaluation: How-To: Article by Jakob Nielsen," 1995. [Online]. Available: https://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/

[52] "Prototypes, Specifications, and Diagrams in One Tool — Axure Software." [Online]. Available: https://www.axure.com/

[53] "Kjøp Adobe Photoshop CC — Prøv programvare for bilderedigering gratis." [Online]. Available: http://www.adobe.com/no/products/photoshop.html

[54] "Xtensio — Documents = Web Pages = Presentations." [Online]. Available: https://xtensio.com/

[55] "Trello Tour." [Online]. Available: https://trello.com/tour

[56] "Balsamiq. Rapid, effective and fun wireframing software. — Balsamiq." [Online]. Available: https://balsamiq.com/

[57] J. Johnson and A. Henderson, "Conceptual Models: Begin by Designing What to Design," *Interactions*, vol. 9, no. 1, pp. 25–32, 2002.

[58] L. Nielsen, "Personas: The Encyclopedia of Human-Computer Interaction, 2nd Ed. — Interaction Design Foundation," 2012. [Online]. Available: https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/personas

[59] J. Berrewaerts, L. Delbecque, P. Orban, and M. Desseilles, "Patient Participation and the Use of Ehealth Tools for Pharmacoviligance," vol. 7, no. April, pp. 1–10, 2016.

[60] Ø. Ertkjern, "Postmarket Surveillance of Orthopaedic Implants using Web-technologies," 2015. [Online]. Available: http://bora.uib.no/handle/1956/9996

[61] "MAUDE - Manufacturer and User Facility Device Experience." [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[62] "PubMed - NCBI." [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/

[63] "ClinicalTrials.gov." [Online]. Available: https://clinicaltrials.gov/