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User-Centered Design in a Clinical Context: Challenges and Success

Master's Thesis in Interaction Design

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Abstract

Background
Involving users into every step of the design process materialized into a design approach called User Centered Design (UCD) to which more and more adhere in order to increase the usability of their products.

Aim
Starting from a history of products that are abandoned in the medical field, this thesis aims at establishing the state of the art in applying UCD in the clinical field as well as document the benefits and challenges behind this process. The results shall be collected in a guideline that can be use for the development of medical systems.

Methodology
The thesis starts with a systematic literature review and continues with an empirical study that further verifies the results of the review. Throughtout the literature review, articles documenting medical systems development and the process behind it have been scrutinized for UCD methods applied and their knowledge of UCD in general. As part of the empirical study, interviews have been performed with developers, designers and researchers of medical systems in order to collect their experiences on employing UCD as well as the benefits and challenges related to it.

Conclusion
In conclusions of the thesis, the most used methods as well as the general design process behind clinical systems are presented and discussed. A guideline on best practices and a path to creating relevant and usable products is described.

Keywords: Systematic Literature Review, User Centered Design, Medical Informatics, Health Information Systems, Design Guideline

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1

Introduction

Over the past decade, the benefits of technology have become more apparent in the clinical field through the emerging new information systems [1, 2]. However, problems with user acceptance often have led to users abandoning these systems or refusing to learn how to use them [3]. The cause of this is the fact that systems are often designed following an engineering and technology centric approach which makes them difficult to learn and use [4]. Instead of highlighting the importance of creating usable systems, the clinical field still trains users to adapt to poorly designed systems [5]. As an article has shown, the lack of adopting appropriate computer support systems toward improving patient care is annually causing more than 1 million injuries and 98,000 deaths in the United States alone due to medical errors [6]. So the need for usable and user-friendly systems is imperative. How can this problem be solved? Most researchers in the field agree that involving users in the design process will help in creating a usable system [7–9]. This type of involvement of the users in the design process is known as user-centered design (UCD). The UCD approach might be the solution to problems such as low user acceptance as it focuses on creating a system that accommodates for the users' needs. Along with increasing user acceptance, UCD methods can also help increase productivity, reduce errors, reduce training and support costs [10] and alleviate some of the pitfalls of poor design, which to begin with is the reason behind 80% of total maintenance costs [11]. So the question is: how do you successfully apply UCD methods when designing?

In this first chapter, an introduction to the thesis, its aims and methodology are presented and a background on the concepts tackled in the thesis is given in order to facilitate further understanding of the work described. The second chapter continues by introducing the framework of the systematic literature review, while the third one discusses the findings of the review. To further investigate the results of the literature review, the authors have designed a series of interviews with researchers and industry developers of medical applications that are being described. The design of the interviews is presented in the fourth chapter while their results are discussed in the fifth one. The final chapter of this thesis builds a bridge between the literature review and the empirical research and discusses further ramifications of them.

1.1 Background

This section covers a brief introduction to some of the key definitions and concepts that are used throughout the thesis along with related work.

1.1.1 Starting points

An approach generally defined as the involvement of users in every step of the design process [12], UCD has established itself as a design phylosophy that enables a process of making sense of the environment, understanding user behaviour in regard to the products and making sure that the users' needs are met [13, 14].

A classic model of the UCD approach has been presented by Barrington [14] and, as can be seen in Fig. 1.1, it starts off with requirements gathering, which generally involves an analysis of the stakeholders' needs for the new product as well as a context of use analysis. The latter involves designers assessing the environment in which the product is to be used through etnographic techniques such as observation and videotaping the users in action. A task analysis phase follows which allows a deconstruction of each of the tasks required from the product and the ways in which they will be performed. Naturally, the design team shall prototype a series of mockup products which they shall test for usability issues with the user groups. This is an iterative step and it gets repeated until a consensus is reached upon the interaction and the look and feel of the future system. The last phase entails the implementation of the system followed by thorough usability evaluations in order to decide the degree to which it is being adopted and whether there are still things that could be improved in the design. If necessary, this step is repeated until the best solution is reached.

The most defining difference between UCD and traditional software design processes is that of UCD developing products around the user, while the latter forces a certain behaviour upon the user in order to adopt the product [13]. As can be seen in Fig. 1.2, Alan Cooper goes from presenting the early practices of when "smart programmers dreamed up products, and then built and tested them" to including managers that brought to the table their understanding of the market, to the more fortunate practices of adding Quality Assurance (QA) professionals and designers to the brew [16]. The fourth process flow presented in Fig 1.2 is what Cooper calls the Goal-Directed Approach where "decisions about a product's capabilities, form and behavior are made before the expensive and challenging construction phase" [16]. This the direction in which the industry should be moving, suggests Cooper. He goes on highlighting the importance of understanding and involving users in this process, of having a UCD approach [16].

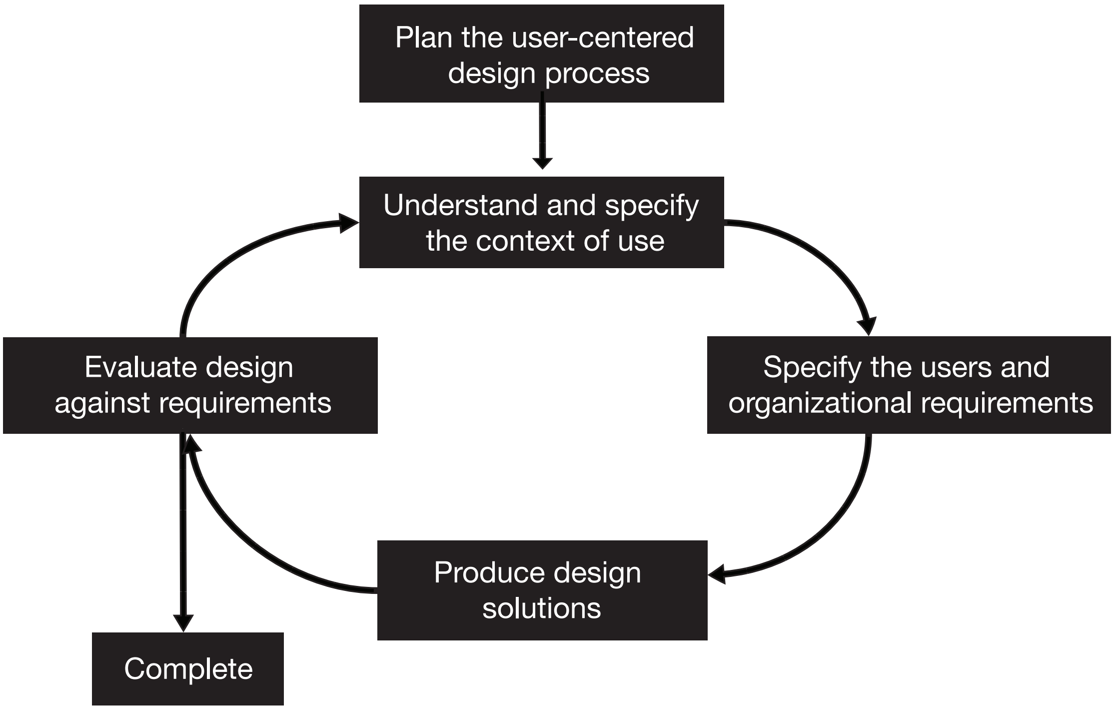

Figure 1.1: UCD process (taken from [15])

Throughout this thesis, the authors shall refer to the second and third process flows presented in Fig. 1.2 as *traditional software development processes.*

1.1.2 Delimitations

For the purpose of this thesis, the researchers have considered medical applications that include but are not limited to a software interface, as their previous studies have extensively covered the subject. Purely physical medical products, although they entail knowledge of interaction design and UCD principles, go beyond that into studies of ergonomics and industrial design principles and therefore have been left outside the scope of this study.

1.1.3 Related work

To beging with, it is important to mention the work from which this thesis derived. That is the research of Kashfi [17] in the field of Clinical Decision Support Systems (CDSS) and openEHR. She has explored the use of UCD principles throughout the creation of openEHR-aware CDSSs and presents an applied model of UCD in designing a usable CDSS. Her work has been the starting point in questioning the application of UCD in a successful way in the clinical field.

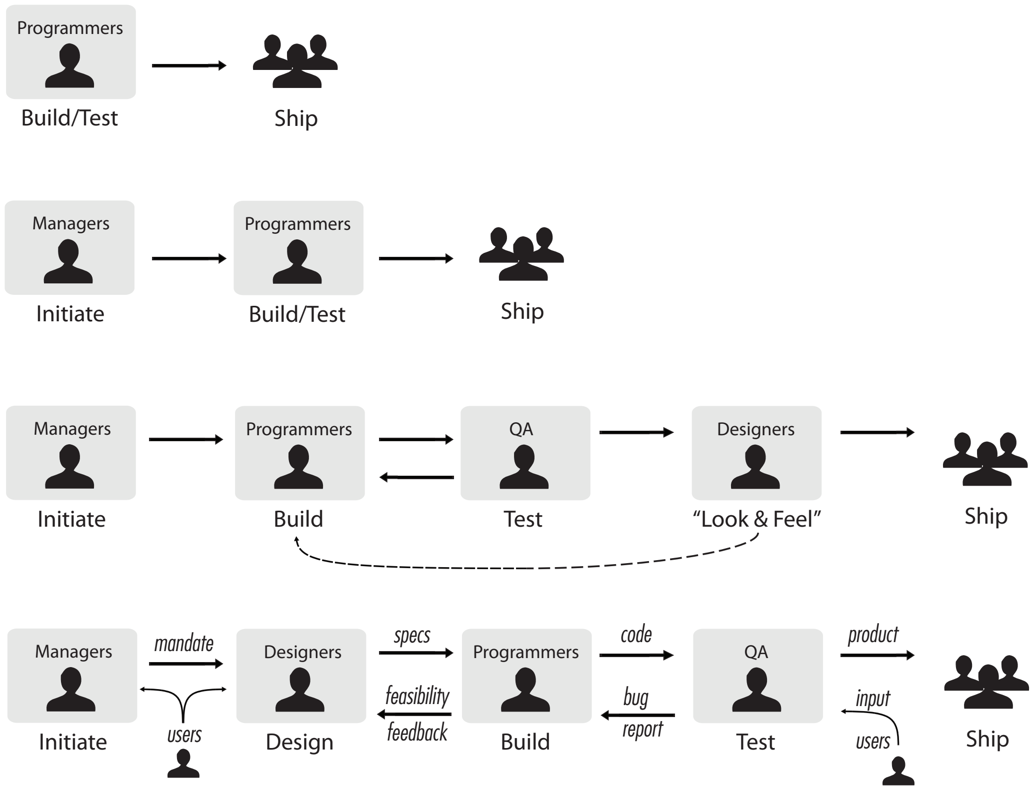

Figure 1.2: Software development evolution (taken from [16])

On the subject of UCD much has been written towards how a successful process looks like. The authors shall recollect part of these best practices in the final chapter and output new guidelines relevant to the clinical field, as a result of the research presented in this thesis. However, few authors have ventured in discussing these methods applied.

One author that touches the topic is Fleischmann [18]. Fleischmann discusses different design approaches to encourage user-designer interaction. He suggests a role hybridization approach. He mentions two ways of applying this approach. The first is trying to get the designers to act as users. The second, which is the one discussed in more detail in his paper, is the opposite, the user acting as the designer. He gives an example of a teacher who uses his knowledge in the area, where he is teaching, to be able to create a good and useful system for that particular area. The author concludes that this new approach gives an increased potential for empowering users and also making sure that information technology is beneficial to society.

Another author that describes an approach for creating user friendly systems is Barrington [14]. In her paper, the author goes into detail on the UCD approach and its benefits towards creating usable systems. She goes through each step of a UCD process and gives examples of methods you could use in each step. She also talks about heuristics, which are based on Nielsen's ten heuristics [19]. She ends her paper with stating that incorporating UCD in your design process need not to be difficult. She also states some possible benefits of using UCD compared to more traditional software development processes.

Although the body of work on the subject of UCD applied to the medical field is quite limited, there are authors whose efforts in outlining the benefits and principles of engaging users have been a solid starting point for some of the work presented in this thesis.

Tejani et al. [20] present in their paper the development of a hand-held assessment tool for physicians and nurses with the use of a UCD process. In creating their system, they describe how their design process works and also states some principles that, as a designer, one could use to develop fundamentally correct user interfaces. This description of their design process along with the recommendations would allow for a designer to use this as a sound foundation when designing clinically useful systems.

Searl et al. [21] argue for the use of a human-centered orientation when designing in the medical field. They do not give an example of how you could use the human-centered approach, but they argue that it is time to shift focus to a more human-centered approach when designing. They give some examples of work that has been done with the use of an human-centered approach. But they also state that the integration of the human-centered approach is long overdue and that the focus should have shifted towards the human-centered approach long time ago. The authors conclude their paper with stating that the use of an human-centered approach is necessary for the creation of usable and sustainable healthcare systems.

One author that describes how you can apply UCD when designing for the clinical field is Wiklund [22]. In his paper, he presents useful guidelines for how you can design effective systems with the use of an UCD approach. However, he focuses mostly on voice devices and some of his steps in the guidelines are not applicable across other systems. But the two first steps of his guideline are applicable in general. These steps are that you should learn about the user and also ensure the proper task and information flow. The next steps in his guideline are mostly focused on the design of a voice device.

In his paper, Alden [13] describes UCD and the tasks that you need to think of. The author does not give a concrete example of how you use UCD but more mentioning things that you should think about in each step of the process. He describes each step and what you should perform in each step. He also mentions methods that you could use to perform each step in a good way to ensure an usable system.

The last paper presented here is written by Weinger [12]. In his paper, he describes and discusses on Norman's [23] key recommendations for creating usable systems. The focus of these recommendations is on the design of user interfaces. He states that the bad performance of a device may be related to poor design and that these recommendations might help with this problem. The author also states that an excellent device should allow the user to interact with the device correctly, even when they interact with it for the first time.

1.2 Research process

1.2.1 Research motivation

As can be seen from the related work presented, there is not much work done on describing a good way to incorporate UCD when you are designing for the medical field. Most authors limit themselves to mentioning the design process used and which methods have been performed. There is no discussion on which of these methods have been successful and which have not and why. Therefore, there is a great need for this kind of research, as it focuses on how to incorporate UCD throughout the development process and the possible benefits and challenges designers might encounter.

The purpose of this thesis is to research what the state of the art is in employing UCD in the medical field and how to apply UCD to be successful in creating useful systems. And also create guidelines that will help designers to create usable systems for the medical field as this will hopefully solve the problem with the high abandonment of newly designed systems. This will be achieved through the use of a literature review, as well as an empirical study where designers, researchers and medical staff will give their opinion on how you design through employing UCD and the possible benefits and challenges that they have encountered when designing for the clinical field with the help of UCD.

Research questions

The research questions (RQ) that are to be answered throughout this thesis are:

RQ1. What is the state of the art in applying UCD methods to the medical field?

RQ2. What are the methods that ensure creation of usable clinical systems?

RQ3. What are the challenges in applying UCD in a clinical context and how to tackle these challenges?

Aims and objectives

Several research objectives can be identified in order to answer the research questions stated below.

- Conducting a literature review in order to identify the state of the art in the intersection between Human Computer Interaction (HCI) and the clinical application development.
- Gathering and investigating difficulties and benefits that designers and developers of clinical applications have faced so far.
- Providing a user-centered design guideline aimed at designers and developers of clinical applications.

Expected outcomes

- A systematic review paper, describing the state of the art in using UCD and related concepts in the medical field, published in a relevant journal such as ”Elsevier: Computer Methods and Programs in Biomedicine” or ”Elsevier: International Journal of Medical Informatics”.
- A UCD guideline, aimed at the designers and developers of clinical applications, containing a comparison of different UCD methods, listing benefits and drawbacks.
- A paper covering the guidelines resulted from the thesis presented at a conference

1.2.2 Research strategy

For the purpose of this thesis, a systematic literature review has been coupled with empirical research in order to answer the research questions in an exhaustive way. A model of the research process used throughout this study can be seen in Fig. 1.3. The model has been based on Oates' [24] model of the research process.

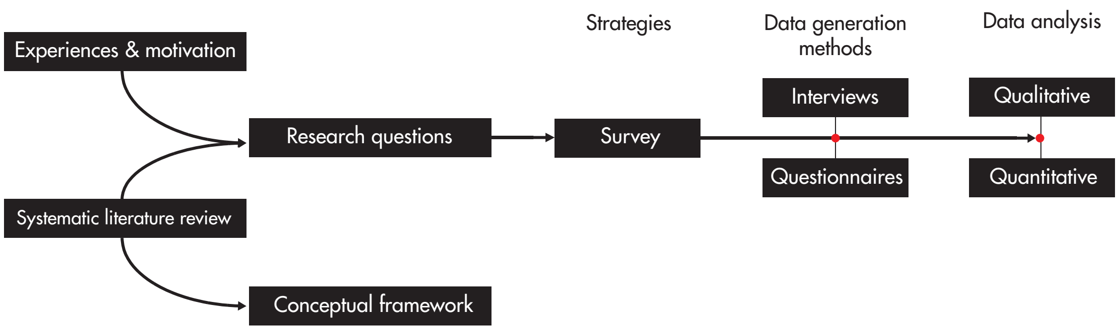

Figure 1.3: Research strategy (adapted from [24])

As seen in the Fig. 1.3, the process is quite straightforward. Once the area of interest has been decided and the research questions have been defined the next step in the process is to perform the systematic literature review in order to try and answer the research questions. When the data gathering and analysis has been performed, an initial answer to the research questions will be discussed. The information gathered throughout the literature review will then form the foundation for the next step. An interview guide will be created making use of the information gathered from the literature review. This guide will be used during the survey, or empirical study, to answer the questions that were not answered by the literature review, as well as comparing the findings from the literature review with the information gathered from the interviewees. When these two major data gathering steps have been performed the data will be analyzed and finally presented as the results of this thesis. How each step is performed will be discussed more in depth later in the thesis.

1.2.2.1 Literature review

To start with, a literature review is defined as an ”objective, thorough summary and critical analysis of the available research and non-research on the topic being studied” [25]. The purpose of this review is to bring forth not only arguments that support a certain theory or approach, but rather a whole body of expressed views on the subject [26]. Along with being clear structured, the written review should present a well-documented search and extraction/selection strategy of the sources and be thoroughly referenced [25].

1.2.2.2 Empirical research

The empirical research emphasizes control, in the sense that the investigator sets up the conditions of the investigation and specifies detailed questions that will be answered or hypotheses that will be tested [27]. The way this empirical research is to be performed, is through the use of interviews. Using interviews is a good way to extract experiences and information that otherwise might be missed if only a literature review is performed. The empirical research will be performed with the use of interviews to further explore the experiences that experts from the field have had, compared to what the literature states. The interviews will be performed with researchers and designers in the field of clinical application design. To be able to get relevant and consistent information, an interview guide will be created and used throughout the interviews.

2

Systematic Review: Design and execution

A systematic literature review is a review that gathers papers on primary research and produces a summary, as well as an analysis, of the findings of other authors [28]. This type of review offers a solution to the fact that there are a large amount of articles that by themselves offer little insight [28]. But when a systematic literature review has been conducted the resulting review can offer a better understanding on the complete subject. Kitchenham [28] defines a systematic review as "a means of evaluating and interpreting all available research relevant to a particular research question, topic area, or phenomenon of interest".

The systematic literature review became well used in the late 80s when the problems with the traditional literature reviews were exposed [29]. The biggest problem with the traditional literature review was that it lacked the peer-review that the systematic literature review benefits from. This problem caused the traditional literature review to have major problems with bias. The use of peer-reviews makes the systematic literature review to be considered more accurate and less biased [29].

When a systematic literature study is to be conducted there are some points or steps that are beneficial to follow to conduct a good systematic literature review. According to Hemingway [29] the steps for developing a systematic literature review are: defining an appropriate research question, searching the literature, assessing the studies, combining the results, placing the findings in context as can be seen in the Fig. 2.1. These steps are good to follow, when performing a systematic literature review, as they allow the researchers to perform their study and present the results in a clear way. The systematic review consists of three phases that are executed as in the Fig. 2.2. Each step will be described further in the sections below.

Figure 2.1: Systematic review steps

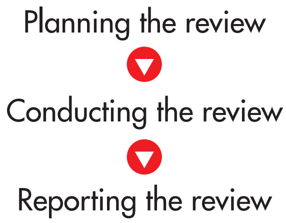

Figure 2.2: Systematic review phases

2.1 Planning the review

To be able to conduct a good systematic review you need to plan each step thoroughly. During the planning phase the keywords for the search will be defined, along with the decision on which databases to cover in the search to get extensive and relevant results. The keywords, that are to be used in the search, will be extracted from the research questions as this will make the keywords focus on the particular area of interest. The choice of databases will depend on which databases are deemed suitable. This choice will be based on which types of articles and journals the databases cover. These two tasks, choice of database and defining keywords, are an important step in the process of writing a systematic literature review as they are the foundation for getting correct and relevant articles for the review.

2.1.1 Purpose of the systematic review

A systematic review is a useful tool when you are searching for information about a defined area. As the systematic review allows the researcher to get the most relevant articles on the subject of interest. The purpose of this systematic review is to extract information on what is state of the art when designing systems, with the use of UCD methods, in the medical field and also to see the potential benefits and problems you encounter when using the UCD methods in the design process as this type of research has not been done yet.

2.1.2 Defining Research Questions

Through the systematic review the first research question posed in section 1.2.1 will be answered: *"What is the state of the art in applying UCD methods to the medical field?"* An assessment of the methods reported in the articles reviewed will give a picture of the state of the art in using UCD methods for developing clinical applications.

The results of the systematic review and the interviews performed with some of the developers and designers of these systems will help answer the second and third question: *What are the methods that ensure creation of usable clinical systems? What are the challenges in applying UCD in a clinical context and how to tackle these challenges?*

2.1.3 Review protocol development

The procedures used to perform a systematic review are defined in a review protocol [30]. This helps minimize researcher bias and ensures the search has not been driven by subjective reasoning [30]. The search strategy, study selection criteria, data extraction table and the data synthesis strategy form the review protocol.

2.1.3.1 Search strategy

To be able to perform a relevant search there are three major tasks that need to be done. First you need to define what the keywords are for your search. The keywords are words that describe or define the area of interest, for example if you are looking for information around a certain manufacturer it might be wise to include their name as a keyword. The two following steps of the search are to define the search strings as well as the database, or resource, you are going to use when performing the search. The search string is often a combination of the keywords formed through the use of Boolean expressions, such as AND, OR, NOT. This will allow the researcher to extract articles that match the area of interest. To get the most out of the search you need to consider carefully which resources to use as they need to cover the area you are searching for information in. These three tasks will be described further in later sections.

Figure 2.3: Keyword definition process

When the search has been performed there are a lot of papers that need to be checked for relevance. The first step, after the search has been done, is to perform the selection of papers. The whole process of paper selection can be seen in Fig. 2.4. During this process the articles will be scrutinised for relevance. The first stage in the process is to read the titles of the articles and try to determine if they are relevant for the study. When this initial filtering has been performed, the next stage will be focusing on reading the abstracts of the remaining articles and, yet again, trying to determine the relevance of the articles. After this stage, the articles will be fully read by both researchers and during this stage the data extraction tables will be filled with the extracted information. When all these steps have been performed, the researchers will decide upon which papers to use in their study. All decisions made during this process will be based on the researchers' best knowledge.

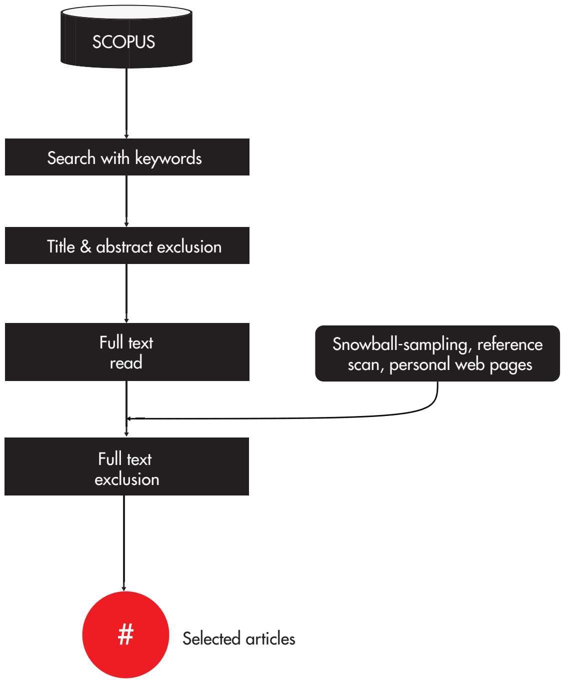

Figure 2.4: Search strategy

a) Keywords

To perform the literature search a number of keywords were extracted from the research questions in order to give relevant results when used in the search process as they are meant to be representative for the area that is of interest. The keywords that were extracted from the RQs were organized into two different categories. The two categories used were the UCD category and the medical one. These categories were used based on the research questions.

The following keywords were defined as can be seen in Table 2.1: user-centered, health information systems, human-centered, clinic and medical. During the process there were many other keywords that were discussed as well, but in the end many of them were deemed to be either too narrow or too wide for this study. In the end, the keywords were considered as the best keywords to use for this study.

Table 2.1: Defined keywords

UCD	MEDICAL
user-centered	health information system
human-centered	clinic
	medical

b) Search string

To get an extensive and relevant search, the search string had to combine two or more keywords. And the search strings were also to contain both categories mentioned earlier as this is the focus of the research questions. The basic search string was to have a UCD keyword combined, through Boolean operator AND, with a medical keyword as shown in the example below. The resulting search strings however, are more complex than the simple example given here, having to exclude previously used terms in order to avoid duplicates. The final search strings can be found in Table 2.4, section 2.2.2 of this thesis.

UCD keyword AND Medical keyword

c) Resources

Given the nature of this thesis, the databases chosen as sources for the articles needed to cover both publications in the information systems design field as well as the clinical one. At this point, for the purpose of this review the SciVerse Hub[1] has been chosen as the main search point. This new web service aggregates the content from SciVerse ScienceDirect[2], SciVerse Scopus[3], PubMed[4] and the ACM Digital Library[5] and has a flexible and intuitive interface that offers multiple tools to the researcher. These databases cover extensively the published biomedical research as well as information systems and computing publications.

This chosen database will be searched for English-based articles on the use of UCD methods or related concepts within the clinical field. In order to get a reasonable amount of information the focus of the search shall be on the abstract of the papers [31].

[1] *http://www.hub.sciverse.com*
[2] *http://www.sciencedirect.com/*
[3] *http://www.scopus.com*
[4] *http://www.ncbi.nlm.nih.gov*
[5] *http://dl.acm.org*

2.1.3.2 Study selection criteria

To limit the resulting articles from the search, some criteria were introduced. This type of criteria allow researchers to remove irrelevant articles early in the search process. The criteria are listed below, both the inclusion and exclusion ones.

a) Inclusion Criteria

- English-based only
- 1970 onwards
- Primary research
- Published literature only

b) Exclusion Criteria

- Non English-based
- Published before 1970
- Non-primary research

2.1.3.3 Data extraction strategy

A data extraction strategy will be used to allow for an easier extraction and analysis of the information gathered from the articles. A table containing information on what to extract will be used, see Table 2.2. This data extraction strategy forces the researchers to follow a set structure which is beneficial as this type of forced form is a good way to try and prevent bias from the researchers [30]. In addition, it will allow the researchers to more easily discuss the findings of the papers since they have extracted the information in an easily accessible form. Important to mention is the fact that each of the authors shall fill in their own data extraction table upon which they will discuss and summarize them into a new one, which is the one that shall be included in the thesis.

When the search is conducted, each search result shall be documented as follows:

Database: PubMed 2011 - Search term: user centered design AND implement Total number of hits: 46*

Throughout the search for literature, there is a high possibility that some of the key terms shall be added either as inclusion terms or exclusion ones. These shall be documented accordingly. Depending on the number of relevant hits, publication databases might be added to the study.

Table 2.2: Data extraction table with sample entry

NAME	AUTHORS	YEAR	METHODS USED	SYSTEM DETAILS	DESIGN PROCESS	SUMMARY
Designing Clinically Useful Systems: Examples from Medicine and Dentistry	Koch, S.	2003	Interviews, prototypes, master-apprentice	ICT support system & Dental chairside support system	An iterative design process	A short summary placed here

2.1.3.4 Data synthesis strategy

When the search has been performed, all data has been gathered and the data extraction tables have been filled in, it is time for the next step of the process. The next step in the process is the data synthesis. The data will be synthesized with the use of a method filing table as can be seen in Table 2.3. The table shall contain information on the methods documented in each of the articles. The names of the articles will be placed in the column of P1 to Pn. If an article uses a method the table will be filled in with an 'X' under the corresponding name. For example, if paper P1 uses method M1, the 'X' will be placed in the intersection between these two. This strategy will be used on the articles that are chosen for full-text reading.

Table 2.3: Method filing table

Article / Method	M1	M2	...	Mn
P1	X			
...				
Pn				

This type of strategy will allow for easier overview of the methods used, and it will also be easier to create different figures and graphs representing these results.

2.2 Conducting the review

This section will describe each step that was performed during this study and how the literature review was performed. The section will start off with a brief discussion about how the final search strings were defined and then it will present how many articles each search string yielded. The next part will describe how the paper selection process was conducted. The section will also describe the results of the data extraction and synthesis steps.

2.2.1 Identification of research

Previous to beginning the search, in order to facilitate the referencing process, it was decided that a free reference management system, Mendeley[6], was to be used to keep track of the articles. This tool provides an easy way for keeping track of the articles and allows access to the articles as long as you have a computer with Internet connection. Mendeley also allows its users to make notes that all users invited to the same group can see.

It was decided that the search strings should combine the two categories mentioned earlier, UCD and medical, as this is the area of interest for answering the questions. And it was decided that this was a good approach when conducting the search as it produces more focused and relevant articles. All things considered, the first search string became:

(user-centered AND ((”health information systems”) OR clinic OR medical*))*

In order to ensure an exhaustive search, a second string was defined as follows:

(human-centered AND ((”health information system”) OR clinic OR medical) AND NOT (user-centered))*

2.2.2 Selection of primary studies

To select which papers to be used, the papers had to pass the inclusion criteria mentioned earlier. If the papers did not match the inclusion criteria they were deemed to be irrelevant and were excluded from the study. The table below shows the search strings that were used during the search and the resulting amount of articles that each search yielded.

Table 2.4 shows the results with and without the abstract search filtering. This means that the search string and its keywords need to be found in the abstract. This leads to the search providing fewer and more relevant articles. It is important to mention that this automated abstract filtering has been the starting point for the next step: the manual abstract filtering. This step has been performed by the researchers in order to

[6] *www.mendeley.com*

Table 2.4: Table of search terms and number of articles found

Search string	Number of articles without abstract filtering	Number of articles with abstract filtering
(user-centered AND (("health information system") OR clinic* OR medical))	645	135
(human-centered AND (("health information system") OR clinic* OR medical) AND NOT(user-centered))	317	45

verify the relevance of the articles that were to be fully read. There is literature to support the decision of performing automated abstract filtering at this point [31].

2.2.2.1 Papers selected from primary studies

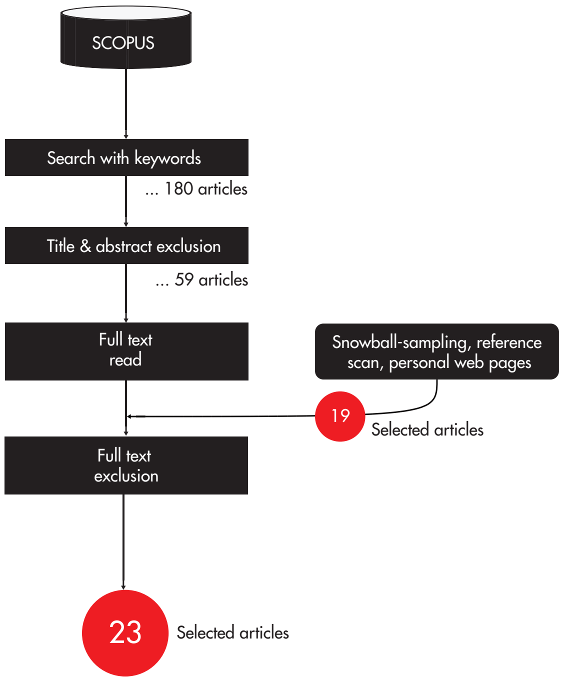

Figure 2.5: Search strategy results

The paper selection phase consists of six stages, as it has been mentioned previously in the search strategy section of this thesis. After the limitation of searching in the abstracts, the first stage yielded 180 articles that were deemed relevant to the study at this point. Fig. 2.5 shows the steps performed in the search and the number of articles each step resulted in.

The second stage was to go through the titles of the 180 articles to see which of these articles might be relevant. The researchers read the titles and discussed, based upon their knowledge, if the title seemed to describe a project that had created a clinical application with the use of UCD. If the title pointed towards that, it was decided to keep the article until the next stage. After this stage, of title-filtering, the amount of relevant articles was narrowed down to 98 articles. Due to limitations in getting access to articles 19 of them were excluded. This limitation brings the number of articles down to 79 after the second stage of the selection phase was performed.

The third stage was to read through the abstract of the 79 relevant articles. At this point the researchers looked at the aim, methods and conclusions of the articles in order to establish whether the papers were relevant. Yet again, if it was not certain that an article was irrelevant, the article was kept through to the next step. This stage removed 20 articles as they were deemed irrelevant to the study. After this stage, the amount of relevant articles was 59.

The next stage in the process was the actual reading of the whole paper. During this stage the articles were read and the data extraction table was filled with relevant information on the 59 articles. During this stage, a method called snowball-sampling was used, this yielded another 19 articles. The snowball-sampling method will be discussed in a section below. This combination of the paper selection process and snowball-sampling brings the amount of papers up to a total of 78 articles that were fully read.

The last stage in the paper selection phase was the discussion, between the researchers, of the 78 read articles. This was done after the data was extracted and the data extraction table filled in. During this step, the focus was on extracting the articles that showed a clear UCD process when designing or articles that discussed the potential benefits and challenges of using UCD. After this final stage, 23 articles were deemed relevant and were to be used in the study as they contained information to answer the RQs.

2.2.2.2 Snowball-sampling

The method called snowball-sampling [31] was used to extract even more relevant articles. The way the method is performed is that you go through either the articles that referenced to the article you have read, or you go through the reference list of the article you have read and add the articles that are relevant to your study. By doing this, you will most likely increase the amount of relevant articles because since they are referencing to each other, they are likely to discuss the same topic, or at least a similar topic. This method is best used on articles that you find relevant, and not on all of the articles. The snowball-sampling method was used during the paper selection phase. The method was used in the way that the reference lists of the read articles were scanned for more relevant articles. The focus of the method was put on the articles that were deemed very relevant for the study, this felt as a natural choice.

The first stage that was performed was the reading of the titles when browsing through the reference lists. During this first stage an extra 33 articles were found that, according to the title, described how to use UCD in the clinical field. After this initial phase, the abstracts were read and the relevance of these 33 articles was considered. The abstracts were discussed on how relevant they seemed to be for this study. After reading the abstracts, 19 of the 33 articles were found relevant to the study. These 19 articles were then added to the list of relevant articles and they were fully read by the authors.

2.2.3 Data extraction

During the data extraction step, both authors read the 78 articles that were chosen for full-text reading. During this step the data extraction tables were filled in by both authors with the corresponding information as the articles were read. After all articles had been read and added to each author's data extraction table, the results were discussed and summarized in a new data extraction table that can be found in Appendix A.

2.2.4 Data synthesis

After having selected the most relevant articles to include in the study, a full text reading followed where methods and more details were extracted from the papers. This information was then added to the data extraction table along with the methods table. Following this data extraction, there was a discussion on the research questions and the ways the analysis so far addresses and changes their status from relevant to irrelevant. At this point, the methods table (Table 2.5) presented in the next chapter was synthesized as well.

2.3 Reporting the review

The final stage is the reporting of the results. The systematic review results shall be presented in a paper that will be submitted for publishing in journals such as "Elsevier: Computer Methods and Programs in Biomedicine" or "Elsevier: International Journal of Medical Informatics". These results will also be discussed in the next chapter of this thesis.

3

Systematic review results

This chapter contains the results gained from the systematic literature review. The topics discussed in here will start with an overview of the articles that were selected for this study. This overview will describe the characteristics found in the articles: publication year, methods used, trends in design process, etc. After the overview of the articles, an ending discussion on the results and findings will be held.

3.1 Characteristics of primary studies

This section contains all the characteristics that were found during the reading of the articles. The section will start off with presenting the resulting data extraction table and an overview of the publication year of each paper. After this initial information, the focus will be on what type of systems were designed and on the context in which the studies were performed. The following sections will discuss trends that were found in both the design process and methods documented by the researchers in their articles. The final section will address the benefits and challenges in employing UCD that were found during this study.

3.1.1 Selected primary research studies

The articles selected for this study were read by both authors and the information extracted from these articles was filed into each of the researchers' data extraction table. The final table that was filled with the information extracted from each article is presented in Appendix A. Both authors read through all of the articles that were chosen and each filled in a copy of the data extraction table. When all the articles had been read and the data extraction tables filled, the articles were discussed and a data extraction table was filled with the combined information that both authors had extracted.

3.1.2 Publication years

Fig. 3.1 shows the amount of articles that were included in the study and their distribution over publication years. The articles range from the year 1999 to 2010.

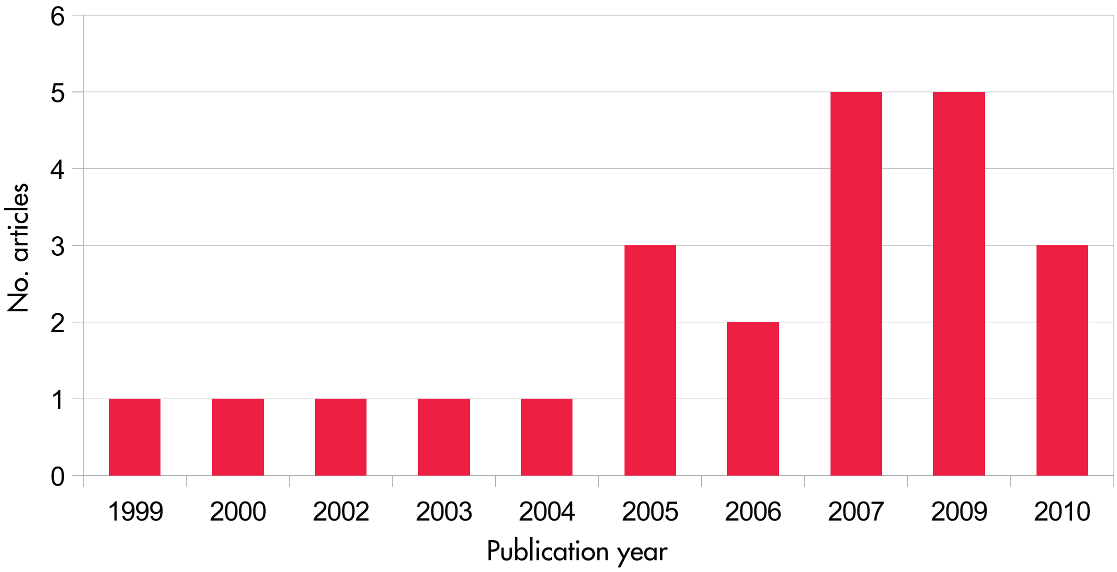

Figure 3.1: Publication years of the selected articles

3.1.3 Systems

The articles included in this study had one major thing in common: documenting the design of a clinical system. But the variety of systems was quite vast and ranged from electronic health records (EHR) to clinical decision support systems (CDSS) as can be seen in Fig. 3.2, which shows the distribution of the systems. Systems that are more often created have been found to be CDSSs, Healthcare Information Systems and Health Records. CDSSs amount to 26% of all the systems. Next in line stands a generic category of reported Health Information Systems at 17.3%, followed by EHRs, patient monitoring systems and family history tracking, each holding 8.6%.

3.1.4 Context

During the study, the context of the articles was found to be of two particular kinds. The context of the articles was either general hospitals or research labs. The main focus of the articles being on research, the context was often a research lab with real life simulations.

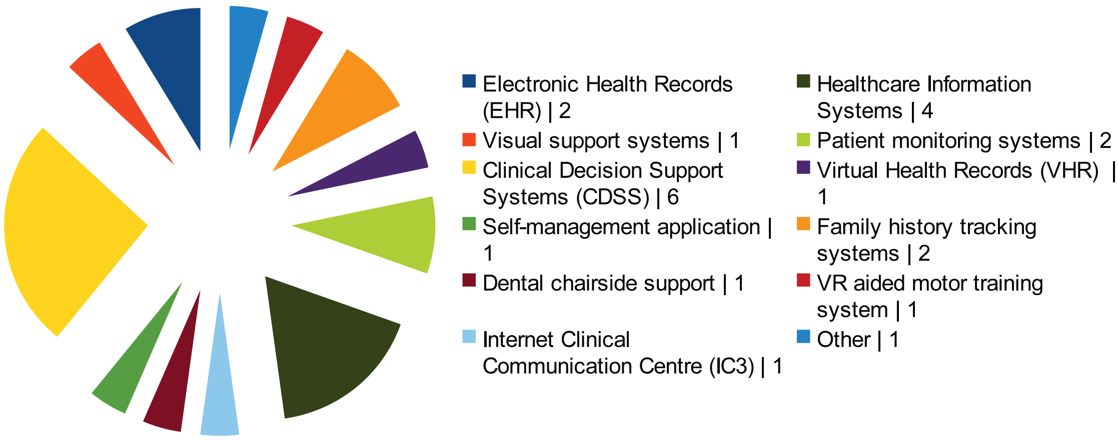

Figure 3.2: Categories of systems covered in the selected articles

3.1.5 Design process

Most of the articles used an iterative design process and they usually had the same foundation. The design process consisted of between three to seven steps. Four steps were found to be common to all the articles: *user study*, *requirements elicitation*, *prototyping*, *usability testing/evaluation.*

3.1.6 Reported user-centered methods

This section will report on the findings on what methods were used in the articles included in the study. The way the different articles reported on which methods they had used was very diverse. Some of the papers mentioned the methods by name and described how they had been applied. On the other hand, some of the articles only mentioned that they had used UCD in their design and they did not mention any concrete methods by name. But it was sometimes obvious that they had used UCD methods, without using the names of them. This diversity made the task of extracting data even harder.

Table 2.5 shows the findings of this particular topic. Some of the methods, that were extracted from the articles, were quite similar to each other and were therefore combined in to one method. This combination of methods were a judgement call since many authors had used their own names for a method but it was deemed that this method were similar to a more ”standard” name and they were therefore combined into one method in the table. The same combination also applied for methods that were of the same category, for example open-ended interviews and close-ended interviews were combined into interviews. This usage of their own names along with creating their own methods made the list of methods quite large, but many of the methods were only used a few times.

Even though the list was large, there were some methods that were more regularly used than others. Fig 3.3 shows the distribution of the most common methods across the articles. Categorized per process phase, these methods would be as follows:

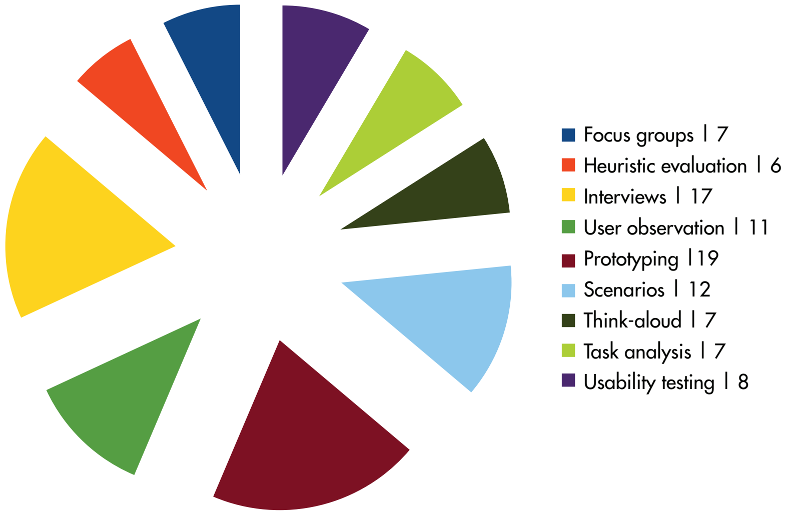

Figure 3.3: UCD methods covered in the articles

- User study
  - User observation
  - Task analysis
- Requirements
  - Focus groups
  - Interviews
  - Think-aloud
  - Scenarios
- Prototyping
- Testing/Evaluation
  - Heuristic evaluation
  - Usability testing
  - Scenarios
  - Interviews
  - Think-aloud

Table 2.5 Collection of methods found in the articles

Articles / Methods	Card sorting	Cognitive walkthrough	Comparison of the users' and designers' conceptualization of the tasks	Evaluation of existing system	Competitor analysis	Color analysis evaluation	Documentation analysis	Expert Reviews
Borges et al. 2007								
Wolfgang and Miksch. 2006								•
Ehrhart et al. 1999								
Nischelwitzer et al. 2007	•							
Koch 2003								
Kindsmüller et al. 2009								
Wong et al. 2005								
Salman et al 2010								
Narasimhadevara et al 2007								
Gao et al. 2007								
Koch et al 2004								
Thursky and Mahemoff								
Teixeira et al. 2010								
Peleg et al. 2009								
Teixeira et al. 2009							•	
Konstantinidis et. al, 2010								
Johnson et. al, 2005			•	•	•			
Hyun et. al. 2009								
Johnson, C.M., et. al., 2000		•						
Carroll, C. et al., 2002		•						
Gao, T. et al., 2006		•						
Yeh, S.-C. et al., 2007								
Nakano, N., et. al, 2009					•	•		•
Total	**1**	**3**	**1**	**1**	**2**	**1**	**1**	**2**

Table 2.5 Collection of methods found in the articles

Articles / Methods	Environmental analysis	Expert Walkthroughs	Formative evaluation	Focus groups	Functional analysis	Heuristic evaluation	Interviews	User observation	Prototyping	Questionnaires	Representational analysis
Borges et al.								•	•		
Wolfgang and							•		•	•	
Ehrhart et al.		•		•			•	•	•		
Nischelwitzer							•		•		
Koch 2003							•				
Kindsmüller et							•	•	•		
Wong et al.				•		•	•		•	•	
Salman et al						•	•	•	•	•	
Narasimhadeva				•			•	•			
Gao et al. 2007							•		•	•	
Koch et al							•	•	•		
Thursky and							•	•	•		
Teixeira et al.				•			•	•	•		
Peleg et al.						•	•	•	•		
Teixeira et al.				•				•	•		
Konstantinidis						•		•	•		
Johnson et. al,	•				•	•			•		•
Hyun et. al.			•	•			•		•	•	
Johnson, C.M.,	•										
Carroll, C. et				•		•	•		•		
Gao, T. et al.,							•		•		
Yeh, S.-C. et											
Nakano, N., et.							•		•		
Total	**2**	**1**	**1**	**7**	**1**	**6**	**17**	**11**	**19**	**5**	1

Table 2.5 Collection of methods found in the articles

Articles / Methods	Requirements meeting	Scenarios	Storyboards	Survey	System Usability Questionnaire (SUS)	Task analysis	Think-Aloud	Usability Testing	User Study
Borges et al. 2007		•						•	
Wolfgang and		•							•
Ehrhart et al.		•	•				•		
Nischelwitzer et							•		
Koch 2003		•							
Kindsmüller et al.								•	
Wong et al. 2005								•	
Salman et al 2010		•					•		
Narasimhadevara		•					•		
Gao et al. 2007	•	•		•					
Koch et al 2004		•							
Thursky and							•		
Teixeira et al.		•				•	•		
Peleg et al. 2009		•							
Teixeira et al.						•			
Konstantinidis et.			•					•	
Johnson et. al,					•	•		•	•
Hyun et. al. 2009						•			
Johnson, C.M., et.						•		•	
Carroll, C. et al.,		•					•		
Gao, T. et al.,	•			•				•	
Yeh, S.-C. et al.,						•			
Nakano, N., et. al,						•		•	•
Total	2	12	2	2	1	7	7	8	3

3.1.7 Reported benefits and challenges

There were many benefits and challenges that were mentioned throughout all of the articles read. Some of them were small while some of them addressed bigger concerns. One of the latter ones that many authors had, was the problem of low user acceptance and the causes behind it [3, 9, 32, 33]. Most authors argued that the reason behind this problem was the lack of user focus when designing [3, 9, 32, 33]. This problem was even more obvious when the systems that were designed were part of a complex environment, such as the clinical field is, because this meant that the systems themselves had to be complex and this hinders their usability. Since the clinical field is such a complex environment it needs complex systems that are usable. Unfortunately, instead of trying to incorporate a more user friendly design process which focuses more on the user, the culture in the clinical field is still to build it, without much user focus, and then train the users to use it [11, 34]. But this is starting to change, and to solve this problem with lack of usability and low user acceptance the authors suggests that an UCD approach should be used when designing these complex systems in the clinical field [34–37].

The most commonly stated problems with the systems designed in the clinical field were the low adoption and low satisfaction rates. Many of the authors claimed that the reason behind these problems where the poor regard to usability when these systems were designed [3, 9, 32, 33]. However, most of the authors also mentioned a possible solution to this problem. The incorporation of users within the design process was mentioned as the best solution [9, 11, 33, 34, 36, 38–40]. Most authors claimed that this user participation were bound to be beneficial for the resulting system as it increases the quality of design as well as improving user acceptance [9, 11, 33, 34, 36, 38–40]. This was the reason for the claim of using an UCD process which involves the users early to create usable systems. However, even though UCD might be beneficial in most cases there are some pitfalls that designers can encounter. When you are creating a system for a hospital, some authors claims that you must be certain that you address the needs of all categories of employees that will be using the system [36]. All categories at a hospital have different needs from these systems. Even though it might sound easy, some authors encountered problems with users not participating to the extent the authors had wanted them to [35]. Sometimes the reason behind this was the lack of interest or lack of time as most of the users are quite busy. Apart from the more general benefits and challenges there were two main areas that the literature addressed when mentioning benefits and challenges, the users and the process.

3.1.7.1 User-related benefits and challenges

The literature review revealed problems that researchers had with trying to involve users in their design process to create a more user-centered process. Some authors stated that they were having problems in finding end-users that were knowledgeable in the subject of project development [6, 11, 35]. This was a much wanted knowledge for the designers as they often had a hard time interacting with users that lacked this knowledge because they could not use their ordinary technical language when addressing the end users. These knowledgeable users were sometimes mentioned as ”champions” because they took it upon themselves of being a link between the end-users and the designers [6]. There was also mentioned problems with making generalisations from few observations or interviews in order to design systems for a certain user group as most user groups had their own idea on how the system were to be designed [36]. These different user groups often had different requirements for the system and since the systems often were to be used by different user groups, this caused problems. This problem should be addressed by making sure that you involve all different user groups throughout the whole design process. Another paper claimed to have problems with the planning of their project. The reason behind this was that they wanted to maximize the user feedback during development, but they encountered problems with the end-users' schedule [6].

However, if you are successful in incorporating users throughout your design process there are great benefits to get. The biggest problems of any newly designed system is the problem with usability and acceptance [3, 9, 32, 33]. If you involve users throughout the design process in a good way, these two problems will most likely be solved. Solving these two problems would be a major benefit as it will create a system that will be used and not abandoned. And it will also lower the maintenance costs drastically because of the increased usability.

3.1.7.2 Process related benefits and challenges

The literature review also revealed some benefits and challenges that the authors had with performing their process and what effects a bad process could lead to. However, there were quite few that mentioned their challenges and most just mentioned the more general benefits of performing UCD. But designing in the clinical field is hard since the clinical field is such a complex environment and it is therefore necessary that the systems created are usable and free of major problems. As it is obvious, some authors states that problems with development of these systems might reduce the quality of health care [35]. One of the greatest challenges for designers in the clinical field is to try and move away from the current culture. The culture of building it and then forcing the users to train to be able to use the system [11, 34]. This approach is bad and often results in poor systems. But the slow change that is moving towards a more user-centered approach might be the solution to these problems.

During the literature review, many authors claimed that the use of an UCD approach might help reduce the time and cost spent on producing new systems [33, 40, 41]. Along with being beneficial throughout the design process, by reducing time and cost, UCD also has the effect of creating more usable systems which in turn will reduce maintenance costs [42]. If the problems with usability could be solved early in the design, it would lower the cost drastically. A rule of thumb is that fixing a problem in the development phase is estimated to cost 10 times more than fixing a problem in the design phase. Fixing a problem after shipping a system costs 100 times more than fixing a problem in the design phase [41]. The constant evaluation and feedback throughout an iterative UCD process would reveal most of these problems early on in the process.

But even though it sounds very useful to incorporate an UCD process there are challenges to it. Some authors claims that the designers need to have the necessary experience on how to perform UCD otherwise it might do more harm then good [39]. If you, as a designer, are not able to extract the necessary requirements you will end up with a system that is of no use and will be abandoned or possibly harmful. But you must also be careful to not allow the process to become designer-centered rather then user-centered because you, as a designer, is central to the process and might influence the development through preconceptualisation [39].

3.2 Discussion

Even though the inclusion criteria allowed for articles as early as 1970, an easy observation is that of the relevant articles having been published much later than 1970. The fact that the articles range between 1999 and 2010 might be due to a lack of formal knowledge of UCD before that and thus a lack of proper wording in documenting the approach. As was presented in Fig. 3.2, a large variety of systems has been covered throughout the papers included in the study. This was seen as beneficial for the study as it implies that the findings are applicable throughout a large range of systems in the clinical field and not just one in particular. One possible reason for this might be that they are more focused on by designers and other researchers. Also, it might be that they are a more general term for systems that are similar to each other instead of an exact name for one system. For example, Healthcare Information Systems covers not only one system but instead it covers a particular kind of system.

The systematic literature review revealed that there is a growing focus towards using UCD methods when designing in the clinical field. The reason behind this growing interest is the fact that a large percentage of newly designed systems in the clinical field are abandoned due to poor design and lack of usability. It has been shown multiple times that incorporating UCD methods in your design process increases the usability and user-acceptance. These two benefits lead to a system that is more easily used and accepted by the users, which often prevents abandonment. This problem with low acceptance was the biggest problem mentioned by most authors. Apart from the benefits with increasing acceptance and usability of the system, there is the possibility of saving money from a better designed system. As mentioned earlier there seems to be a big advantage when it comes down to maintenance costs, if you create a usable system. As was mentioned earlier, up to 80% of total maintenance costs are from poorly designed systems that lacks the necessary usability and not technical bugs. This allows for major savings if the usability could be improved and this maintenance cost could be lowered. But it feels a bit depressing that we can not create usable systems throughout all different work environments.

The approach against which UCD is mentioned as a better alternative is the traditional software development one that lacks the necessary user focus. The statement of needing to combine the ordinary technical development process with user centered methods, sounds as a good approach if you want to be able to create usable systems. However, when we read through the articles in the study, there was often a lack of motivation on why the authors have chosen to use UCD. It sometimes feels as it at some point have come in place and then stayed as the right way of doing things, at least in the field of research.

During this study, the literature revealed a lot of papers that mention that they have used an UCD approach but often they do not go further into discussing it or how they performed it. Overall, the papers did not cover the topic as much as we would have liked to, even though it felt as most of the authors had a very sound knowledge about UCD. We can really see that there is a need for this kind of research, especially now when the UCD is growing and people are starting to understand the benefits of using it.

Even though the results seems to point at one thing, UCD is beneficial and almost a must, we feel that there are some issues that should be addressed. There is a lack of guidelines on how to use the UCD approach when designing in the clinical field, we feel that this kind of research could be of great benefit. And there is also very little discussion on the challenges that the designers might encounter if they perform a certain design process, this could be very useful for designers throughout the field. Also, most authors create their own design process and methods and we know it is hard to have a general approach that fits all different projects out there, but we think that the lack of not at least having a more general approach that designers could glance upon for guidance is hurting the evolution of UCD in the clinical field.

During the literature study we also found out that there seems to be different opinions on what is called an approach, design process, method or technique. Some authors mentioned methods that we thought were more of a technique then a method. It might be confusing for people that are new to the field when many authors used their own reworked methods, instead of using the ”normal” method. When we had extracted the data from all articles this confusion or differences caused a lot of work as trying to interpret what each author meant with their names and claims. This problem might be because some authors created their own methods or tweaked the ”standard” methods a bit and then gave them their own name. This was especially noticeable when we sat down and tried filling in the methods table. There were a lot of methods that were used only once throughout all articles.

Even though the authors had performed a UCD approach that they often mentioned as successful there seemed to be very few reports of post-implementation testing and how successful these projects actually had been. There were however some cases where they mentioned that their system were used in a hospital. But there were also cases where the authors mentioned that this only was a first step and further research had to be done on this subject. As expected, early papers do not reference much their use/choice of a certain method, but rather just go with it, while some of the later ones reference and even present a background of the methods but this was sometimes very scarce. But overall, there felt to be a more elaborate and descriptive process in the later papers, then compared to the early ones.

As this topic, UCD guidelines for the clinical field, has not been covered thoroughly it is hard for us to draw exact conclusions on the findings the we have had. The results show that UCD is seemed as beneficial for the medical field and the use of UCD methods are becoming more and more the daily basis when designing in the clinical field. However, there is still a long way to go as the culture of the healthcare is hard to change. But we think that to be able to create usable systems in the healthcare we need to incorporate UCD when designing, in the clinical field, in some way as this user focus has been shown to improve on the problems that currently are present in the clinical field.

3.3 Validity threats

3.3.1 Researcher bias

Comments on the articles included in the study that have been assembled in the data extraction table might have been affected by individual judgment limitations as well as other related researcher biases such as authoring and adjustment [43]. In order to try and reduce this threat, the thesis has been submitted for review to the researchers' supervisor that has extensive experience in working with and assessing literature reviews and their validity.

3.3.2 Publication bias

The chances of research being published on failed projects are known to be smaller [30]. Therefore, we could assume that some interesting cases where either UCD has not given expected results or where the approach being combined with other factors has led to systems not performing as they should have, have not been reported.

4

Survey design

To further explore the area, and what the practitioners think about the benefits and challenges, a survey was conducted. This survey was conducted to give the possibility to compare what was found in the literature with what actual practitioners think and to get their experiences. These experiences are often left out by the researchers in their papers and the survey was therefore necessary for the extraction of this type of data. The survey was performed by doing interviews with researchers and medical application designers that had the experience necessary in designing of applications and systems for the clinical field with the use of UCD.

The benefits of conducting a survey after performing the literature review is that there might be some new questions appearing when the literature review has been performed. And also, the personal experience that the designers and researchers has during their study, are often left out when presenting their results. This was a crucial part of the study as it allows for more information around the topic of benefits and challenges as these areas are often only mentioned briefly or not at all in the papers. The survey and how it was performed will be described further in the next section.

4.1 Interview guide design

To perform the interviews in an structure way, an interview guide was created to accommodate questions that were useful to answer the research questions. The guide was created after the review of the literature had been performed, as the review provided the knowledge needed to create a good interview guide for the purpose of this thesis. The aim of the interview guide is to guide the interviewer when trying to find information to answer the second and third research question and also confirm the information gathered so far from the literature review concerning especially research question number one. The basic structure of the guide were five topics that covered different areas around the interviewee and his/her experience with UCD and designing in the medical field. The topics were as follows:

- Identity & respondent role
- Usability expertise
- Clinical application history
- Design process
- Benefits & challenges

These topics focused on different aspects of the interviewee and his/her experience in UCD as these were the crucial areas for the information that were to be gathered. The way the interview was planned to be conducted was to be an open-ended interview as we wanted the interviewees to elaborate on their answers. It started of with some general information about the interviewee and then moved on to see what kind of experience the interviewee had from designing clinical systems with the use of UCD. The reason for performing an interview instead of a questionnaire is that an interview allows for the interviewee to be more elaborate and to express their feelings and experiences better. The resulting interview guide can be found in Appendix B.

4.2 Interview logistics

The interviews were performed with experts in medical informatics. These experts were extracted from research papers as well as personal knowledge of our examiner and supervisor. They came from both the research field as well as the industry. The experts were people with experience from designing clinically useful systems in the medical field. After the list of experts was created, the experts were contacted through an email presenting the thesis and the reasons why their input would be valuable and interviews were booked. These interviews were mostly performed face to face, but in some cases they were performed through Skype[1], a video and phone conference program, due to the experts living in a distant city.

4.3 Survey Piloting

After the initial literature review had been performed, some questions were raised as the answer for them could not be found in the articles read. Therefore, it was necessary to perform the survey to be able to answer these questions. The questions raised were focused on what experience in UCD the researchers had. And also about problems and experience they had encountered during their project. To be able to answer these questions interviews had to be performed with researchers and designers. The interview

[1] *www.skype.com*

guide was designed in such a way that it covered all the areas of interest but it was a open-ended interview guide as the need for elaborate personal answers by the interviewees were strong.

5

Survey results and analysis

In this section the results from the interviews will be presented along with a presentation of the amount of experts interviewed and their background. The section will then describe the results that are relevant for the research questions stated earlier in this thesis. These findings will also be discussed in the end of the section.

5.1 Number of respondents

There were a number of different experts that were approached with the intention of performing an interview. However, it was hard to get in contact with many researchers during this study. The main reason behind this is that the interview part of the study was performed during the summer holidays and a number of respondent were unable to schedule in an interview. During this study there were seven interviews performed with different experts in the field. There was an interest in getting information from experts with experience in both the research field as well as the industry. The reason behind wanting this spread is a need to check the validity of the literature review results from both perspectives.

As can be seen in Fig. 5.1, 71% of the interviewees belonged to the research field, while 29% to the industry. However, most respondents have been exposed to both environments and have often collaborated on projects that extended to both areas.

5.2 Clinical applications history

As mentioned in the previous chapter, after having introduced the subject of the thesis to the interviewee and established the interviewee's background, a discussion on their history in researching and/or developing/designing clinical applications was held.

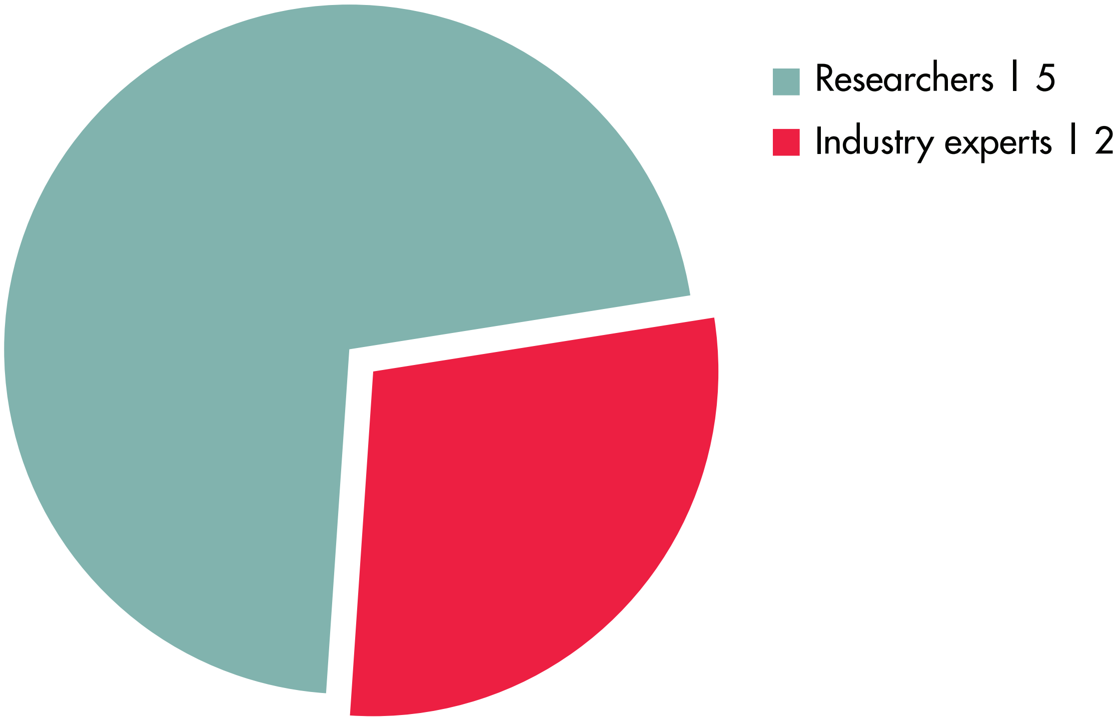

Figure 5.1: Interviewees background

The majority of the respondents have backgrounds in Computer Science and have turned their attention to the medical field at a certain point in their career either as a fertile ground for investigating the use of novel technologies or due to an intersection of their interests and an interesting project. Interviewees have been involved in various clinical systems either as researchers, developers or designers. Systems they have worked on vary from knowledge respresentation systems that allow for a learning process from previous patient cases, for example, to mobile emergency management systems used in post-crash situations in order to facilitate the work of paramedics at a car accident site. Combined, these experts have brought to the discussion decades of working within the medical information systems field.

5.3 UCD expertise

With the exception of one, none of the other interviewees had any formal training in performing usability tests or using a UCD approach. The interviewee that had been trained, had received a Master's degree in Interaction Design. The rest of the interviewees have reported learning through practicing. When asked whether there are people with formal usability or interaction design/human-computer interaction training present throughout their usual project development teams, opinions have been split to 42%(respondents) answering yes and the rest of 58%(4 respondents) answering no. The ones that answered ”no” have mentioned as a reason the fact that just recently development teams have become aware of the need for someone with this expertise. Until now, a big part of applying UCD stem mostly from ”common sense” in design. Another reason that was given towards this was the lack of interest in undergoing medical projects of people with the relevant background.

One oddity that arose in the discussion was related to the fact that although there were people formally trained present in the development team, most of the steps in the design and testing phases were attributed to ”years of having done it that way” and not to those people following a certain methodology.

5.4 Identified usable methods

This section recollects methods elicited from the interviewees as having been employed successfully when designing and their experiences in working with them.

All of the interviewees mentioned that during the user study and requirements phase they all had performed different types of interviews, either formal interviews or a simple meeting with the customer. They often used these methods as a first step in trying to elicit what the user or customer wanted from the system. Using these types of methods early in the process is a good way of trying to involve the user. A method that was used during the requirements gathering phase was *task analysis* [16]. When you are using this method you try to understand what tasks the users perform and how your system should be designed to accommodate these requirements. Reported as a useful method, this was one that also proved to be very challenging due to the high-complexity of the tasks involved by clinical applications.

Another way that some of the interviewees tried to involve the users was through *observations* [44] coupled with *think-aloud* [44]. This allows you to see how the user actually uses his/her current system and the users thoughts during the time they work with it. This approach to observations coupled with think-aloud is also useful when you are testing your prototypes or the finished system. Another quite common method that was mentioned was the think-aloud one. Throughout this method the designer asks the user to walk him through his tasks. The use of observations and think-aloud can take the form of a method called master-apprentice, this means that the designer becomes an apprentice to the user, the master, and listens when he/she is trying to teach how the system works. The think-aloud and master-apprentice methods are quite similar and useful during requirements gathering as well as testing. Another common approach to the phase of requirements gathering was to put together focus groups. These groups involve end-users discussing the possible requirements of the future system. This is somewhat similar to performing interviews, but it takes place in group while the designer becomes the observer and tries to moderate as less as possible the discussion. Using this method has both its benefits and drawbacks. The benefit is that one spends less time performing this type of requirements gathering, but there is also the possibility that you will extract less information than having performed a number of single interviews. So in the end, as most interviewees have mentioned, it is a judgement call by the designers which one of these methods should be applied.

When this initial user study and requirements gathering has been performed, the next step reported was to take these requirements and develop in accordance with them. All interviewees have agreed on the importance of using prototypes in portraying a concept to the end-users as it might be hard to grasp a simple descriptive text. All interviewees mentioned prototyping as a very useful method, and well worth the time spent on it. During the use of prototypes and testing them on users they often got feedback on the system as it was very easy for the users to understand the thoughts behind the design and how the finite system would look and work. The prototyping and getting feedback from users were mentioned to be performed iteratively, as you produced a prototype, tested it on users and got feedback and then redid the prototype and tested it again. This step should be performed until both designers and users are happy with the resulting prototype.

The interviews revealed a lack of thorough testing of the developed systems. On both sides, the industry interviewees and the researchers mentioned there is very little time spent on this part. The practice is rather to implement the systems as soons as an acceptable product has been achieved and hope everything works out. At this point most of the interviewees have said to have used only a standard usability test and do one interation of it before launching the product.

During these interviews there was a clear difference between how the researchers underwent their development process compared to how the industry experts performed theirs. The researchers often used clear methods throughout their process, compared to the industry designers which relied more on previous experience. The industry experts mentioned that it was hard to perform the ”best” practice out in the industry and therefore they often had their own way of performing their process.

5.5 Identified challenges

In this section we will present the challenges that were found throughout the interviews that were performed.

As mentioned earlier in the report, the purpose of these interviews is to try and validate the findings of the literature review and answer the last two RQs. An important aspect of the interviews was also to cover undocumented ground such as personal experiences in working with UCD.

After having performed the interviews, two lines of discussion could be observed: one that had to do with the user-related challenges and another with the design-related ones.

a) User-related challenges

When asked how they see user participation in a project, most of the interviewees answered that they find the most important thing to be making sure all categories of users are taken into consideration. Attention should be paid as well to how the different groups use the system and the tasks they require from it. A problem that one of the interviewees reported in this case was dealing with the difference in knowledge each user group possessed either related to discussing technologies in general or to the system that was being designed in particular.

A second issue that became apparent throughout these discussions was that of engaging users in the design process to begin with. There was a connection that became clear when discussing the level of commitment the different user groups showed towards the project and that was the relation between the extent to which they used the future system and their will to partipate in design decisions. In one project, nurses and secretaries who were going to use extensively an EHR system were more eager to give their input and feedback on interface and content design compared to clinicians who were only going to use the system occasionally and who did not find it compelling to participate all the time.

Another significant difference in engaging users was between the older and younger user groups. Younger users seem to better understand the underlying technology and be willing to get involved in making design decisions, while elderly groups expressed interest only in the features and scope of the systems developed, not the technologies behind them.

When discussing different user groups, the interviewees all mentioned that it is predominantly easier to get nurses and secretaries involved in a project, than it is to get doctors. One of the reasons this seems to happen is because doctors have trouble scheduling in time for this kind of activities.

A major issue that was met throughout their practice by most respondents was the difficulty in communicating certain system behaviour to the clinicians, due to their lack of knowledge in the field of Information Technology (IT). It is important to mention here that this has also been stated as a problem when users need to express their requirements of the system in terms of interface and navigation. As reported by the interviewees, it is a common situation that in which users refer to existing systems when expressing their needs from a system.

On a last note, one of the interviewees mentioned an interesting fact which is that sometimes if a clinician is the main stakeholder in a project, problems with his wanting to be the sole user involved in the design can arise. The interviewee thought this is because at times the outcome of a project can be uncertain and people are afraid of negative exposure.

b) Design-related challenges

A main challenge that all the interviwees seem to have met in the beginning of their involvement with the medical projects is having a hard time observing and gathering requirements due to the complex clinical environment. Along the same lines, in some cases, the data involved (patient records, treatments, etc.) was extremely sensitive and therefore was restricted.

A second challenge in designing for the medical field seems to be the budgeting of IT development projects, which according to most of the interviewees, both on the industry and the research sides, lacks an even distribution over the course of a project, being very scarse in the end. This lack of resources towards the end of a project causes many development teams to "drop" a system and unless there is specific feedback coming back from the users on its misbehaviour, they do not follow-up on them. This situation is fixed if there is a specific need for reporting on the success of the implementation, which happens at times in research where in order to receive new funding it is important to present concrete results. "We need to start focusing more on the process and not on the finished product" says one of our industry interviewees concernign developers usually rushing towards something tangible that can be implemented as opposed to placing more importance on the decisions that led to it.

Another interesting point raised by one of our interviewed researchers is that not only is there a lack of post-evaluations in implementing systems, but more importantly if a system fails there is no learning structure in place to be able to learn in the future from past mistakes. He mentions this as being an important step in developing good systems and he finds the need for change things in this direction.

One last challenge pointed out by one of researchers was the difficulty in getting healthcare institutions to fund IT research in the medical field. When asked why he thinks this happens he answered that it is probably due to the fundamental differences in the two research processes behind the two fields. In IT, in order to fuel novel ideas, there is often a need for investigative research that might or might not lead to concrete results, but is nonetheless very valuable, while in the medical field all research either works or does not.

5.6 Identified benefits

At all ends of the interviews performed there has been a consensus that it is with the help of UCD principles that they develop relevant systems, systems that make sense and cover the user's needs. Other benefits that have been mentioned have been those of saving on training and maintenance costs once a system is in place due to having had users from an institution involved in the process all along the way.

5.7 Discussion

The interviews revealed a lot of new information about the experiences and how projects were carried out in the industry. Though there were problems with getting experts to accept interviews, we felt that it was a new experience that gave us insight on how working with UCD in the medical field really is. Even though we wished we could have performed more interviews, we quickly found out that the interviewees produced mostly the same result. After the first few initial interviews, the later interviewees mostly confirmed the information we had been getting. This might be because the interviewees actually performed their processes in quite a similar way and therefore agreed on most of the key concepts. During the interviews with researchers and industry experts we saw that the answers differed from researchers and experts from the industry, we would therefore have liked to have a more even distribution on the area the experts were from along with a greater number of interviewees. As it is hard to draw certain conclusions based on quite a low number of interviews.

6

Conclusions

This final chapter summarized the answers to the research questions, mentions guidelines that could be followed and points to possible future research work that this thesis encourages.

6.1 Answers to the research questions

As has been presented in the first chapter of this thesis, there have been three research questions that the researchers have been looking to answer throughout their study:

- (RQ1) What is the state of the art in applying UCD methods to the medical field?
- (RQ2) What are the methods that ensure creation of usable clinical systems?
- (RQ3) What are the challenges in applying UCD in a clinical context and how to tackle these challenges?

6.1.1 Answer to RQ1

As we have seen through the results of the literature review presented in the third chapter, there is a gradual change from traditional software development processes towards UCD based ones. Although the researchers feel it is in its incipient phase and there is still a lot of focus on the technical development rather than on the user interaction with a system, there is an obvious progress in the way medical projects are being undergone. There is a noticeable lack of formal knowledge of UCD in the field of medical applications and this came forth in the papers reporting on their development. These reflect very little on the methodology and they fail at times to use established naming of the methods that they are using.

At a method level, the field of clinical applications limits itself to using some of the basic methods of the UCD approach such as think-aloud, interviews, usability testing. These methods are usually applied on top of classic software development practices. The most commonly used UCD methods are user observations and task analysis throughout the first phase of a project, that of user studies. For gathering requirements most papers report on focus groups, interviews, think-aloud and scenarios as being used. Prototyping is reported as a method and a step in itself without further mention to its level of fidelity and other types of it. Throughout the final step of testing the most common one is usability testing as well as interviews.

There is a lack of post-implementation reporting throughout the papers which leads to questioning whether this is simply not documented or not performed at all. Also, the lack of more primary studies that discuss UCD in the medical field leads the researchers to believe that although this is becoming an established design philosophy, it is still not being documented as such by researchers.

6.1.2 Answer to RQ2

In order to answer this question the researchers have taken some of the assumptions fueled by the literature review and investigated them further through interviews with members of the research field and of the clinical applications industry. The literature review has shown that a basic number of UCD methods are capable of turning a system into a more usable one in the end. These methods have been user observations, task analysis, focus groups, interviews, think-aloud, scenarios, prototyping, usability testing and heuristic evaluations. Further on, these have been discussed with the interviewees who have agreed that employing these methods as part of one's development process helps in creating more relevant systems capable of addressing users' needs in an easy to learn and use way. On the process that embodies these methods, the interviewees have also agreed with the literature review results in that it has to be an iterative one, that goes back on its steps and redoes them till a consensus is met from both the designers and users.

6.1.3 Answer to RQ3

The answer to this question lies again partly with the literature review results as well as in the interviews performed. One concern that any development team has to be aware of is the complexity of the tasks involved in the medical field and the difficulty in observing some of the clinicians perform their work. The challenges addressed both by the literature review and the interviews have been covering two branches in the form of user-related challenges and design-related ones. On the first subject the literature suggested that finding users knowledgeable enough to participate in the project development team. This was confirmed by the interviews. Another significant challenge was to involve all user groups in the design process in order to make sure all the requirements of the future system are accounted for. Being easier to engage nurses and secretaries than doctors was another challenge reported throughout the interviews. To tackling these challenges the solution seemed only to plan ahead and try to account for having to pay perhaps for the users' time in order for them to be involved in the process. Having users reference certain mediating objects such as existing systems has made it easier for them to express themselves when discussing a system's interface and navigation.

Moving further to design-related challenges met when developing for the medical field, these spanned from the beginning phases of a project until the end of it. The interviews performed have revealed problems in observing certain medical practices due to the sensitive data and to the complexity of the tasks. A challenge has also been the lack of post-implementation review of the projects. Although some systems fail even before being implemented and are dropped by the developers, there is no system in place that would allow for documenting the reasons behind these failures in order to help avoid them in the future. For these difficulties not to be met when applying UCD in the medical field, researchers and industry experts should try to make the practice of UCD a household commodity and introduce it at every level of the design process.

6.2 UCD guidelines

In this section, a generic development process using a UCD approach shall be outlined in order to make it easier for future designers and developers of medical applications to apply it.

6.2.1 Design process

There is no specific design process that is the best for every system being designed, instead each situation requires adapting to. There is a plethora of literature that points to user-centered design in general so in order to avoid redundancy, the researchers will refrain from restating everything. However, we will point here to the process suggested by the ISO 13407 that specifies the key human-centered activities that need to be performed when designing systems. As can be seen in Fig.1.1 there are five steps that are useful to have as a foundation when you are designing: *planning*, *specifying the context of use*, *gathering requirements*, *designing* and *evaluating*. Next we will briefly present methods that can be applied as part of each of these steps in order to achieve more usable medical devices. For a complete overview of this process along with more methods that support it as well as a detailed view of each of them, please refer to Maguire's research [10].

6.2.1.1 Planning the design process

Throughout this phase, the usability efforts needed by the project are planned and distributed over time and affected stakeholders and users. Two important activities present at this time are the *usability planning and scoping* and the *usability cost-benefit analysis*. The first one requires mapping the stakeholders' vision to the usability efforts [10]. The usability cost-benefit analysis is performed in order to assess the financial benefits of applying a human-centered approach throughout the project [10]. Since there is a prevalent opinion that UCD efforts could be quite costly, performing this method becomes an important step in convincing stakeholders to adopt the design process or not [10, 45].

6.2.1.2 Specifying the context of use

Throughout this phase, field work studies are performed using ethnographic techniques such as observations and probing. This phase of the design process ensures an understanding of the environment the application will be used in as well as the nature of its users, their tasks and conditions of working; this is often referred to as the context of the system. At this point already, the designers of the application can put together a list of requirements to take into the next step of the design process. The technical, physical and social/organizational conditions under which the future developed system will be used, are defined in this phase. For medical device interfaces in particular, understanding the context of use plays a crucial role since the conditions could mean a very fast-paced environment, high user workload and short response times. Although generally, context analysis through a stakeholder meeting could fulfill this method, since a medical device is a more complex system, further methods such as user observations and task analysis are recommended [10]. Next, the mentioned methods will be briefly presented.

Identifying stakeholders The people affected by the future system, both direct users as well as indirect ones, are considered stakeholders in the project [10, 46]. In the case of a medical software interface this could mean the clinical facility's IT department as well as its board of directors and not mention the direct users which would be the medical staff.

Context of use analysis After having identified them, a stakeholder meeting follows in order to analyze the context of use. This a rather straightforward mediated meeting in which the stakeholders fill in a questionnaire regarding the characteristics of the users, their environment and the tasks they will perform using the system [10, 47]. A complete walkthrough of the method can be found in Thomas and Bevan's practical guide [48].

User observations/field studies This method in particular can take many forms depending on the scale of the project. On a general note, it requires the designer to get immersed in the users' environment and study up close the tasks they perform. This could be done through a number of techniques ranging from contextual inquiry, on-site interviews to apprenticeship (a technique which requires the designer acting as a student and the user as the teacher) [44]. In the case of medical devices, close observations of the users are of vital importance as they can help convey information such as response time, distractions, interruptions as well as other systems' attention demand [44].

Task analysis As an applied method, task analysis identifies more precisely parameters of certain tasks performed by users. These parameters include but are not limited to users' overall goals, steps taken, time needed, communication exchange with other users, problems encountered, annoyances. It is important for the analysis to convey in the end not only the physical aspects of performing the task, but also the cognitive ones: the knowledge and train of thought of the users [44]. This method can be performed through many techniques such as: interviews, field studies [44], as well as procedural analysis, job analysis, workflow analysis, and error analysis [46]. A complete overview of task analysis techniques can be found in Crystal and Ellington's paper [49].

6.2.1.3 Gathering requirements

Perhaps the defining phase of a project's success is gathering requirements [10]. As mentioned in the ISO 13407 [15], the following user and organizational elements should be assessed when eliciting requirements: clearly stated design goals, range of users, requirements prioritization, statutory and legal requirements, change management of future occurring requirements. Requirements gathering defines the main functions of the future system. The designers or usability experts meet with the future users of the system and through the use of various methods they gather the needed requirements. A lot of work is put into interpreting the information elicited from the users, as a big part of this does not regard a certain requirement but rather the aspects of the task the user uses the system for. Although there are a number of methods that can be employed as part of this phase, we shall mention here two which we consider very important as they cover a big part of the user requirements for the future system. A more detailed list of the methods can be found in Maguire's paper [10].

User requirements interviews The designer meets with individual users of the future system and performs semi-structured interviews in which requirements of the system are discussed. The interview being semi-structured, there is room for capturing more detailed views from the participants [10, 46]. If a more collective view is needed from the participants then a *focus group* is a more appropriate method in this case.

Scenarios of use Based on the information gathered in the context of use analysis, the designers can create a list of the most important tasks within the new system. To each of the tasks, a use scenario (very similar to a use case) is built in order to better understand the user requirements. The scenarios produced throughout this method can be further used in the usability testing [10, 16, 46].

6.2.1.4 Designing

The design phase starts with brainstorming based on the elicited requirements. The development team implements a first version, a prototype of the system. In a user-centered process, this phase followed by the next one, the usability testing/evaluation against requirements phase, are repeated a number of times until the system design reaches a fully functional state [10]. Throughout this phase there are a number of methods that designers apply in order to go from the ideation step all the way to a fully polished design. We will next present a couple of methods that are very common to use in this phase and which should be considered a foundation to build upon.

Brainstorming At the beginning of the design phase there is an ideation step in which the project team generates possible ideas for solutions. This can be done through number of methods, the most common being brainstorming. It is important to keep an open mind when brainstorming in order to be able to accept new ideas on the future system. When this method is performed, the members of the development team meet and share ideas based on the requirements elicited from the users in the previous phase [10, 16]. They generate many ideas of which in the end just the most plausible ones remain. These are further discussed and put through other methods in order to have just one that is followed in the future development of the system.

Card sorting As a method applied in the designing phase, card sorting is a way "to understand how users organize information and concepts" [16]. For a medical application, users could be given cards with the functions of the future system and asked to group them under categories and sub-categories where needed. This usually leads to a common pattern emerging in the groupings of many users, which designers then use as an organizational map for the future application [10, 16, 44].

Software prototyping After the ideation step, a prototyping step follows which has the role of generating a set of primitive interfaces of the new system. These will be taken further into the evaluation phase and re-iterated until the prototype reaches a high-fidelity level. Given this passes the evaluation phase successfully, it is further taken into development. Software prototyping implies a set of computer aided interactive visualizations of the future system [10]. The behaviour of the future system is simulated as close as possible in order to allow for testing with users. Cooper points out a series of important principles in the interaction and visual design of application interfaces, of which we mention: providing clear hierarchy, providing visual structure and flow, using consistent imagery, avoiding visual clutter [16].

6.2.1.5 Evaluating

Perhaps the most critical phase of the UCD design process, the testing phase has been somewhat underestimated in the medical application field. Applications are often released without thorough testing and upon implementation and use by clinicians they fail. As previously mentioned, a recurring practice has been that of training users in using bad systems rather than putting more work into the testing phase of the design process and making sure they are usable and easy to learn. At this point in the system development lifecycle, it is important to check the design against the elicited requirements, against the initial objectives of the project and identify opportunities for improvement. Several methods are appropriate for use in this stage of the design process. Some of those are usability tests, cognitive walkthroughs, expert walkthroughs, heuristic evaluations, think-aloud tests. The methods presented next are again to be taken as a minimum in a user-centered design process as they are critical to ensuring the creation of a usable system.

Participatory evaluation A common approach to usability testing has been the participatory evaluation, which can take the form of a one-on-one meeting with a user, or a multiple users workshop, and finally of a walkthrough [10]. In the first two instances of this evaluation the user is asked to perform various tasks using a prototype of the system and the usability expert, playing the role of the observer, records the way he chooses to do this. At times the observer can ask questions in order to get the user's opinion on certain features of the system or to better understand the user's train of thought [16]. In the last instance, the case of an evaluation walkthrough, the users along with the usability experts are going through the system design and identifying concerns [10].

Heuristic evaluation When the usability experts themselves perform the evaluation of the system, it is called a heuristic or an expert evaluation [10, 46]. A number of experts sit down and walk through the system and discuss and identify features that need improvement. A detailed description and guide to performing heuristic evaluations can be found in Wilson et al.'s book on user experience [46].

6.2.2 Design principles

After having presented the guidelines for the user-centered design process that a medical application developer should follow in order to ensure it is usable, easy to adopt by the future users and with as few errors as possible, we would like to conclude with an enumeration of design principles to be applied. The principles have been extracted from several sources, the prominent ones being Nielsen [19] and Cooper [16]. This can be regarded as a checklist for developers of medical systems.

Identify the users of the application The developed system should support both novice and expert users [19]. As an example, although testing with users that have been exposed to similar systems can indicate a usable application, a newly hired person might find it hard to learn.

Make things visible The application should communicate clearly to the user what is its purpose. Any available modes that exist on the system, such as basic or advanced for examples should be made visible and the user should be able to change this to a desired state. The user should be aware of each of the available functions and at a certain point in navigating the interface. If there is a clear process of reporting or transmitting information, the steps should be stated clearly as well as the user's position in the process. The user should always be informed of the possible results of his actions [12, 16, 19, 23].

Provide good mapping The relation between an action and its result should be constantly clear to the user. The mapping functions and their outcome can be either natural or artificial, meaning it is either intuitive or it has to be learned [12, 23]. Highly recognizable mappings become conventional mapping, such as turning a knob to increase/decrease a function.

Create appropriate constraints The options that a user has at a certain position in the interface are important in his navigation process. The designers should constrain his navigational possibilities in order to help the user easily reach his goals [12, 23].

Design for error This is one of the most important principles when it comes to medical applications since an error could have disastrous consequences. Along with the general recommendation of displaying informative messages when an error occurs in the system [16, 19, 23], Weinger suggests that in the case of medical devices the designers should consider forcing functions that limit undesirable actions [12]. This could be done through checking already inputted parameters and having predefined undesired scenarios in mind when designing the application.

Minimize memory load Information about the steps needed in order to achieve a task should be presented clearly to the user. It is suggested to aim for *knowledge in the world* rather than *knowledge in the head* [19, 23].

Provide help and documentation Since most of the medical tasks performed are standardized and described in detail in documentation it helps to give the user easy access to their location through the interface in case he needs it [14].

Design well-behaved systems Cooper states: "If we want users to like our products, we should design them to behave in the same manner as a likeable person. If we want users to be productive with our software, we should design it to behave like a supportive human colleague. To this end, it's useful to consider the appropriate working relationship between human beings and computers" [16]. According to him, there are two big qualities that a system should embody in order to make their relationship to humans work: *considerate* and *smart*. Considerate means they should take an interest, be forthcoming, use common sense, anticipate people's needs, keep you informed, don't ask a lot of questions and know when to bend the rules [16]. Smart translates to being efficient, have a good memory and be coherent [16].

Less is more The principle of shortest path should be applied when designing the interface navigation. The screens should be uncluttered but informative at the same time [16]. Striving for simple, yet powerful designs that encourage people to use them and assist them in their daily tasks.

6.3 Thesis limitations

In regard to the literature review limitations, there have been papers that had to be disconsidered due to inaccessibility issues. This perhaps has given us a limited view of the field of medical informatics and its application of UCD. Due to the scheduling of the thesis work and failing to foresee certain difficulties in getting access to interviewees throughout the summer period, we had to limit the number of interviews. This is one thing that we would have liked to go more in depth with since each of the interviews have been an extraordinary learning opportunity for us as new designers going into the field.

6.4 Future work

Through the literature review a number of ideas that deserve more looking into have come up. A first would be the lack of voices among the researchers that have had formal training in usability and in applying UCD principles. A second would definitely be that of other industries that are as high-complex in tasks as the medical one, have successfully implemented UCD in their development processes for years now. This has been the case of the aviation one as it seems. A study into why this has happened there and not in the medical one would be extremely interesting to pursue.

During the interviews a number of interesting possible future investigations have come to mind. A first would be the lack of post-evaluation in implementing medical systems and the connection this might have with a certain budgeting model projects like these benefit from. Investigating further the differences between industry driven projects and research fueled ones seems also an exciting pursuit.

Bibliography

[1] P. Edwards, K. Moloney, J. Jacko, F. Sainfort, Evaluating usability of a commercial electronic health record: A case study, International Journal of Human-Computer Studies 66 (10) (2008) 718–728.

[2] B. Kaplan, Evaluating informatics applications–clinical decision support systems literature review., International journal of medical informatics 64 (1) (2001) 15–37.

[3] C. M. Johnson, T. Johnson, J. Zhang, Increasing productivity and reducing errors through usability analysis: a case study and recommendations., Proceedings / AMIA Annual Symposium. AMIA Symposium (2000) 394–8.

[4] J. Zhang, V. Patel, K. Johnson, J. Smith, Designing human-centered distributed information systems, Intelligent Systems, IEEE 17 (5) (2002) 42–47.

[5] J. Zhang, Human-centered computing in health information systems. Part 1: analysis and design., Journal of biomedical informatics 38 (1) (2005) 1–3.

[6] a. Narasimhadevara, T. Radhakrishnan, B. Leung, R. Jayakumar, On designing a usable interactive system to support transplant nursing., Journal of biomedical informatics 41 (1) (2008) 137–51.

[7] S. Kujala, User involvement: a review of the benefits and challenges, Behaviour & Information Technology.

[8] S. Koch, Designing Clinically Useful Systems: Examples from Medicine and Dentistry, Advances in Dental Research 17 (1) (2003) 65–68.

[9] J. Wong, J. Hohenadel, C. Rizo, A. Jadad, Development of the Internet Clinical Communication Centre: a Patient Centered Application for Prostate Cancer Follow-up, in: Human Factors and Ergonomics Society Annual Meeting Proceedings, Human Factors and Ergonomics Society, 2005, pp. 1094–1098.

[10] M. Maguire, Methods to support human-centred design, International Journal of Human-Computer Studies 55 (4) (2001) 587–634.

[11] L. Teixeira, C. Ferreira, B. S. Santos, User-centered requirements engineering in health information systems: A study in the hemophilia field., Computer methods and programs in biomedicine (2010) 1–15.

[12] M. Weinger, User-Centered Design: A Clinician's Perspective MDDI, Psychology (2000) 1–7.

[13] T. Alden, User-Centered Design and the Medical Device Start-Up, Medical Device and Diagnostic Industry 29 (Issue 9) (2011) 42–46.

[14] S. Barrington, Usability in the Lab: Techniques for Creating Usable Products, Journal of the Association for Laboratory Automation 12 (1) (2007) 6–11.

[15] ISO 13407:1999, Human-centred design processes for interactive systems, Tech. rep., International Standards Organization.

[16] A. Cooper, R. Reimann, D. Cronin, About face 3: the essentials of interaction design, Safari Books Online, Wiley Pub., 2007.

[17] H. Kashfi, Applying a user centered design methodology in a clinical context., Studies In Health Technology And Informatics 160 (Pt 2) (2010) 927–931.

[18] K. Fleischmann, Do-it-yourself information technology: Role hybridization and the design–use interface, for Information Science and Technology 57 (October 2005) (2006) 87–95.

[19] J. Nielsen, R. Mack, Usability inspection methods, Wiley, 1994.

[20] N. Tejani, T. R. Dresselhaus, M. B. Weinger, Development of a hand-held computer platform for real-time behavioral assessment of physicians and nurses., Journal of biomedical informatics 43 (1) (2010) 75–80.

[21] M. M. Searl, L. Borgi, Z. Chemali, It is time to talk about people: a human-centered healthcare system., Health research policy and systems / BioMed Central 8 (1) (2010) 35.

[22] M. Wiklund, Medical Devices That Talk, Designing usability into medical products (2005) 215.

[23] D. Norman, The psychology of everyday things, Basic Books, 1988.

[24] B. Oates, Researching information systems and computing, SAGE, 2006.

[25] P. Cronin, F. Ryan, M. Coughlan, Undertaking a literature review: a step-by-step approach, British Journal of Nursing 17 (1) (2008) 38–43.

[26] P. Brereton, Performing systematic literature reviews in software engineering, icse (2006) 1051.

[27] J. Mauch, N. Park, Guide to the successful thesis and dissertation: a handbook for students and faculty, Books in library and information science, M. Dekker, 2003.

[28] B. Kitchenham, Procedures for performing systematic reviews, Keele, UK, Keele University 33.

[29] P. Hemingway, N. Brereton, What is a systematic review? (2nd ed), What is...? series [online].

[30] B. Kitchenham, S. Charters, Guidelines for performing systematic literature reviews in software engineering, Engineering 2 (EBSE 2007-001).

[31] H. Aveyard, Doing a literature review in health and social care: a practical guide, Open University Press, 2007.

[32] C. Carroll, P. Marsden, P. Soden, E. Naylor, J. New, T. Dornan, Involving users in the design and usability evaluation of a clinical decision support system., Computer methods and programs in biomedicine 69 (2) (2002) 123–35.

[33] G. Konstantinidis, G. C. Anastassopoulos, A. S. Karakos, E. Anagnostou, V. Danielides, A User-Centered, Object-Oriented Methodology for Developing Health Information Systems: A Clinical Information System (CIS) Example., Journal of medical systems.

[34] L. S. Ehrhart, C. W. Hanson, B. E. Marshall, C. Marshall, C. Medsker, Collaborative prototyping approaches for ICU decision aid design., Proceedings / AMIA Annual Symposium. AMIA Symposium (1999) 750–4.

[35] H. L. Borges, A. Malucelli, E. C. Paraiso, C. C. Moro, A physiotherapy EHR specification based on a user-centered approach in the context of public health., Annual Symposium proceedings / AMIA Symposium. AMIA Symposium (2007) 61–5.

[36] M. C. Kindsmüller, M. Haar, H. Schulz, M. Herczeg, Designing User Interfaces for Smart-Applications for Operating Rooms and Intensive Care Units, IFIP Lecture Notes in Computer Science (LNCS) 5727 (5727) (2011) 684–695.

[37] S. Koch, M. Hägglund, I. Scandurra, D. Moström, Towards a virtual health record for mobile home care of elderly citizens., Studies in health technology and informatics 107 (Pt 2) (2004) 960–3.

[38] W. Aigner, S. Miksch, CareVis: integrated visualization of computerized protocols and temporal patient data., Artificial intelligence in medicine 37 (3) (2006) 203–18.

[39] K. a. Thursky, M. Mahemoff, User-centered design techniques for a computerised antibiotic decision support system in an intensive care unit., International journal of medical informatics 76 (10) (2007) 760–8.

[40] Y. B. Salman, H.-i. Cheng, J. Y. Kim, P. E. Patterson, Medical Information System With Iconic User Interfaces, International Journal of Digital Content Technology and its Applications 4 (1) (2010) 137–148.

[41] C. M. Johnson, T. R. Johnson, J. Zhang, A user-centered framework for redesigning health care interfaces., Journal of biomedical informatics 38 (1) (2005) 75–87.

[42] L. Teixeira, V. Saavedra, C. Ferreira, The User's Role in the Development Process of a Clinical Information System: An Example in Hemophilia Care, Human Centered (2009) 922–931.

[43] T. X. Siau, K., Technical communication in information systems development: The use of cognitive mapping, IEEE Transactions on Professional Communication 48 (3) (2005) 269–284, cited By (since 1996) 18.

[44] C. Courage, K. Baxter, Understanding your users: a practical guide to user requirements : methods, tools, and techniques, Morgan Kaufmann series in interactive technologies, Morgan Kaufmann Publishers, 2005.

[45] M. Rajanen, Different Approaches to Usability Cost-Benefit Analysis, 2006, pp. 391–397.

[46] C. Wilson, User Experience Re-Mastered: Your Guide to Getting the Right Design, Morgan Kaufmann, Elsevier Science & Technology, 2009.

[47] U. B. of Knowledge, Context of use analysis.

[48] B. N. Thomas C., Usability context analysis: A practical guide. (1996) 1–96.

[49] A. Crystal, B. Ellington, Task analysis and human-computer interaction: approaches, techniques, and levels of analysis, in: Proceedings of the Tenth Americas Conference on Information Systems, New York, New York, 2004.

Appendix A – Data extraction table

Name	Authors	Year	Methods used	System details	Design process	Summary
CareVis: Integrated visualization of computerized protocols and temporal patient data	Aigner, Wolfgang Miksch, Silvia	2006	User study, prototyping, expert reviews, interviews, scenarios, questionnaires, design reviews,	CareVis at the General Hospital of Vienna.	User study, conceptual design, design evaluation, prototype implementation, prototype evaluation, empirical study. The process is focused around one common object, the user.	The paper presents the development of a new visualization approach to patient data.
A physiotherapy EHR Specification based on a user-centered approach in the context of public health	Borges, Heloisa L Malucelli, Andreia Paraiso, Emerson C Moro, Cláudia C	2007	Observation, prototyping, usability testing, requirement specification, scenarios, use cases,	EHR in public health, Brazil Curitiba, physiotherapists.	User centered methodology for electronic health record specification(UMEHRS) Five phases: Observation of activities - Observation Requirements specification - Scenarios, use cases Prototype development - Prototyping Usability tests - usability testing Object-oriented modeling	The article brings forth the creation of an EHR from requirements gathering to pre-implementation.
Involving users in the design and usability evaluation of a clinical decision support system.	Carroll, Carmen Marsden, Phil Soden, Pat Naylor, Emma New, John Dornan, Tim	2002	Usability testing, interviews, focus groups, think aloud, scenarios, cognitive walkthrough, observation	A CDSS to support cardiovascular risk prevention in type 2 diabetes	-	The design process, and the usability testing phase in particular, of a CDSS that supports cardiovascular risk prevention in type 2 diabetes are presented throughout this article.
Collaborative Prototyping Approaches for ICU Decision Aid Design	Ehrhart, LS Hanson, CW Marshall, BE Marshall, C Medsker, C	1999	Prototypes, Expert walkthroughs, observations, knowledge elicitations, interviews, focus groups, think-aloud, scenarios, storyboards	A clinical aid to assist respiratory care in the surgical ICU. At the Center for Anesthesia Research Center at the University of Pennsylvania.	Not mentioned	Development of an aid, called the VQ/PQ Assistant. The developers have used the Cognitive Software Engineering process in order to involve the users in the development process.
Iterative User-Centered Design of a Next Generation Patient Monitoring System for Emergency Medical Response	Gao, Tia Kim, M S Matthew I White, David Alm, Alexander M	2006	Interviews, prototypes, cognitive walkthroughs, round table, surveys, questionnaires,	An vital signs monitorer in the case of mass casualty incidents	An iterative process, they mention a bit on what they did in the initial iterations, but not that thoroughly	A system to handle response to mass casualty incidents. More specifically the triage of patients by their degree of severity.

Name	Authors	Year	Methods used	System details	Design process	Summary
Participatory user centered design techniques for a large scale ad-hoc health information system	Gao, Tia Massey, Tammara Sarrafzadeh, Majid Selavo, Leo Welsh, Matt	2007	Interviews, field studies, surveys, round-table discussions, questionnaires, scenarios, prototypes	The Advanced Health and Disaster Aid Network (AID-N)	An iterative design process	The authors present the iterative user-centered design process they undertook in creating a triage system that assists in mass casualty incidents.
Development and evaluation of nursing user interface screens using multiple methods.	Hyun, Sookyung Johnson, Stephen B Stetson, Peter D Bakken, Suzanne	2009	Technology Acceptance Model (TAM), Task-Technology Fit (TTF), structured interview, prototyping, scenarios, questionnaires, heuristic evaluation.	Structured Narrative Electronic Health Record. Where only created in a laboratory environment, and only end user tests were conducted.	Elicit requirements, designing the interface, evaluate the users perception of usability	The development of 3 nursing interface screens based on the Structured Narrative EHR. The authors combined theory-based models (Technology Acceptance Model TAM and Task Technology Fit TTF) and user-centered methods to explore nurses' requirements for an electronic documentation system.
Increasing productivity and reducing errors through usability analysis: a case study and recommendations.	Johnson, C M Johnson, T Zhang, J	2000	User analysis, task analysis, cognitive walkthrough	An approach to analyzing and redesigning healthcare software	-	This is a usability compliance test performed on an existing cancer history program. It showcases a plethora of problems that were found with a system that did not go through a UCD development.
A user-centered framework for redesigning health care interfaces.	Johnson, Constance M Johnson, Todd R Zhang, Jiajie	2005	Heuristic evaluation, questionnaires. They mention the different types of analyses, but not that many concrete methods	Redesigning an health care interface, along with presenting the framework and methods used during this work	Analysis of the original application: User analysis: Comparative analysis: Functional analysis: Representational analysis: Prototyping: Small-scale usability studies: Modifying the prototype:	A framework for redesigning health information systems demonstrated through a case study. The case study was a family-history-tracking and pedigree drawing program.
Designing User Interfaces for Smart-Applications for Operating Rooms and Intensive Care Units	Kindsmüller, M. Haar, Maral Schulz, Hannes Herczeg, Michael	2009	Observations, Interviews, mock-ups, prototypes, usability tests.	Two different applications, an Anaesthesia monitor display and a diagnosis display. Both are a kind of decision support system	Observations: Interviews: Prototyping: Usability testing:	Throughout this article, two Smart Applications are used as alternatives for traditional CDSSs and implementedand tested using a UCD approach.

Name	Authors	Year	Methods used	System details	Design process	Summary
Designing Clinically Useful Systems: Examples from Medicine and Dentistry	Koch, S.	2003	Master-apprentice, brainstorming, scenario-building, in-depth interviews,	Two different systems, IT support for chairside work in dentistry - this has been implemented and commercialized, is currently in use at the Catholic University of Portugal at Viseu. The other system, ICT Support for home health care of elderly citizens - this is currently in development.	Work analysis: Observation, master-apprentice User needs: Brainstorming, focus groups, interview Specification: Story boarding, rapid prototyping Design: user-centered interaction design Implementation: Test: Evaluation:	The paper argues for the use of HCI methods in order to create usable systems. Two successful case studies are presented to support their case.
Towards a virtual health record for mobile home care of elderly citizens.	Koch, Sabine Hägglund, Maria Scandurra, Isabella Moström, Dennis	2004	Observation, master-apprentice, brainstorming, scenarios, interviews, prototypes,	A virtual health record (VHR)	Work analysis: Context analysis, contextual inquiry, observation User needs: Master / apprentice, interview, interdisciplinary working groups. Specification: Storyboarding, use case modeling Design: Participatory design, rapid prototyping Implementation: Rapid prototype Test: cognitive walkthrough, heuristic evaluation, usability test Evaluation: surveys	
A User-Centered, Object-Oriented Methodoloy for Developing Health Information Systems: A Clinical Information System (CIS) Example	Konstantinidis, Georgios Anastassopoulos, George C Karakos, Alexandros S Anagnostou, Emmanouil Danielides, Vasileios	2010	Deep Hanging-Out,storyboards, prototypes, usability testing, heuristic evaluation.	ENTity (Ear Nose Throat) CIS (Clinical Information System) A patient filing application, records the admittance and release dates, diagnosis and health records. Nikaia General Hospital: one inpatient clinic, 2 outpatient ones Nikaia, Piraeus, Greece Jan 2009	Four phases: Inception, Elaboration, construction and Transition. Within each phase there were five workflows: Requirements, Analysis, Designing, Implementation, Test	A research paper documenting the user-centered design of a patient filing application through the use of various UCD methods.

Name	Authors	Year	Methods used	System details	Design process	Summary
On designing a usable interactive system to support transplant nursing.	Narasimhadevara, a Radhakrishnan, T Leung, B Jayakumar, R	2008	Observations, talk-aloud, interviews, participatory design, focus groups, ethnographic studies, scenarios	An interactive system for supporting the activities of transplant nurses	An combination of an agile development process and and UCD.	A detailed paper on designing a usable interactive system to support transplant nursing. The authors have interwined agile development with UCD.
Design and development of a mobile medical application for the management of chronic diseases: methods of improved data input for older people	Nischelwitzer, Alexander Pintoffl, Klaus Loss, Christina Holzinger, Andreas	2007	Card sorting, paper prototyping, think-aloud, interviews,	MyMobileDoc is an mobile application for monitoring diabetes.	Not mentioned	An overview of the design process behind a mobile application for monitoring diabetes.
Human-Centered Design in Medical Fields	Noriyoshi, A Nakano, N Tohyama, N	2009	Interviews, prototypes, competitor analysis, expert reviews, color analysis evaluation, task analysis, usability testing, user studies.	-	An iterative process containing three steps. Planning, Development and evaluation.	The paper describes the process behind developing an error-free EMR system by Fujitsu.
Using multi-perspective methodologies to study users' interactions with the prototype front end of a guideline-based decision support system for diabetic foot care.	Peleg, Mor Shachak, Aviv Wang, Dongwen Karnieli, Eddy	2009	Field observations, interviews, heuristic evaluation, prototyping, scenarios	A guideline-based decision support system.	Data collection: interviews, focus groups, observations, surveys Data analysis: content analysis Requirements prioritization: Defining and ranking potential high-level solutions: Developing a goal/task flow diagram:	An applied case of combining the waterfall development process with principles of UCD.
Medical Information System With Iconic User Interfaces	Salman, Yucel Batu Cheng, Hong-in Kim, Ji Young Patterson, Patrick E	2010	Heuristic evaluation, observations, interviews, scenarios, questionnaires, prototypes, think aloud	An medical information system for emergency service, at a Turkish hospital	Identify the users and usage context: Figure out functional requirements: Design the system from rough concepts: Analyze the system usability:	An emergency management medical information system is presented in this article as well as the UCD process behind it.
The User's Role in the Development Process of a Clinical Information System: An Example in Hemophilia Care	Teixeira, Leonor Saavedra, Vasco Ferreira, Carlos	2009	Observations, documentation analysis, focus groups, hierarchical task analysis, prototyping	A Web-based Information System for managing clinical information.	An iterative process using three distinct phases: 1: Exploratory phase- Observation, documentation analysis, focus groups 2: Project phase- Hierarchical task analysis, prototyping 3: Codification phase-	This article introduces a web-based Information System for managing clinical information.

Name	Authors	Year	Methods used	System details	Design process	Summary
User-centered requirements engineering in health information systems: A study in the hemophilia field.	Teixeira, Leonor Ferreira, Carlos Santos, Beatriz Sousa	2010	Grounded Theory, object-oriented system analysis, task analysis, prototyping, requirements triangulation matrix, ethnograpy, iterative design, observation, interviews, focus groups, use-case diagrams, scenarios, think aloud,	A Web-based information system for Hemophilia care.A Hematology service of a regional hospital in Portugal.	Iterative design process based on triangulation work. Three steps used in the iterative process: Object-oriented system analysis, Heuristic Task Analysis, Prototyping. also mentionds an agile development process, eXtreme Programming (XP).	The researchers have developed a web-based information system for hemophilia care through employing agile development processes and principles of UCD.
User-centered design techniques for a computerised antibiotic decision support system in an intensive care unit.	Thursky, Karin a Mahemoff, Michael	2007	Observations, interviews, participatory design, prototypes, case studies, think aloud	ADVISE, an antibiotic decision support system, at the Royal Melbourne Hospital.	Contextual design, uses five models: Flow model, artifact model, cultural model, physical model, sequence model.	A very good example of contextual design in the form of an antibiotic decision support system. The authors present a thororough walkthrough of their process and the methods they have employed.
Development of the Internet Clinical Communication Centre: a Patient Centered Application for Prostate Cancer Follow-up	Wong, Jennifer Hohenadel, Joanne Rizo, Carlos Jadad, Alejandro R	2005	Usability tests, semi-structured interviews, focus groups, systematic qualitative elicitations methods, heuristic evaluations, prototypings, questionnaires, expert focus groups.	An Internet Clinical Communication Centre (iC3) for follow-ups on patients that have gone through treatment for prostate cancer	Requirements: Focus groups Usability tests: Systematic qualitative elicitation methods Prototyping: Heuristic evaluations, paper prototypes, expert groups	An Internet Clinical Communication Centre (iC3) for follow-ups on patients that have gone through treatment for prostate cancer and the design process behind it.
VR Aided Motor Training for Post-Stroke Rehabilitation: System Design, Clinical Test, Methodology for Evaluation	Yeh, Shih-Ching Stewart, Jill McLaughlin, Margaret Parsons, Thomas Winstein, Carolee J. Rizzo, Albert	2007	Task analysis	An Virtual Reality aided motor training task	-	In the article they shortly present a task analysis as a support for a new way of training patients that are recovering from a stroke

Appendix B – Interview Guide

User-Centered Design in a Clinical Context: Challenges and Success

F. Andersson, R. Teodoru
Interaction Design, Chalmers University of Technology, Gothenburg, Sweden

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IDENTITY & RESPONDENT ROLE

Q1: Introduce ourselves and the interviewee.

Q2: Establish background and possible relation to our research.

CLINICAL APPLICATIONS HISTORY

Q3: Throughout your research/ work experience have you participated in developing any clinical applications?

Q4: If yes, what has been your role in the development process?

Q5: What type of medical applications were the one(s) developed? (Clinical Decision Support Systems, Electronic Health Records, etc.)

Q6: If you answered no to the 3rd question, could you tell us what other applications have you been working on?

UCD EXPERTISE

Q7: Are you familiar with UCD methods in software development?

Q8: What is your experience in working with User-Centered Design (UCD)?

Q9: Do you use a formal UCD approach? With 'use' we understand that one uses the main structure or principles of the method.

Q10: Describe in short what experiences you have with use of this/these methods.

Q11: Does your company collect information about the degree of success in completed IT projects?

DESIGN PROCESS

Q12: How does a "normal" design process look like? Certain steps?

Q13: Why has this been chosen? Is there anything you would like to change with the design process?

Q14: What UCD methods do you usually employ in your design process?

Q15: Could you elaborate a bit on your experiences with the use of certain UCD methods? Such as interviews, focus groups, usability testing?

Q16: Which are the most commonly used in your opinion?

Q17: Which get the best response from users?

Q18: (optional) Could a more participatory approach be beneficial to the process? Involving users more in the design process?

Q19: When it comes to usability, is it more common to have a group of usability experts or just one person working within the development team?

Q20: In your research group/ company, is UCD considered throughout all undertaken projects? Or just this project?

Q21: Is usability an important element in your development projects?

Q22: At what point in the design process do you include usability testing?

Q23: How do you collect requirements for usability?

Q24: How important is usability requirements for the success of your projects? How many users are typically engaged in usability testing?

Q25: How do you select users for usability testing?

Q26: How important is usability testing for the success of your projects?

Q27: To which degree do you think that usability is integrated in your systems development method?

BENEFITS & CHALLENGES

Q28: What are the challenges you have encountered when employing UCD methods in design?

Q29: What benefits have you experienced from the use of UCD?

Q30: Do you find it hard to get a high user acceptance?

Q31: Do you think that using UCD is cost-beneficial?

Q32: Will you continue to use UCD in your projects?

Why? Why not?

Thank you for the time and will to participate in our study.