Towards Usable openEHR-aware Clinical Decision Support:
A User-centered Design Approach

Hajar Kashfi
To my love, Mohsen
and my wonderful parents and brothers
Towards Usable openEHR-aware Clinical Decision Support:
A User-centered Design Approach

Hajar Kashfi
Department of Applied Information Technology,
Chalmers University of Technology

Abstract

Nowadays, the use of computerized approaches to support health care processes in order to improve quality of health care is widespread in the clinical domain. Electronic health records (EHR) and clinical decision support (CDS) are considered to be two complementary approaches to improve quality of health care. It is shown that EHRs are not able to improve quality of health care without being supported by other features such as CDS. On the other hand, one of the success factors of CDS is its integration into EHR, and since there are various international EHR standards (such as openEHR) being developed, it is crucial to take these standards into consideration while developing CDS.

Various clinical decision support systems (CDSS) are developed but unfortunately only a few of them are being used routinely. Two of the reasons for unacceptability of CDSSs among their users, i.e. clinicians, are shown to be their separation from EHRs and poor usability of the user interfaces. Besides integration into underlying information framework, i.e. EHR systems, consideration of human-computer interaction (HCI) in designing and evaluating CDS is one of the success factors that developers of these systems should keep in mind. This thesis addresses the question of how usable openEHR-aware clinical decision support can be designed and developed in order to improve the quality of health care. To answer this research question, several sub-questions were identified and investigated. This included analyzing “state of the art” in two different aspects of design and development and evaluation of CDS and also investigating application of a customized user-centered design (UCD) process in developing openEHR-based clinical applications.

Analysis of state of the art in interplay between HCI and CDS and also the intersection between CDS and EHR revealed that consideration of both HCI and integration of CDS into EHR is more appreciated in theory than in practice.
and there is still a long way to go before reaching an acceptable level in these two success factors of CDS.

Moreover, the experience in designing an openEHR-based clinical application revealed that apart from benefits offered by openEHR approach, such as specifying different roles and involvement of domain experts in defining domain concepts, there are various shortcomings that need to be improved, for instance the limited support for openEHR application developers. Additionally, this study revealed that there are characteristics of the domain, tasks and users in the domain that developers should be informed about while applying UCD methods.

**Keywords:** Medical informatics, Electronic health record, openEHR, Clinical decision support system, User-centered design, Human-computer interaction, Interaction design, Usability.
Acknowledgments

I would like to express my gratitude to all of the individuals whose support and help has made this research a reality; especially my supervisor and advisor, Olof Torgersson. My gratitude also extends to Göran Falkman, Mats Jontell, Marie Lindgren, Marita Nilsson, and the members of the Clinic of Oral Medicine at Sahlgrenska University Hospital who were involved in this project. I also want to thank Sus Lundgren, Martin Hjulström, Erik Fagerholt and Soren Lauesen who provided constructive feedback on the design work presented in this thesis. I am also indebted to Marie Gustafsson Friberger who provided valuable comments on the thesis. Moreover, I appreciate the opportunities for helpful discussions provided by the openEHR community members, especially Ian McNicoll, Koray Atalag, Pablo Pazo, Rong Chen, Seref Arikan, and others whose names may have been omitted here.

I would also like to convey my gratitude to my colleagues in the Interaction Design Division, in particular Staffan Björk and Fang Chen, and members of the Human-Technology Design research school of which I too am a member. Of course, I would be remiss not to mention my kind fellow graduate student, Anna Gryszkiewicz, with whom I share a pleasant and peaceful office. My friends know that they all hold a very special place in my heart and I am grateful to them for all of the joy they have brought into my life over the past few years. But my wonderful family—my parents and brothers—know that they are and always will be a part of my heart. I hope that the realization that their love, patience, and willingness to bear the burden of our separation, has empowered me to make my dreams come true will allow them to look upon my achievements here with pride.

And finally, thanks to you, Mohsen, my love, and the meaning of my life. You are the best and happiest thing that has ever happened to me. You are not only a marvelous life partner, but also a tremendous friend and a remarkable fellow graduate student. I appreciate the fruitful discussions we have had together and the feedback you provided on this thesis. I am grateful to you for being such a cheerful and supportive soul mate through both sunshine and rain, as well as all of the other moments that will forever remain between you and I. Thank you for being my everything and everyone—your love is the axis of my entire being.

Hajar Kashfi
Gothenburg, May 2011
List of Appended Papers

This thesis is a summary of the following four papers. References to the papers will be made using the Roman numbers associated with the papers.

I  Hajar Kashfi, “Towards Interaction Design in Clinical Decision Support Development: A Literature Review,” submitted to International Journal of Medical Informatics, Elsevier

II  Hajar Kashfi, “The Intersection of Clinical Decision Support and Electronic Health Record: A Literature Review,” submitted to 1st International Workshop on Interoperable Healthcare Systems (IHS2011) - Challenges, Technologies, and Trends, Szczecin, Poland, September 19-21, 2011.

III  Hajar Kashfi, “Applying a User Centered Design Methodology in a Clinical Context,” in Proceedings of The 13th International Congress on Medical Informatics (MedInfo2010), Studies in health technology and informatics, 2010 Jan ;160(Pt 2):927-31.

IV  Hajar Kashfi, “Applying a User-centered Approach in Designing a Clinical Decision Support System,” submitted to Computer Methods and Programs in Biomedicine, Elsevier.

V  Hajar Kashfi, Olof Torgersson, “Supporting openEHR Java Desktop Application Developers,” to appear in The XXIII International Conference of the European Federation for Medical Informatics, Proceedings of Medical Informatics in a United and Healthy Europe (MIE2011), Oslo, Norway, 28-31 August, 2011.

VI  Hajar Kashfi, Jairo Robledo Jr., “Towards a Case-Based Reasoning Method for openEHR-Based Clinical Decision Support,” to appear in Proceedings of The 3rd International Workshop on Knowledge Representation for Health Care (KR4HC’11), Bled, Slovenia, 6 July, 2011.
List of Other Papers

I Hajar Kashfi, “An openEHR-Based Clinical Decision Support System: A Case Study,” in The XXII International Conference Of The European Federation For Medical Informatics, Proceedings of Medical Informatics in a United and Healthy Europe (MIE2009), Studies in health technology and informatics. 2009. p. 348.

II Hajar Kashfi and Olof Torgerson, “A Migration to an openEHR-Based Clinical Application,” in The XXII International Conference Of The European Federation For Medical Informatics, Proceedings of Medical Informatics in a United and Healthy Europe (MIE 2009), Studies in health technology and informatics. 2009. p. 152-6.
## Contents

### I Introduction

1 Introduction  
1.1 Overview ........................................... 3

2 Frame of Reference  
2.1 Medical Informatics  
2.2 Electronic Health Record  
2.2.1 The need for Interoperability  
2.3 openEHR  
2.3.1 Two-level Modeling  
2.3.2 Two-level Software Engineering  
2.3.3 The Reference Model  
2.3.4 Archetype  
2.3.5 Template  
2.4 Other EHR Standardization Approaches  
2.4.1 The CEN/ISO EN13606 standard  
2.4.2 The Governmental Computerized Patient Record Project (G-CPR)  
2.4.3 Health Level 7 (HL7)  
2.5 Decision Support  
2.6 Human-Computer Interaction  

### 3 The Research Process

3.1 Conceptual framework  
3.2 Research Questions  
3.3 Objectives  

### 4 Methods and Tools

4.1 Literature Review  
4.2 The Research Methodology  
4.2.1 Design and Creation Research Strategy  
4.3 User-Centered Design Process  
4.4 Assumptions  


Part I

Introduction
Chapter 1

Introduction

Errors that occur in a clinical process are mostly due to cognitive limitations of humans, the potential to forget knowledge in the health care flow, and difficulties in clinical workflows \[1\] \[2\]. Clinicians are prone to making errors, especially because of the limitations of the working memory \[3\]. Various avoidable errors or adverse events in health care are documented in the literature. These errors and events have even lead to patients’ deaths in some cases. About 12 preventable deaths per million inhabitants in Sweden are reported \[4\]. According to the Swedish Parliament, around 100,000 patients suffer from preventable adverse clinical events each year and 3000 of these adverse events lead to patient deaths \[5\]. Preventable medical errors resulted in deaths of up to 98,000 people in the United States in 1999 \[6\]. Around 11% of the patients admitted to two hospitals in London, experienced adverse events; 48% of which were preventable and 8% of which resulted in patient deaths \[7\].

There have been investigations about the quality of care in various countries. The existing quality problems belong to three different categories, namely “underuse” (failure to provide the best expected health care service), “overuse” (providing a health care service that is more harmful than being beneficial for the patient), or “misuse” (unsuccessful delivery of the best expected health care service because of some preventive complications), which occur in both small and large health organizations \[8\].

Obviously, there are many debates surrounding the quality of health care, but one should start with defining the meaning of “quality” in this domain. A widely accepted and robust definition of quality is the definition developed in 1990 by the Institute of Medicine (IOM) as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” \[9\]. According to Graham \[10\] “quality must be judged as good if care, at the time it was given, conformed to the practice that could have been expected to achieve the best results.”

It has been demonstrated that information systems have the ability to decrease avoidable clinical errors by supporting clinicians in health care process or in other
words to improve the quality of care [11]. Medical informatics is the research field that is dealing with this matter. Electronic health records (EHR) have been the leading research focus in this field so far [12] [13] [14]. The EHR research field deals with issues such as capturing, storing, retrieving and sharing patient data. For EHRs to be able to improve quality of care, they should be supported by clinical decision support (CDS) services [15] [14] [16], those services that aid clinicians in the process of decision making. Nonetheless, not all CDS developments have led to improving the clinical practice [17]. Hunt et al. [18] indicate that 66% of the CDS implementations have led to significant improvement in health care while the remaining 34% did not. Various efforts have been made in order to identify barriers to low adoption, acceptability and ineffectiveness of CDS. Efforts have also been made to identify success factors in developing them [13] [17] [19] [20] [21]. Some of those success factors are the level of integration with clinicians’ workflow [13] [20] [17] [22] [23] [24], the degree of patient-specificity [13] [17] [21], availability at the point of care or timely access [13] [17]. Accordingly, two of the main factors that have a direct relation to success of the CDS are integration of the CDS to EHR systems and proper design of CDS by taking human-computer interaction (HCI) into consideration. While there have been various recommendations regarding consideration of these two success factors in development of CDSSs, related literature suggests that these factors are being partially or totally ignored in many of the projects.

1.1 Overview

This thesis investigates the question of how usable openEHR-aware clinical decision support can be designed and developed in order to improve the quality of health care. In order to answer this question, several sub-problems were identified to be investigated. The study has been carried out in oral medicine. However, the outcome of the research should be applicable to medical informatics in general. The structure of the thesis is as follows. The frame of reference of this research is presented in Chapter 2. This chapter includes the definition of different concepts basic to this research namely medical informatics, EHR, openEHR, CDS, HCI, usability and user-centered design (UCD). The research process and the conceptual framework are discussed in Chapter 3. The research questions and objectives of this study are presented in this chapter as well. Methods and tools are introduced in Chapter 4. A summary of the included papers is given in Chapter 5, along with how they can be put in relation to each other and the research questions. Some directions for future work are discussed in Chapter 7. Finally, a conclusion is provided in Chapter 8.
Chapter 2

Frame of Reference

2.1 Medical Informatics

Medical informatics is defined as a scientific discipline “concerned with the systematic processing of data, information and knowledge in medicine and health care” [25, 26]. This domain covers both “computational” and “informational” aspects of the processes in the clinical domain [26]. Medical informatics deals with providing solutions for problems of data, information and knowledge processing in medicine and health care [24]. As a discipline, medical informatics has been around for more than 50 years [12] but still is called young especially compared to other medical disciplines [27]. Nowadays, new names are suggested for this discipline such as health informatics and clinical informatics since the word “medical” does not cover nursing informatics, dental informatics and so on [12].

There are various research areas in the field of medical informatics namely electronic health record (EHR) systems, information systems, decision support systems, and image and signal processing [12]. EHRs have been the leading research focus in this field so far [12, 13, 14]. The EHR research field deals with issues such as capturing, storing, retrieving and sharing patient data. This has led to a number of benefits such as reduced number of transportation errors, higher legibility of reports, and avoiding redundancy [13]. These benefits indirectly affect patient safety, health care quality and efficiency [13]. Recently, there has been more and more interest in adoption of EHRs and developing clinical applications based on EHRs [13, 15, 14].

The idea of benefiting from computers and information technology (IT) in the clinical domain has been around since the 1950s [28] (or the 1960s as observed by [13]) when there were initiatives to automate health care and to simulate the clinical decision making by computers [13, 24]. One of the turning points of medical informatics is considered to be around 50 years ago when in 1959, Ledley and Lusted reported on reasoning foundations of medical diagnosis [29]. Even though the concept of atomization of health care and application of com-
puters and IT in this domain is an old trade, it has a slow adoption pace and low impact level compared to other domains such as engineering, marketing, etc. In other words, health care has fallen behind other disciplines in applying information technology to improve the processes and outcomes [13, 14]. As mentioned above, since the introduction of computers in the clinical domain in the past decades, the main progress in this area has been in coping with information management, i.e. adopting EHRs [13, 14, 12] rather than adopting CDS in order to improve the decision making process. One of the aims of the efforts in the area of EHR has been to improve quality of health care but it is doubted whether EHRs have the ability to fulfill this goal [15]. More information about EHRs is presented in the following section.

2.2 Electronic Health Record

The idea of computerized medical records has been around as one of the key research areas in medical informatics for more than 20 years. Iakovidis [30] defines an EHR as “digitally stored health care information about an individual’s lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times”. EHRs include the whole range of patient-related data such as demographic information, medical history, medications, and allergies [31]. The main aim of EHRs is to make distributed and cooperating health information systems and health networks come true [31]. The first benefit of deploying EHRs is that patients’ information is no longer on a piece of paper and clinicians have access to all patients’ information when required [13]. Since the introduction of EHRs, various projects were initiated that led to development of various commercial EHR products. Nowadays, there are more and more EHR systems being developed. The interest is also increasing at the governmental level in different countries such as the UK and Sweden. However, the EHRs adoption rate is still low in community hospitals and office practices, while higher in academic medical centers [13]. The maximum adoption of EHRs in the United States is demonstrated to be only 40% [32]. In those countries in which there exists a national health care plan, this rate is considered to be higher [13]. Several reasons have been identified for the low adoption rate of EHRs in small hospitals and office practices, viz. high implementation and maintenance costs, additional time and effort and finally the difficulty in choosing among available systems in the market due to a lack of standardization [13].

2.2.1 The need for Interoperability

To to be able to fully benefit from EHRs, timely and secure access to all of the EHR systems should be ensured, EHRs should be up-to-date and accurate in terms of information they contain, and they should be correctly understood when being communicated [33]. This means that EHR systems should be inter-
EHRs are stored in various formats in different products which yields interoperability problems in the domain. Therefore, developing national and international EHR standards is important to support interoperability [34]. Before going into details of the approaches suggested to enhance interoperability of EHRs, it is proper to present a definition of interoperability. Interoperability of health systems is defined as “the ability, facilitated by ICT applications and systems, to exchange, understand and act on citizens/patients and other health-related information and knowledge among linguistically and culturally disparate health professionals, patients and other actors and organizations within and across health system jurisdictions in a collaborative manner” [33]. Four levels of interoperability are defined by Stroetmann [33]:

1. having no interoperability
2. technical and syntactical interoperability
3. partial semantic interoperability
4. full semantic interoperability

A challenging aim regarding EHRs has been to reach semantic interoperability in EHR systems. Interest in this issue in particular is increasing in the EU recently with the aim of reaching semantic interoperability at regional, national and even the EUR level [33]. So far, several efforts have been made to develop EHR standards in order to structure and exchange patient information and to enable semantic interoperability among medical information systems. The main approaches are as follows:

- The European Committee for Standardization (CEN) Electronic Health care Record communication standard (CEN/ISO EN13606)
- The Governmental Computerized Patient Record project
- The Health Level 7 (HL7) Reference Information Model and its clinical document architecture
- The GEHR approach
- The openEHR approach which is a continuation to GEHR

All the above approaches focus on the technical issues related to standardized and interoperable EHRs. More information about these approaches is provided in the following sections. The EHR interoperability standard that is applied in this study is openEHR. According to openEHR website [1] “the Swedish government has decided on the use of ISO 13606 as a base standard for national health data communication. openEHR will be used to define clinical models, terminology integration, and to implement 13606 in some contexts.” ISO/CEN
13606 resembles the openEHR reference model (See Section 2.3.2) in a simplified manner [35] (ISO/CEN 13606 is explained in Section 2.4.1). This has been a huge motivation for us to consider openEHR as our EHR approach to carry out this study.

2.3 openEHR

openEHR has its origins in 1992 in an EU research project named Good European Health Record. This project was later continued under the name of Good Electronic Health Record (GEHR) [36]. Currently the maintenance of openEHR is done by a non-profit organization named the openEHR Foundation [35].

In the openEHR approach, clinicians are in charge of defining the specifications of clinical knowledge to be used in information modeling. The main emphasis of openEHR is on semantic interoperability of medical records. This approach suggests a two-level architecture for clinical applications to separate knowledge and information levels in order to overcome the problems caused by the ever-changing nature of clinical knowledge. Patient data is stored in a generic form which is retrievable in any system using constraints named archetypes. An archetype, which is designed by domain experts, defines some constraints on data in terms of types, values, relation of different items and so on. Archetypes are used for data validation and sharing [37].

The openEHR framework consists of the reference information model (RM), the implementation technology specification, the archetype definition language (ADL), the open-source implementations, and an archetype repository (the repository is explained more in Section 4.5) [37]. A review of the openEHR architecture is presented by Beale [37]. The key concepts of the openEHR architecture are explained in the following sections.

2.3.1 Two-level Modeling

openEHR suggests a two-level architecture for EHR systems, and accordingly a two-level software engineering approach for developing such systems. The key idea in the two-level architecture is the separation of the domain knowledge level and the information level.

The first level or the lower level is a stable reference information model. Software and data are built from this stable object model named the openEHR Reference Model (RM). The second or upper level provides formal definitions of the clinical domain concepts. This reduces the dependency of the system and underlying data to the ever-changing clinical concepts.

2.3.2 Two-level Software Engineering

openEHR suggests a two-level software engineering approach. In this approach, there exists different viewpoints and a separation of responsibilities in software
development. The main roles involved in the openEHR process are domain experts, users and IT developers. Different view points introduced by openEHR are the domain knowledge environment, the runtime system and the technical development environment. The openEHR approach consists of the following steps:

- Domain specialists build reusable archetypes, templates (collections of archetypes, see Section 2.3.4) for local use and terminologies for general use.
- IT developers focus on generic aspects of the system such as data management.
- The user works with a GUI which is derived from the templates. Data is generated by users via the EHR system and is validated by archetypes at runtime.

2.3.3 The Reference Model

The openEHR RM is specific to the clinical domain but still includes very generic clinical concepts such as composition, observation, evaluation, instruction and action. Moreover, in this RM, different data types are defined such as coded text, quantity and multimedia.

2.3.4 Archetype

In the upper level of the openEHR two-level modeling approach, domain level definitions are defined in form of archetypes and templates. These definitions are
used in the EHR system at runtime. Archetypes are used to define constraints on the generic RM. For instance, a blood pressure measurement can be defined in form of an archetype in contrast to a more general clinical concept such as an observation which is the focus of the RM.

All the information that is based on the RM is archetypeable, or in other words, can be controlled by archetypes in terms of its creation, modification and so on. Each archetype is an instance of the archetype model (AM) and is stored separated from data in an archetype repository. The archetype definition language (ADL) is the language that is used to define archetypes based on the AM. It is recommended that when possible, archetypes should be reused and/or customized instead of being created from scratch. The relation of archetypes to the RM is depicted in Figure 2.2.

2.3.5 Template

Templates encapsulate a group of archetypes to be applied for a local use. Templates are trees of one or more archetypes and correspondent to user interface forms, printed reports or other realizations of clinical data [37]. For instance, using a template, one can put different clinical concepts like “blood pressure measurement” and “mouth examination” (both defined as archetypes) together to create an output report for EHRs [37].

2.4 Other EHR Standardization Approaches

Several studies have compared the main interoperability standards and specifications in the clinical domain [31 34]. Based on a survey, Eichelberg provides
information on the most relevant EHR standards \[38\]. This includes the level of interoperability provided by each standard, as well as content structure, access services, multimedia support and security. In the following sections, a brief introduction to the most relevant EHR standardization approaches is presented.

2.4.1 The CEN/ISO EN13606 standard

The CEN/ISO EN13606 is a European norm from CEN which is also approved as an international ISO standard \[39\]. The aim of this standard is to enable semantic interoperability in the electronic health record communication. The CEN standard is actually a subset of the openEHR specification \[34\]. The same as openEHR, this standard is based on the idea of a two-level architecture (i.e. a dual model architecture \[39\]) which consists of a reference model and archetypes.

2.4.2 The Governmental Computerized Patient Record Project (G-CPR)

G-CPR is a joint project between the US Department of Defense (DoD), the US Department of Veterans Affairs (DVA) and the Indian Health Services (IHS) \[31\]. This solution uses object-oriented specification to enable interoperability and is rather a service-oriented solution than an architecture-based solution \[31\].

2.4.3 Health Level 7 (HL7)

HL7 is a well-known EHR communication standard in the clinical domain \[31\]. According to the HL7 website\[2\], “Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services”. HL7 in HL7 version 3 presents a comprehensive Reference Information Model (RIM) \[31\]. The HL7 clinical document architecture (CDA) templates are similar to openEHR archetypes \[38\]. This standard, provides data-level interoperability but functional level interoperability is not provided \[31\].

2.5 Decision Support in the Clinical Domain

Clinical decision support is a sub-domain of a more general research area named decision-making support. According to Gupta \[40\] “decision-making support systems (DMSS) are Information Systems designed to interactively support all phases of a user’s decision-making process.” There are various definitions for CDSS and CDS in the literature three of which are presented here:

\[http://www.hl7.org/\]
“computer-based clinical decision support (CDS) can be defined as the use of the computer to bring relevant knowledge to bear on the health care and well being of a patient” [13].

“clinical decision support refers broadly to providing clinicians or patients with clinical knowledge and patient-related information, intelligently filtered, or presented at appropriate times, to enhance patient care” [14].

“clinical decision support is any EHR-related process that gives a clinician patient-related healthcare info with the intent of making the clinician’s decision making more efficient and better informed” [3].

CDS impacts the process of decision making about individual patients. This support should be provided at the point of care and while the decisions are made [24]. These systems provide support for diagnosis of diseases, prevention of errors in the clinical process, treatment, and future evaluation of the patient. Services supported by CDS include diagnosis, alerting, reminding, treatment suggestions, and patient education. CDS interventions are the CDS content and the method for delivering the content.

In providing CDS, three modes of interaction between human and computer can be defined [13]:

- User in charge (users can override computer’s suggestions)
- Computer in charge (any decision made by computer is expected to be carried out by users)
- Collaborative decision making (computer controls the input, based on users’ entries options are provided, users makes the desired choice)

The idea of having both computers and humans in charge of the health care process is more practical in the clinical domain than building intelligent autonomous systems that are in charge of the decision making process [13, 24]. The latter may work in other disciplines but is less applicable in the clinical domain. Berner [24] discusses that CDS is not meant to come up with “the answer” but should provide information for the user and aid him/her in making decisions.

Not all of the information in a clinician’s mind can be transferred to the computer (the CDSS) so a clinician usually knows more about the patient. Therefore, having a collaborative pattern in which a clinician can eliminate some of the choices made by the computer is better [24].

In this thesis, CDSS and CDS are used interchangeably to refer to a computer program that aids clinicians in the process of decision making, at the point of care, and based on health information of an individual patient, by presenting that information coupled with external knowledge in a way that is more suitable for making decisions regarding the care process of that specific patient. The system is not meant to make the decisions, rather it is the clinician who makes the final decision.
2.6 Human-Computer Interaction

Human-computer interaction (HCI) is defined as “a discipline concerned with the design, evaluation and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them” [41]. The concept of usability is considered to be the heart of HCI [42]. Usability is defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” [43]. A great deal of effort in the field of HCI is aimed at designing and developing more usable computer systems [42].

Usability is a very important factor in designing an interactive system. If the system is not usable enough for the intended users, it is likely that they do not use the system so often (underuse) or use the system improperly (misuse) and stick to their current methods for accomplishing the tasks, that both bring costs to the organization or ruin the reputation of the team/company that developed the system [44]. There are benefits in designing a usable system both for the developer team and for the customers: increased productivity, reduced errors, reduced training and support, improved acceptance and enhanced reputation [44].

To develop a usable interactive system, both functional requirements and non-
functional requirements, including usability requirements, should be considered. Traditionally, the focus of software design processes have been on functional requirements, but nowadays there are design frameworks integrating these two [44]. According to Shneiderman [45], usability requirements are of five types: learnability, efficiency, memorability, errors, and satisfaction.

By involving users in the design and development process of a system, the system will be more usable for the intended users [46, 47, 48]. The design approach which places emphasis on involving users in the design is called user-centered design (UCD) or human-centered design (HCD) [46, 47]. The main focuses of UCD are active user involvement in the design process, multidisciplinary design teams and iterative design [44]. UCD is not a substitute for software development methods, but a complementary process to them. The UCD process is depicted in Figure 4.2. The process starts with planning then context of use analysis, requirements specification, design and evaluation are repeated until the user is satisfied with the design and usability requirements are achieved.

Various methods are defined to support UCD. A broad range of methods are specified by Maguire [44]. This collection is considered to be a proper introduction of various well-known methods and their relation to different UCD steps. The methods are summarized in Table 2.1, column names correspond to different steps in the UCD process.
Chapter 3

The Research Process

Oates describes a model of the research process which consists of various categories of methods such as research strategy, data generation methods, and data analysis. Oates describes how self-experiences and motivations along with the knowledge gained from reviewing the literature in the field and being informed about the existing gaps lead to a “conceptual framework” and “research questions” (see Section 3.2).

A conceptual framework clarifies a researcher’s way of thinking and structuring a research topic and the research process undertaken. A conceptual framework includes the research topic and its comprising factors, the research methodology (a combination of strategies and methods used), the data analysis approaches, the development methodology, and the research evaluation approach. Details about the conceptual framework in this study is presented in Section 3.1.

In order to conduct a research study, a research strategy should be selected (see Section 4.2.1), also data generation methods should be applied in order to gather data and finally analyze the data using qualitative or quantitative methods. In this study, data generation methods are those methods applied in the system development process (see Section 4.3) along with the literature published on the topic of interest, i.e., CDS (referred to as “documents” in the Oates’s model). Both qualitative (used as part of the system development process) and quantitative data analysis methods are applied in this study in order to analyze data. Oates’s model is depicted in Figure 3.1. This figure also highlights how the process of this study fits into this model.
Figure 3.1: Model of research process adapted from [49]. The methods applied in this study are colored in gray.
3.1 Conceptual framework

As mentioned previously, there have been various efforts in defining CDS success factors and development difficulties ranging from a local, and practical view [14, 50, 51, 15] to wider national-level views that have tried to provide guidelines or road-maps for developing more effective CDS [52, 53, 21, 54]. Accordingly, four main categories of challenges and success factors faced in design and development of CDS can be defined:

- **technical issues** concerning knowledge representation and reasoning and also maintenance of knowledge

- **integration into EHRs** that deals with the integration to the underlying IT framework or more specifically EHR systems in the clinical organizations which is a sub class of the “technical issues”, but because of its importance, is considered as a separate category in this thesis.

- **human-computer interaction issues** that focus on the user interface design of these systems and the way users interact with them. User satisfaction, effectiveness and acceptability of CDS in a practical setting, and involving clinicians in the design and development of CDS all belong to this category.

- **cultural and organizational issues** that deal with the higher level aspects of motivations, utilizations, monitoring and acceptance of these systems at local, national and international levels.

According to the road-map for the United States national action on clinical decision support [21] to reach widespread adoption of effective CDS, it is crucial that system developers be supported to design “easy to deploy and use” applications. It is also recommended that best practices in system development should be disseminated so that other developers can learn from previous successful experiences.

As discussed before, the ultimate goal of efforts in the area of medical informatics is to improve the quality of care, specially by introducing and applying EHRs and CDS. To improve the quality of health care, neither of these two concepts is an optimal solution individually. It is shown that to improve quality of health care, EHR systems should be supported by other services such as CDS. On the other hand, in order to develop effective CDS and to broaden its adoption, CDS should be integrated into the existing EHR platform in the clinical organizations and HCI should seriously be taken into consideration in designing and developing them.

So far, this study has been done in relation to two of the categories of challenges and success factors in developing CDS namely integration of CDS to EHRs and taking HCI into account in designing and developing CDS. Figure 3.2 depicts the factors the comprise this study. In the following, the research questions (Section 3.2) and objectives (Section 3.3) are presented. Chapter 4 includes
more information about the research strategy and methods applied to answer the research questions.

Figure 3.2: In order to improve the quality of health-care focus on two areas are inevitable: adopting clinical decision support and adopting electronic health records (EHR). Development of highly acceptable clinical decision supports is dependent on its integration into EHRs, and also consideration of human-computer interaction (HCI) with the aim of developing usable clinical decision support systems (CDSS). There are however other issues such as technical considerations (e.g. knowledge representation and reasoning) and cultural and organizational aspects of adopting clinical decision support in health organizations. Among these pillars, technical issues have gained the most attention so far, but interest in other aspects has also been increasing recently. This thesis involves two aspects (i.e. colored pillars) namely integration of clinical decision support system into EHRs, and taking HCI into consideration with the aim of developing a usable CDSS that is aware of an EHR standard named openEHR.

### 3.2 Research Questions

The aim of this study has been to answer this research question:

**How can usable openEHR-aware clinical decision support be designed and developed in order to improve the quality of health care?**

In order to answer this question, several sub-problems were set to be investigated:
RQ1 Are usability of clinical decision support and methods to reach and assure usability taken into consideration by developers of clinical decision support?

RQ2 Are integration of clinical decision support into electronic health records and adopting electronic health record standards taken into consideration by developers of clinical decision support?

RQ3 Is the openEHR suggested approach suitable for designing and developing openEHR-aware clinical applications, including clinical decision support systems?

- Does the two-level software engineering approach suggested by openEHR work in practice?

RQ4 How can current successful design and development processes such as user-centered design be customized for designing and developing clinical applications and clinical decision support?

The question involves the following sub-problem:

- How can the design and development process of an openEHR-aware clinical application, including clinical decision support systems, be structured with focus on human-computer interaction and involving clinicians in the process?

RQ5 Does openEHR offer any new opportunities for clinical decision support in terms of knowledge representation and reasoning?

The question involves the following sub-problems:

- Can openEHR be used to improve the process of knowledge representation and reasoning in clinical decision support?
- Can clinical decision support benefit from structured, quality validated openEHR-based electronic health records?
- Is it feasible and practical to integrate clinical decision support interventions into openEHR-based electronic health records?

To answer the above research questions, several objectives should be accomplished. These objectives are defined in the following section.

3.3 Objectives

To investigate openEHR and also UCD in a clinical context with the aim of answering the research questions, it was decided to develop a CDSS for an oral disease. It was also planned to accomplish the following objectives:

---

1It should be mentioned that the work presented in this thesis is actually related to RQ1-RQ4. RQ5 is suggested as the future direction of this study.
Literature reviews should be conducted in order to analyze state of the art in interplay between HCI and CDS, also the intersection of EHR and CDS.

The openEHR framework should be studied and understood. The archetype concept, two-level modeling, and two-level software engineering suggested by openEHR should be analyzed.

A UCD process should be applied from the beginning of the project. Different UCD methods that are applicable for the project should be selected for designing and developing both the CDSS and archetypes.

Domain-specific information about the disease should be gathered and structured using openEHR archetypes. Additionally, as suggested by openEHR, reusable existing archetypes should be specified and customized if applicable.

The strengths and shortcomings of the openEHR approach and the limitations of the two-level software engineering suggested by openEHR should be identified in order to be reconsidered in the proposed approach in this study.

The characteristics of the clinical domain, clinical tasks and clinicians that may have an effect on the user-centered design process should be identified.
Chapter 4

Methods and Tools

In this section, the methods and tools applied in order to answer the research questions (see Section 3.2) are elaborated.

4.1 Literature Review

*Literature review* is a research methodology that aims at summarizing the available literature on a topic and presenting an analysis based on that and providing a full picture on the topic [55]. In this study, literature review is used to analyze *state of the art* in two different but related topics namely “interplay between HCI and CDS development”, and “Intersection of CDS and EHR”. The search strategies are discussed more in detail in the papers I and Paper II.

4.2 The Research Methodology

Oates in [49] defines research methodology in information systems as a combination of “research strategy”, “design and development process” and “data generation methods”. This is depicted in Figure 4.1.

In this study a *design and creation research strategy* is used as the research strategy and a *user-centered design process* is used as the development process. More information about these methods can be found in the following sections.

4.2.1 Design and Creation Research Strategy

The focus of a design and creation research strategy is on developing new software products i.e. artefacts [49]. In this study the “artefact” to be developed is a *clinical decision support system for dry mouth*. To understand this artifact a description of the disease, i.e. dry mouth, and the characteristics of the CDS are provided in the following.
A Clinical Decision Support for Dry Mouth

"Dry mouth or xerostomia is the abnormal reduction of saliva and can be a symptom of certain diseases or be an adverse effect of certain medications" [56]. Treatment of Xerostomia is related to finding its cause(s). There are five main categories for xerostomia namely drug-induced, disease-induced, radiation-induced, chemotherapy-induced, and cGVHD-induced [56]. Finding cause(s) of dry mouth is a challenge for clinicians and needs to be supported by a clinical application.

A potential dry mouth patient should answer, or a clinician should find an answer to various types of questions such as:

- Do you need to moisten your mouth frequently or sip liquids often?
- Have you noticed any swelling of your salivary glands?
- Do you smoke or have been smoking regularly?
- Are you currently taking 3 drugs or more?
- Have you been subjected to therapeutical radiation against your head-and-neck region?
- Have you had a feeling of dry mouth daily for more than 3 months?

As in other diseases, each of these questions is considered very important in diagnosis. They sound very straightforward, but the difficulty arises when all of these questions should be remembered at the point of care [3] while the answer provided by a patient should also be supported with an examination by clinicians, e.g. the swollen salivary gland.
The dry mouth CDS is meant to be used in the clinic of oral medicine in Sahlgrenska University Hospital, Gothenburg, Sweden. Since this system is going to be used integrated with an existing clinical data entry application, i.e. MedView [57], data entry forms are not part of the Graphical User Interface (GUI), however users should be provided with options to edit existing data. Finally, users need to be able to enter their own comments; including diagnosis or treatments to the system.

The intended decision support process includes these four main steps:

1. Presenting an overview of patient-specific information and external knowledge in a way that makes decision making easier
2. Providing proper reminders and alarms
3. Helping the user in finding the cause(s) of disease based on the patient’s medical record
4. Suggesting related materials and treatment options, patient health information and external knowledge

This study has been conducted in oral medicine, however, the outcome of the research should be applicable to medical informatics in general, i.e. other diseases, and other clinical applications.

4.3 User-Centered Design Process

UCD is a process that places emphasis on involving users in the design [46, 47]. As depicted in Figure 4.2 UCD is a circular design process. The UCD process consists of five steps [47]. These steps are

1. plan the human-centered process
2. understand and specify the context of use
3. specify the users and organizational requirements
4. produce design solutions
5. evaluate design against requirements

This circle will be repeated until the users are satisfied with the design and the requirements are met in the design solution.

As recommended [58], a customized UCD process has been applied in this study. The customization was done in order to make the process suitable for the context and also the nature of the project i.e. having openEHR as the underlying EHR standard. To accomplish the UCD process, several methods were utilized such as prototyping, usability tests, and interviews. Different UCD methods that were applied in this project are summarized in Table 4.1 and discussed more in detail in Paper V.
Plan the user-centered design process

Understand and specify the context of use

Evaluate design against requirements

Specify the users and organizational requirements

Produce design solutions

Meets requirements?

Figure 4.2: The user centered design cycle [47, 41], see Section 4.3

| Context of Use                  | Requirements                                      | Design                                      | Evaluate                                      |
|--------------------------------|---------------------------------------------------|---------------------------------------------|-----------------------------------------------|
| o Identifying stakeholders     | o Interview                                       | o Brainstorming                             | o Informal user evaluation                    |
| o Informal context of use analysis | o Persona                                      | o Design guidelines and standards          | o Informal expert evaluations                 |
| o Interviews                    | o Existing system or competitor analysis         | o Paper prototyping                        | o Usability test                              |
| o Multidisciplinary group sessions | o User, usability and organizational requirements | o Software prototyping                      | o Think aloud protocol                        |
|                                | o Literature study                                |                                             | o Satisfaction questionnaires                 |
|                                | o Domain concept modeling                         |                                             | o Post experience interviews                  |

Table 4.1: The UCD methods applied in the project
The work presented here is the outcome of the first three iterations of this project. Several users and domain experts were involved in this process. Several user interface prototypes were developed, evaluated and improved iteratively. The characteristics of this clinical context that have an effect on applying a UCD process were detected and analyzed. Moreover, UCD was not only applied to reach usability in the design, but also to develop domain concept models to create archetypes. The latter was also accomplished iteratively by involving clinicians (see Paper III).

The Multidisciplinary Project Team

The project team included the following members: one specialist in dentistry, who was also one of the stakeholders and initiators of the project (from now on, we refer to this person as the main clinical partner), three computer scientists, with knowledge of human-computer interaction, usability and software engineering, and one programmer.

Users Involved

Besides our main clinical partner, who was involved in the project from the beginning, three more specialists in dentistry and one dental hygienist were interviewed during this study both for requirements gathering, archetypes development, and informal evaluation of the user interface paper prototypes (from now on, we refer to this group as expert panel). Another group of three specialists in dentistry and one dental hygienist were also asked to participate in the project as test users for user interface evaluations.

4.4 Assumptions

The focus of the project is on the design and development process and clinicians’ involvement in the process. We assume that openEHR as an interoperability standard is acceptable for our purposes. The aim of this project is “not” to prove if openEHR has been successful in EHRs interoperability. The evaluation process that is mentioned in this thesis refers to the evaluation which is done before releasing the CDS and even before evaluations based on clinical trials which is required to prove reliability of CDS before deployment. Only the openEHR archetype concept is applied in this work and no template is created. The idea of openEHR templates is skipped for several reasons: immaturity, no implementation, and finally since it was possible to develop the system without applying them.
4.5 Archetype Development Process

Domain concept modeling (information modeling) was required to understand and specify the data needed to be gathered and presented in the CDS system. Moreover, the domain modeling process was the first step in knowledge gathering for providing CDS. The openEHR approach suggests archetypes creation as a more structured way of modeling domain concepts. The archetype development was conducted in close collaboration with clinicians, i.e. experts in the domain. The development process was iterative, this means that domain concept models were created and evaluated by experts in various steps. More information about the process and tools used to develop archetypes is provided in the following.

Iterative Domain Concept Modeling

The domain concept modeling started with sessions in which our main clinical partner was asked to think about dry mouth and its related concepts and to put as much information as possible on paper. Later, he was asked to prepare a questionnaire based on this question. The reason for this was that the current clinical system that clinicians in the clinic use in their everyday work is based on the idea of clinical questionnaires. Questions on the questionnaire were then categorized based on openEHR concepts; in other words, their logical relation, e.g. is it related to the patient’s history or examining the patient?

Mind Mapping Diagrams

For better communication of the domain concepts in order to create archetypes, simple diagrams were created based on the questionnaires and also the outcome of the brainstorming sessions. For this purpose, a mind-map application was used to make it possible for our expert panel to simply understand and edit the created diagrams. The mind mapping software used in this step is called XMind.

Evaluation

Iterative design of the domain concept model includes evaluations of the current model based on the literature and experts’ opinions, and story-based assessment. Information modeling diagrams were improved several times based on the experts’ opinions. Several experts were involved in this process to minimize the subjectivity of the design and to be as broad as possible in collecting knowledge. A sample mind map is depicted in Figure 4.3.

1 http://www.xmind.net
Figure 4.3: The domain concept modeling (information modeling) was done iteratively and together with the experts in the disease. The XMind application was used in order to easily understand and create diagrams and to communicate information.
Figure 4.4: Ocean Archetype Editor is a freely available tool for authoring openEHR archetypes. This tool is meant to be used by clinicians to define specifications of the domain concepts. This tool is developed based on the openEHR reference model and supports various concept types introduced by it. In this figure a sample examination archetype is being edited. On the left side of the tool, there is a tree structure of the nodes in the archetype. The tools provided several tabs to support editing various aspects of the archetype such as definition and terminology.

Archetype Editor

For authoring archetypes, a free tool named the Ocean Archetype Editor was used. The Ocean Archetype Editor is a visual tool that supports the authoring of openEHR archetypes. The editor is unicode-enabled, therefore archetypes in any language, including Swedish, can be created in this tool, however, in this project the main language for creating archetypes has been English so far. This editor supports full openEHR data types and saves archetypes as different formats such as ADL and XML.

Reusing Existing Archetypes

It is recommended that whenever possible existing archetypes be reused and/or customized instead of being created from scratch for different local developers. Accordingly, we have also tried to reuse some of the existing archetypes in this project. The openEHR community along with other efforts has tried to make
Figure 4.5: The openEHR clinical knowledge manager (CKM) is a common repository of archetypes. Users interested in modeling clinical content may participate in the creation and/or enhancement of this international set of archetypes via this online repository.

the idea of share-ability and reuse-ability of archetypes possible by creating an online repository of reviewed international archetypes. This repository is called The openEHR Clinical Knowledge Manager which is explained below.

The **openEHR Clinical Knowledge Manager**

The openEHR clinical knowledge manager (CKM) is an international, online clinical knowledge resource. CKM is a library of clinical knowledge artifacts which at the moment is limited to openEHR archetypes and templates. It is anticipated that a complementary repository for other related artifacts like terminology subsets be provided in the future. This repository provides the foundation for interoperable EHRs. The openEHR archetypes available in the CKM go under a review and publication process in order to be accessible to others. Users interested in modeling clinical content may participate in the creation and/or enhancement of this international set of archetypes.

[^1]: http://www.openehr.org/knowledge
Chapter 5

Summary of the Attached Papers

In this section, a summary of the appended papers is given, along with how they can be put in relation to each other and the research questions. Figure 5.1 depicts different areas covered in the publications.

5.1 Paper I

A literature review on interplay between HCI and CDS development is presented in Paper I which is related to RQ1: are usability of clinical decision support and methods to reach and assure usability taken into consideration by developers of clinical decision support? This paper contributes to objective O1. The paper starts with a brief review of the studies dealing with the question of which factors should be considered in design and development of CDS to result in an acceptable and effective CDS, to motivate the importance of HCI, usability and UCD in developing CDSSs. In order to conduct the literature review, two databases (ScienceDirect and PubMed) were searched using boolean combinations of some related keywords (usability, human-computer interaction, user-centered design, clinical decision support, medical decision support). This resulted in a total of 153 studies of which only 17 were relevant to the review. Various concepts such as iterative design, involving clinicians in design and evaluation, qualitative evaluation methods, usability and UCD were the focus of this review. More about the findings of this literature review can be found in Section 6.1.

1 http://sciencedirect.com
2 http://pubmed.org
Figure 5.1: A more empirical view of the study compared to (Figure 3.2) is presented in this figure. Instead of categorization in an abstract level (i.e. HCI issues, integration into EHRs) realization of these aspects in form of applying specific approaches (i.e. openEHR, user-centered design) are introduced here. Moreover, it is shown how these aspects are covered in various publications attached to this thesis.

5.2 Paper II

Paper II includes a literature review conducted in order to answer RQ2: Are integration of clinical decision support into electronic health records and adopting electronic health record standards taken into consideration by developers of clinical decision support? This paper contributes to objectives O1 and O5. The paper motivates the important of integrating CDS into EHRs based on findings by other researchers in the field. It is discussed how CDS and EHRs support each other’s success, and finally improving the quality of care. Based on searching one database, i.e. ScienceDirect, and using boolean combinations of some related keywords (electronic health record, medical health record, clinical decision support, openEHR, HL7) a total of 98 studies were found where only 25 of them were relevant to the review. In addition, since the focus of the thesis has been on openEHR, a discussion of the causes of low adoption of the openEHR approach is presented in this paper as well. More about the findings of this literature review and the reasons for low adoption of openEHR can be found in Section 6.2.

5.3 Paper III

Paper III is related to RQ3: Is the openEHR suggested approach suitable for designing and developing openEHR-aware clinical applications, including clinical decision support systems? and RQ4: How can current successful design and development processes such as user-centered design be customized for designing
and developing clinical applications and clinical decision support? This paper contributes to objectives O2, O3, and O4.

This paper describes how a UCD approach can be used in a clinical context for developing an openEHR-based CDSS. The paper includes a proposed customized UCD approach along with the preliminary results of designing the GUI, domain concept models and archetypes. Additionally, some challenges faced in adopting openEHR are discussed in Paper III.

5.4 Paper IV

Paper IV is related to RQ4: How can current successful design and development processes such as user-centered design be customized for designing and developing clinical applications and clinical decision support? This paper contributes to objectives O3 and O6.

This paper reports on employing a UCD process in developing a CDSS. Paper IV can be seen as a more detailed version of Paper III, in which the focus has been on the UCD process and the applied methods while details regarding openEHR are skipped in this Paper. The paper includes results of the three iterations of the project and includes various prototypes of the system, evaluations and analysis of the evaluation results. In addition, those characteristics of the clinical context that have an effect on applying a UCD process are identified and analyzed in the paper.

5.5 Paper V

Paper V is indirectly related to RQ3. By “indirect” we mean the paper does not include an answer to this question but is a more practical effort dealing with one of the weaknesses of openEHR that has been discussed in Paper II and Paper III. In this paper, we have dealt with the question: how can developers of openEHR-based clinical applications connect iteratively designed and evaluated user interfaces to the underlying framework with minimum effort? This paper contributes to objective O2 and O5.

In this Paper, a framework for binding pre-designed GUIs to openEHR-based backends is proposed. The proposed framework contributes to the set of options available for developers. This approach can be useful especially for various small scale and experimental systems as well as systems in which the quality of the user interface is of great importance.

5.6 Paper VI

Paper VI is indirectly related to RQ5. This means that the paper does not cover the answer to the research question but includes discussions about the
opportunities openEHR may provide for knowledge representation and reasoning in CDSSs.
In this paper, a software architecture for the CDSS for dry mouth is proposed. The architecture benefits from an existing openEHR framework and also a case-based reasoning (CBR) framework. Case-based reasoning is a knowledge representation and reasoning method that has been popular in the clinical domain and, based on the available domain knowledge and patient data, seems to be a proper choice for this project as well.
The paper also includes a methodological approach to developing openEHR archetypes. In addition, motivations for selecting the knowledge representation and reasoning method are given in the paper.
Chapter 6

Thesis Contributions

The major contributions of this study are the result of accomplishing the objectives O1-O6 (see Chapter 5) and answering the research questions RQ1-RQ4. This is actually documented in the attached papers as results. A brief summary of the contributions is provided in the following.

6.1 The Answer to RQ1

The aim of efforts in the area of CDS is to develop such systems that result in the wider adoption of CDS and accordingly improvement in quality of health care. Various studies have dealt with the question of which factors should be considered in design and development of CDS to result in an acceptable and effective CDS. According to these studies, success factors of CDS can be divided in two main categories of technical and non-technical (i.e. human-related) factors. Most of these human-related factors, are the issues covered by the HCI discipline and related to the concept of usability. HCI suggests methods and approaches to address the human-related (i.e. user-related) factors and to assure usability of the applications.

Based on a literature review (see Paper I), one can conclude that while various researchers have so far introduced human-related factors as factors important in the success of CDSSs, HCI is not still a routine practice in this field. Only 17 studies were relevant to the literature review whereas just in ScienceDirect more than 100 practical studies on CDSSs are published. In particular, when it comes to viewing UCD as a life-long process, very few studies can be found that have covered this aspect in developing a CDSS. It was observed that some of the recommended UCD methods are not applied or rarely are applied in CDS developments. Task analysis, usability expert reviews and heuristic evaluation are some of those rarely applied methods. Finally, there are still cases in which evaluation of the system (our focus is on qualitative evaluations) is only conducted after system deployment. All in all, there is a need for further adoption...
of HCI (including usability) in this field.

6.2 The Answer to RQ2

Taking standards into consideration in any clinical application (and generally any information system) is very important [14]. Since CDS operates by utilizing both patient/organizational-specific data and clinical knowledge, it is important to take the standards that support each of these areas into account [14]. Only 25 studies were found in ScienceDirect to have considered integration of CDS into EHRs (from more than 100 studies that have documented CDS developments). For more information please refer to Paper II. We did not find any study that reports on implementation of a CDS by applying openEHR.

The only study which considers the intersection between openEHR and CDS is [59] in which the idea of integrating guideline rules into openEHR archetypes is discussed.

The selected articles were reviewed in order to find out whether they consider any of the standards related to CDS (i.e., EHR standards, guideline representation standards, and terminology or vocabulary standards). It was observed that standardization of guidelines and integration of guidelines into EHR has been discussed in several studies [59] [60] [61].

The idea of applying standards even for EHR systems is still not mature enough, and it is not surprising to see that researchers rarely consider this in CDS development. For instance, from the 25 studies we reviewed only 6 had considered EHR standardization (all of them applied HL7).

In conclusion, theory supports the benefits offered by integrating CDS into EHRs, still, a great deal of effort should be put into this in order to reach an acceptable level of integration in practice, especially considering standardization aspects of EHR.

Moreover, if we put the the results of the literature review with focus on HCI (see Section 5.1), it is observable that there are only a small number of studies that have considered both HCI and EHR integration while developing CDS as depicted in Figure 6.1.
Figure 6.1: This chart represents how many of the studies have considered integration of CDS into EHRs, as well as HCI in developing CDS.

6.3 The Answer to RQ3

In this study, investigations were carried out into various aspects of developing openEHR-based applications with the focus on the design and development “process” and with the aim of developing “usable” CDS.

As discussed in Section 2.3, openEHR suggests defining various “roles” in developing clinical applications, and to divide responsibilities among different roles. The openEHR two-level software engineering, as might be expected, is compatible with the multi-disciplinary team work suggested in UCD. The clinicians’ expertise can be used by involving them in the domain concept modeling as suggested by openEHR and additionally in user interface design as recommended in the HCI field. The two-level software engineering (see Figure 2.1) suggested by the openEHR community is not by itself enough for developing user-friendly applications inasmuch as it does not consider the importance of involving clinicians in designing and evaluating the GUI. To develop usable clinical applications, a close collaboration between clinicians and IT developers is needed. Moreover, automatic user interface generation results in interfaces with poor usability. This is discussed further in the following.

Regardless of its advantages, the openEHR standard suffers from a rather low adoption rate. Some possible reasons for the low adoption are the complexity of the standard, lack of documentation and training for developers, and a limited set of tools and frameworks available to ease application development (see Paper II). The openEHR community seems to have mostly focused on representing and modeling domain concepts and perfecting the specifications. However, to make openEHR more practical, there is a need for supporting application developers with APIs, frameworks and tools.

Surely, a number of application development projects exist such as the open
source health information platform [62] (OSHIP), the open EHR-Gen framework [63], GastrOS [64], and the openEHR reference framework and application [65] (opereffa). To the best of our knowledge, current openEHR frameworks and tools are based on the idea that clinicians design and create archetypes (and templates) using existing tools. Later on, a GUI, or some GUI artifacts are generated based on these archetypes/templates. In order to improve the GUI design, there is a need for manual adjustment of the GUI or its style files (depicted in Figure 6.2-A). In contrast to this automatic or semi-automatic approach, there is an alternative approach where there is no generation of GUI based on archetypes. Instead, the interface is designed by experts based on the users’ requirements. Afterwards, there is a need to connect this GUI to the archetypes designed by domain experts (illustrated in Figure 6.2-B). Unfortunately, the current frameworks do not provide sufficient support for this approach. Therefore, we have developed an extension, a Java desktop user interface data binding layer, to one of the openEHR application development frameworks, i.e. opereffa with the aim of supporting openEHR Java application developers who develop applications according to the aforementioned approach.
Figure 6.3: The customized user-centered design applied in this study.
6.4 The Answer to RQ4

In this study, we have applied a design and development process that combines UCD and openEHR principles. The suggested approach considers active involvement of the clinicians in design and evaluation of the archetypes, and also the user interface. Moreover, the effect of the archetypes on the user interface has been taken into consideration. This customized UCD approach is depicted in Figure 6.3. The proposed UCD process is compatible with the openEHR software development approach illustrated in Figure 6.2B (see the previous section for details) More about this UCD process can be found in Paper III.

In addition, we have tried to learn from applying UCD in a clinical context. Characteristics of the context, users and tasks that may have an effect on applying UCD are also identified in this study. These characteristics should be taken into consideration in design and development of clinical applications including CDS (see Paper IV).
Chapter 7

Future Work

The main future direction of this study is to address RQ5:

Does openEHR offer any new opportunities for clinical decision support in terms of knowledge representation and reasoning?

Various sub-problems related to this RQ would be:

1. Can openEHR be used to improve the process of knowledge representation and reasoning in clinical decision support?
2. Can clinical decision support benefit from structured, quality validated openEHR-based electronic health records?
3. Is it feasible and practical to integrate clinical decision support interventions into openEHR-based electronic health records?

Moreover, there are other aspects of the study that need more investigations:

- What are the challenges in applying user-centered design in a clinical context and how to tackle these challenges?
- Is the idea of automatic user interface generation acceptable from a human-computer interaction perspective?
Chapter 8

Conclusion

This thesis investigates the question: how can usable openEHR-aware clinical decision support be designed and developed in order to improve the quality of health care? In order to answer this question, several sub-problems were identified to be investigated, and accordingly, several objectives to be accomplished. Both theoretical and empirical research strategies were used in order to address the identified research questions (see Chapter 3). Of the five specified research questions, four are answered in this thesis.

Analysis of state of the art in interplay between HCI and CDS and also the intersection between CDS and EHRs revealed that consideration of both HCI and integration of CDS into EHRs is more appreciated in theory than practice and are yet to be developed (see Paper I and Paper II). Moreover, the experience in designing an openEHR-based clinical application revealed that apart from benefits offered by the openEHR approach such as defining different roles and involvement of users in defining domain concepts, there are various shortcomings that should be improved, for instance the insufficient support for openEHR application developers. Additionally, it was observed that there are characteristics of the domain, tasks and users in the domain that developers should be informed about while applying UCD methods. Finally, several future directions of the research were presented with focus on both the UCD development process, and investigation of openEHR more in depth (see Chapter 7).
[1] D. Bates and A. Gawande, “Improving safety with information technology,” *New England Journal of Medicine*, vol. 348, no. 25, pp. 2526–2534, 2003.

[2] A. Kushniruka, M. Triolab, B. Steinc, E. Boryckid, and J. Kannrye, “The relationship of usability to medical error: an evaluation of errors associated with usability problems in the use of a handheld application for prescribing medications,” in *Medinfo 2004: Proceedings Of The 11th World Congress On Medical Informatics*, vol. 107, p. 1073, Ios Pr Inc, Jan. 2004.

[3] J. Walker, E. Bieber, and F. Richards, *Implementing an electronic health record system*. Springer Verlag, 2006.

[4] P. Reizenstein, “Safety problems in health care cause 100 avoidable deaths,” *Lakartidningen*, vol. 84, pp. 1680–1681, 1987.

[5] H. Hoff, “Motion 2009/10: So278 Patient safety in healthcare - The Parliament.” Website, 2010. [http://www.riksdagen.se/Webbnav/index.aspx?nid=410&typ=mot&rm=2009/10&bet=So278](http://www.riksdagen.se/Webbnav/index.aspx?nid=410&typ=mot&rm=2009/10&bet=So278).

[6] L. Kohn, J. Corrigan, M. Donaldson, and Others, *To err is human: building a safer health system*. Washington, D.C.: NATIONAL ACADEMY PRESS, 1999.

[7] C. Vincent, G. Neale, and M. Woloshynowych, “Adverse events in British hospitals: preliminary retrospective record review,” *Brmj*, vol. 322, no. 7285, p. 517, 2001.

[8] M. R. Chassin, “The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality,” *JAMA: The Journal of the American Medical Association*, vol. 280, pp. 1000–1005, Sept. 1998.

[9] “Crossing the Quality Chasm: The IOM Health Care Quality Initiative.” *Institute Of Medicine (IOM) Website*, 2010. [http://www.iom.edu/Global/NewsQuality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx](http://www.iom.edu/Global/NewsQuality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx).
[10] N. Graham, Quality in health care: Theory, application, and evolution. Aspen publishers, Inc., 1995.

[11] T. Graham, A. Kushniruk, M. Bullard, B. Holroyd, D. Meurer, and B. Rowe, “How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events,” in AMIA Annual Symposium Proceedings, vol. 2008, p. 257, American Medical Informatics Association, Jan. 2008.

[12] A. Hasman, “Challenges for medical informatics in the 21st century,” International journal of medical informatics, vol. 44, no. 1, pp. 1–7, 1997.

[13] R. Greenes, Clinical decision support: the road ahead. Academic Press, 2007.

[14] J. Osheroff, E. Pifer, J. Teich, D. Sittig, and R. Jenders, Improving outcomes with clinical decision support: An implementer’s guide. HIMSS, 2005.

[15] D. F. Sittig, A. Wright, J. a. Osheroff, B. Middleton, J. M. Teich, J. S. Ash, E. Campbell, and D. W. Bates, “Grand challenges in clinical decision support.,” Journal of biomedical informatics, vol. 41, pp. 387–92, Apr. 2008.

[16] R. Greenes, M. Sordo, D. Zaccagnini, M. Meyer, and GJ, “Design of a standards-based external rules engine for decision support in a variety of application contexts: report of a feasibility study at Partners HealthCare System,” Medinfo, 2004.

[17] K. Kawamoto, C. A. Houlihan, E. A. Balas, and D. F. Lobach, “Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success.,” BMJ (Clinical research ed.), vol. 330, no. 7494, p. 765, 2005.

[18] D. Hunt, R. Haynes, S. Hanna, and K. Smith, “Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review,” Jama, vol. 280, p. 1339, Oct. 1998.

[19] J. Bennett and P. Glasziou, “Computerised reminders and feedback in medication management: a systematic review of randomised controlled trials,” Medical Journal of Australia, vol. 178, no. 5, pp. 217–222, 2003.

[20] M. Trivedi, J. Kern, A. Marce, B. Grannemann, B. Kleiber, T. Bettinger, K. Altshuler, and A. McClelland, “Development and Implementation of Computerized Clinical Guidelines: Barriers and Solutions,” Methods of information in medicine, vol. 41, no. 5, pp. 435–442, 2002.

[21] J. Osheroff, J. Teich, B. Middleton, E. Steen, A. Wright, and D. Detmer, “A roadmap for national action on clinical decision support,” Journal of the American medical informatics association, vol. 14, no. 2, p. 141, 2007.
[22] J. Anderson, “Increasing the acceptance of clinical Information,” *MD computing: computers in medical practice*, vol. 16, no. 1, p. 62, 1999.

[23] T. Wetter, “Lessons learnt from bringing knowledge-based decision support into routine use.,” *Artificial intelligence in medicine*, vol. 24, pp. 195–203, Mar. 2002.

[24] E. Berner, *Clinical Decision Support Systems: Theory and Practice (Health Informatics)*. New York, NY 10013, USA: Springer, 2007.

[25] A. Hasman, R. Haux, and a. Albert, “A systematic view on medical informatics.,” *Computer methods and programs in biomedicine*, vol. 51, pp. 131–9, Nov. 1996.

[26] R. Haux, “Aims and tasks of medical informatics,” *International journal of medical informatics*, vol. 44, pp. 9–20; discussion 39–44, 45–52, 61–6, Mar. 1997.

[27] R. Haux, “Medical informatics: Past, present, future.,” *International journal of medical informatics*, vol. 44, pp. 9–20; discussion 39–44, 45–52, 61–6, Mar. 1997.

[28] M. Collen, “Origins of medical informatics,” *Western Journal of Medicine*, vol. 145, pp. 778–785, 1986.

[29] R. S. Ledley and L. B. Lusted, “Reasoning Foundations of Medical Diagnosis: Symbolic logic, probability, and value theory aid our understanding of how physicians reason,” *Science*, vol. 130, pp. 9–21, July 1959.

[30] I. Iakovidis, “Towards personal health record: current situation, obstacles and trends in implementation of electronic healthcare record in Europe.,” *International journal of medical informatics*, vol. 52, no. 1-3, pp. 105–15, 1998.

[31] B. Blobel, “Advanced and secure architectural EHR approaches.,” *International journal of medical informatics*, vol. 75, no. 3-4, pp. 185–90, 2006.

[32] J. Ash and D. Bates, “Factors and forces affecting EHR system adoption: report of a 2004 ACMI discussion,” *Journal of the American Medical Informatics*, pp. 8–12, 2005.

[33] V. Stroetmann, D. Kalra, P. Lewalle, J. Rodrigues, and KA, “Semantic Interoperability for Better Health and Safer Health Care,” *Deployment and Research*, no. January, 2009.

[34] P. Schloeffel, T. Beale, G. Hayworth, S. Heard, and H. Leslie, “The relationship between CEN 13606, HL7, and openEHR,” in *Health Informatics Conference (2006)*, vol. 7, p. 24, Health Informatics Society of Australia, 2006.

[35] “openEHR.” Website, 2010. [http://openEHR.org](http://openEHR.org).
[36] L. Bird, A. Goodchild, and Z. Tun, “Experiences with a two-level modelling approach to electronic health records,” Journal of Research and Practice in Information Technology, vol. 35, pp. 121–138, Apr. 2003.

[37] T. Beale and S. Heard, “openehr architecture overview.” Website, 2008. [http://www.openehr.org/releases/1.0.2/architecture/overview.pdf](http://www.openehr.org/releases/1.0.2/architecture/overview.pdf).

[38] M. Eichelberg, T. Aden, J. Riesmeier, A. Dogac, and G. B. Laleci, “A survey and analysis of Electronic Healthcare Record standards,” ACM Computing Surveys, vol. 37, pp. 277–315, Dec. 2005.

[39] “CEN.” Website, 2011. [http://pangea.upv.es/en13606](http://pangea.upv.es/en13606).

[40] J. Gupta, G. Forgione, and M. Mora, Intelligent Decision-making Support Systems: Foundations, Applications and Challenges. Springer-Verlag New York, Inc. Secaucus, NJ, USA, 2006.

[41] T. Hewett, R. Baecker, S. Card, and T. Carey, “ACM SIGCHI Curricula for Human-Computer Interaction,” 1996.

[42] M. G. Helander, T. K. Landauer, and P. V. Prabhu, Handbook of Human-Computer Interaction. Elsevier Science Pub Co, Aug. 1998.

[43] ISO 9241-11, Ergonomic requirements for office work with visual display terminals (VDTs):Part 11: Guidance on usability. Geneva, Swiss: International Organization for Standardization, 1998.

[44] M. Maguire, “Methods to support human-centred design,” International Journal of Human-Computer Studies, vol. 55, pp. 587–634, Oct. 2001.

[45] H. Sharp, Y. Rogers, and J. Preece, Interaction Design: Beyond Human-Computer Interaction. Wiley, 2007.

[46] K. Vredenburg, S. Isensee, and C. Righi, User-Centered Design: An Integrated Approach. Prentice Hall PTR, Upper Saddle River, NJ, 2002.

[47] ISO 13407, Human-Centred Design Process for Interactive Systems. Geneva, Swiss: International Organization for Standardization, 1999.

[48] “User-Centered Design.” Website, 2010. [https://www-01.ibm.com/software/ucd/ucd.html](https://www-01.ibm.com/software/ucd/ucd.html).

[49] B. Oates, Researching information systems and computing. Sage Publications Ltd, 2006.

[50] E. Årsand and G. Demiris, “User-Centered methods for designing patient-centric self-help tools,” Informatics for Health and Social Care, vol. 33, no. 3, pp. 158–169, 2008.
[51] R. A. K. Horasani, M. I. T. Anasijevic, B. L. M. Iddleton, and M. S. C, “Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality,” Journal of the American Medical Informatics Association, vol. 10, pp. 523–530, 2003.

[52] K. Kawamoto and D. Lobach, “Proposal for fulfilling strategic objectives of the US roadmap for national action on decision support through a service-oriented architecture leveraging HL7 services,” Journal of the American medical, pp. 146–155, 2007.

[53] I. Cho, J. Kim, J. H. Kim, H. Y. Kim, and Y. Kim, “Design and implementation of a standards-based interoperable clinical decision support architecture in the context of the Korean EHR,” International journal of medical informatics, vol. 9, pp. 611–622, July 2010.

[54] Y. Huang, L. Noirot, and K. Heard, “Migrating toward a next-generation clinical decision support application: the BJC HealthCare experience,” in AMIA Annual, pp. 344–8, Jan. 2007.

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

[56] S. Porter, “An update of the etiology and management of xerostomia,” Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology & Endodontics, vol. 97, pp. 28–46, Jan 2004.

[57] M. Jontell, U. Mattsson, and O. Torgersson, “MedView: an instrument for clinical research and education in oral medicine,” Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics, vol. 99, pp. 55–63, January 2005.

[58] J. Gulliksen, B. Göransson, I. Boivie, S. Blomkvist, J. Persson, and A. s. Cajander, “Key principles for user-centred systems design,” Behaviour & Information Technology, vol. 22, pp. 397–409, January 2003.

[59] R. Chen, P. Georgii-hemming, and H. Å hlfeldt, “Representing a Chemotherapy Guideline Using openEHR and Rules,” Medical Informatics, pp. 653–657, 2009.

[60] S. Barretto, J. Warren, A. Goodchild, L. Bird, S. Heard, and M. Stumptner, “Linking guidelines to Electronic Health Record design for improved chronic disease management,” in AMIA Annual Symposium Proceedings, pp. 66–70, American Medical Informatics Association, Jan. 2003.

[61] G. Schadow, D. C. Russler, and C. J. McDonald, “Conceptual alignment of electronic health record data with guideline and workflow knowledge,” International journal of medical informatics, vol. 64, pp. 259–74, Dec. 2001.

[62] “OSHIP.” Website, 2011. http://www.oship.org/
[63] “Open-EHR-Gen.” Website, 2011. http://code.google.com/p/open-ehr-gen-framework/.

[64] “GastrOS.” Website, 2011. http://sourceforge.net/projects/gastros

[65] “opereffa.” Website, 2011. http://opereffa.chime.ucl.ac.uk/introduction.jsf.
Part II
Publications
Towards Interaction Design in Clinical Decision Support Development: A Literature Review

Hajar Kashfi

*International Journal of Medical Informatics, Elsevier.*

(manuscript submitted)
Towards Interaction Design in Clinical Decision Support Development: A Literature Review

H.Kashfi

Department of Applied Information Technology
Chalmers University of Technology
SE–412 96 Göteborg, Sweden

Abstract

Aim: After motivating the importance of human-related factors in developing highly adoptable clinical decision support systems (CDSS) according to the previous studies, this paper presents the results of a literature review on clinical CDSS published literature, with a focus on interaction design (ID) activities that naturally deal with human-related factors in designing interactive systems. Methods: Two related databases were searched without any limitations on the publication year. The search yielded a final collection of 17 studies. Relevance criteria included (i) discussing development and or evaluation of a CDSS (ii) taking one or several ID activities into account. Results: It was observed that the main emphasis of the literature has so far been on evaluation after design which is more compatible with the traditional view of human-computer interaction (HCI) rather than ID. It was also observed that evaluation methods that are based on user participation were used more often than evaluation based on usability expert participation. The review results indicate a need for disseminating the knowledge gained by experience and the existing ID knowledge among CDSS developers. Conclusion: To develop highly adoptable CDSSs and in order to overcome the chronic problem of CDSSs not being used in practice, human-related factors are considered to play an important role. ID (or more traditionally HCI) deals with such factors with an aim to develop usable interactive products. Applying the existing ID knowledge and adopting various methods to support ID in the clinical domain and especially in developing CDSSs provides highly valuable opportunities in developing more usable CDSSs and clinical applications in general. Nonetheless, the adoption rate of ID activities among CDSS developers is low. Educating CDSS developers about such existing approaches and methods, together with disseminating the knowledge gained by experience in applying ID in developing CDSSs are two means to improve the current situation.

Keywords: clinical decision support, clinical decision support system, user-centered design, usability, qualitative evaluation, interactive system design, user interface evaluation, human-computer interaction, interaction design

Corresponding author
Email address: hajar.kashfi@chalmers.se (H.Kashfi)
1. Introduction

More than 40 years of research have been spent on clinical decision support (CDS) but as many studies reveal, clinical decision support systems (CDSS) have been more appreciated in theory than in practice [1, 2]. Many of the developed CDSSs are mostly research prototypes and designed for a specific context [2, 3], therefore not suitable for mainstream use. Consequently, CDS is still suffering from a low adoption rate [4, 5, 1, 2, 6]. Several researchers have been dealing with specifying challenges that developers of such systems face, and defining success factors. The final aim of these studies is to provide insight in developing more acceptable and adoptable CDSSs. Many of these challenges and success factors belong to the category of human-related factors and goes under the definition of usability. This has been the focus of the interaction design (ID) research field for years. ID suggests various methods to design and evaluate interactive systems with focus on users of such systems with the aim of achieving usability and user satisfaction. The interesting question is whether developers of CDSSs have applied the existing knowledge in order to develop more acceptable CDSSs or not at the time usability evaluation is considered to be crucial for developing interactive applications.

In an effort to discover the practical attitude of CDSS developers towards human-related factors and ID, this paper reviews the related literature to find out more about the practical attitude of the CDSS developers towards ID and the related concepts. We will start with a review on difficulties and success factors reported in developing CDSSs. Then, results from the literature review is presented. We will end with analysis of the results and suggestions for further studies.

2. Background

The issue of applying computers in clinical decision making is a challenging problem [1]. This difficulty is not limited to complex decision support processes. Even in the easiest cases, the process of design, development, deployment and maintenance of a CDSS requires a huge amount of effort.

Several studies have been conducted in order to answer the question of which factors should be considered in design and development of CDS to result in an acceptable and effective CDS? A broad range of difficulties and success factors in developing CDS have been identified accordingly. A discussion of what has been observed in these studies is presented in the following; in addition, a summary of the factors reported in these studies is tabulated in Table 1.

- Technical Factors

A great deal of focus is on the issues related to knowledge extraction and maintenance. Some of the technical factors reported in these studies are: compatibility with the legacy systems [4], knowledge extraction [7, 4, 8, 6, 9], reliability of the knowledge, and taking knowledge from reliable sources [9, 7], maintaining, improving and monitoring the knowledge base [9, 8, 8, 4, 7, 6], and creating new types of CDS interventions [5].

One of the other technical factors observed in the literature is integration of CDS into the systems that are used to record, organize, and retrieve digitally stored health care information of individual patients (electronic health record (EHR) systems). Integration of CDS into EHR systems as one of the factors that are beneficial in wider adoption of CDS, is advocated in several studies [2, 1, 5, 4, 7, 10]. Several studies discuss that delivery of decision support through EHR can improve the quality of care [4, 3, 11, 12]. In overall, EHR is considered as a leverage for CDS [6, 1].
• Efficiency

Being time efficient is considered to be one of the factors that affects adopting CDS [9, 8]. Efficient data entry is one other factor discussed in the literature [8, 13]. One suggestion to improve efficiency has been to remove tedious duplicate data entry required by some CDSSs [7] and to utilize existing data for instance by integrating the CDS into EHR systems.

• Users’ interaction with the system

The importance of user interface design is reported in various studies [14, 7, 5]. Considering the interaction of the user with the system is important in identifying how the system is expected to be used [7]. There are many CDSSs that are reported to be implemented but are not used in practice due to the poor user interface design among other factors [14]. In the ranked list of ten grand challenges in CDS development by Sitting et al. [5] the most important challenge is considered to be improving the user interface. It should be noted that clinical information systems with low usability not only do not improve patient care and reduce clinical errors, but also may have the opposite effect [15, 16, 17, 18, 19, 20]. According to the literature, some detailed factors related to the interaction of users with CDS are as follows: being understandable and controllable [9], anticipating when and what information is needed and real time delivery of best knowledge available to overcome that need at the point of care [8, 6, 21], and changing direction rather than stopping clinicians [8].

• Workflow

Beside proper design of the user interface other human-related factors such as cultural issues, users’ workflow and the complex context of use have been considered important factors in developing CDS [22, 7]. It is observed that the success of CDS is in relation to its integration to the complex clinical environment [22]. CDS should fit and be integrated into users’, i.e. clinicians’, workflow [8, 21, 4]. Especially since clinicians are resistant to changes in their workflow [8]. Integration of the CDS to both culture and the care workflow is considered to be necessary [7] in order for these systems to be used optimally.

• Users’ satisfaction and acceptance

As mentioned before, it has been demonstrated that CDS can have a potential influence on health care, but there will be no effects on improvement in health care if the developed system is not accepted by users and is not used in practice [7]. In order to design an acceptable CDS it is required to understand clinicians’ characteristics [8]. Adoption planning of a CDS should be done in relation to the end users [9]. It is recommended that in case of using commercial products, the system should be customizable for local use [13]. Finally, users should be trained properly for using the system and they should also be informed about limitations of providing automatic CDS so that their expectations are adjusted [13]. All in all, user acceptance and satisfaction are considered to be important factors in adopting CDS [4], therefore, measuring and considering the user reaction to the CDS is crucial in order to develop a successful application [23].

• Monitoring, getting feedback and evaluating
In order to improve the CDS and also to keep the knowledge base updated, maintenance of CDS and getting feedback from clinicians is needed [4, 8]. Clinicians should somehow be motivated to apply CDS [7]. Effectiveness of CDS should be evaluated by the health organizations [7]; moreover, health organizations should monitor the usage of the system after deployment [8, 21, 13, 23, 1] to assure proper adoption of CDS by clinicians.

| Who                  | Year | Difficulties and success factors | non-technical | technical |
|----------------------|------|----------------------------------|---------------|-----------|
| Wetter [9]           | 2002 | Planning in relation to the end users |               | Reliability of the knowledge base |
|                      |      | Time and cost efficiency         |               | 1         |
|                      |      | Understandability and controllability |           |           |
| Trivedi et al. [23]  | 2002 | Human related issues             |               | Technical issues |
|                      |      | Organizational issues            |               |           |
| Bates et al. [8]     | 2003 | Efficiency                       |               | Maintaining the knowledge base |
|                      |      | Real time delivery of information |               |           |
|                      |      | Presenting correct information at the correct time | |           |
|                      |      | Fitting into user’s workflow     |               |           |
|                      |      | Changing direction rather than stopping | |           |
|                      |      | Understanding clinicians’ characteristics | |           |
|                      |      | Simple interventions             |               |           |
|                      |      | Efficient data entry             |               |           |
|                      |      | Monitoring and getting feedback  |               |           |
| Kawamoto et al. [21] | 2005 | Integration of automatic decision support to clinician’s workflow | Computer aided decision support | |
|                      |      | Timely access to decision support at point of care | |           |
|                      |      | Providing actionable recommendations | |           |
|                      |      | Monitoring the use of system after deployment | |           |
| Garg et al. [4]      | 2005 | User acceptance                  |               | Being compatible with the legacy systems |
|                      |      | Integration to the user workflow | | Maturity of the developed system |
|                      |      | System maintenance               |               |           |

Table 1: Clinical Decision Support Challenges (continued on next page).

1 In this paper 22 technical and non-technical factors are specified five of which are considered to be highly correlated to the success of CDS.
Table 1: Clinical Decision Support Challenges (continued from previous page)

| Who                | Year | Difficulties and success factors non-technical | technical |
|--------------------|------|-----------------------------------------------|-----------|
| Osheroff et al. [6] | 2007 | ◦ Social and technical aspects of developing a CDSS 2  
◦ Best knowledge be available when needed  
◦ High adoption and effective use | ◦ Natural complexity of decision making  
◦ Knowledge extraction issues  
◦ Continuous improvement of knowledge and CDS interventions |
| Berner et al. [13] | 2007 | ◦ Data entry process  
◦ User interface and vocabulary  
◦ Motivation of use for clinicians  
◦ Informing users about the limitation  
◦ User training  
◦ Evaluation of the system  
◦ Customizing commercial applications for the local use  
◦ Monitoring the usage of the system after deployment | ◦ Knowledge-base creation and maintenance  
◦ Reliable knowledge base  
◦ Monitoring and maintaining the knowledge base |
| Sittig et al. [5]  | 2008 | ◦ Improving the effectiveness of CDS interventions | ◦ Creating new interventions  
◦ Disseminating existing CDS knowledge and interventions |
| Cho et al. [10]    | 2010 | ◦ Defining a national CDS architecture 3  
◦ Integration to the EHR context  
◦ Having access to a sustainable and robust CDS  
◦ A sharable and reusable knowledge base | |

2 In this paper three pillars in order to increase the widespread adoption of effective CDS are demonstrated. Several activities are also recommended considering these three pillars.

3 Cho et al. in 2010 published their experience in defining and implementing a national CDS architecture with the aim of broad adoption of CDS services in Korea. The goal of this study has been to "achieve widespread adoption of EHR by health care organizations to improve the quality, safety, and efficiency of care", "to establish a sharable lifetime EHR system to improve the quality of care and reduce health care costs incurred by care redundancy in Korea". They demonstrate that to reach these goals it should be assured that clinical application providers have access to a "sustainable and robust CDS" when it is needed.

Putting technical factors aside, the related literature suggests the importance of (i) understanding users, i.e. clinicians, their needs and characteristics and designing a system according to them (ii) understanding users’ workflow and design a system that fits into the workflow and requires the minimum changes in the workflow (iii) user interface and the way users interact with the system (iv) efficiency of the system (v) finally, getting feedback from users and assuring users’ satisfaction and acceptance.

The interesting point is that the aforementioned issues have not been in focus just in the CDSS field. Around 30 years ago, the need for investigating such factors in developing inter-
active systems in various domains resulted in the creation of a multidisciplinary field concerned
with designing, evaluating and implementing usable interactive systems with focus on users of
such systems, i.e. human [24, 25]. This field is called Human-computer interaction (HCI) and
later extended to Interaction design (ID) [26]. More about interaction design is discussed in the
following section.

2.1. Interaction Design

ID concerns the development of interactive systems that are usable [26]. By usable it is meant
easy to learn, effective to use and providing an enjoyable user experience [26]. User experience
is how a user feels about a specific product and includes various qualities such as satisfaction
and pleasure [26]. ID is concerned with theory, research and practice of design [26] and covers
a wider scope of issues, topics and paradigms compared to what HCI has traditionally been con-
cerned with [26]. Sharp [26] defines ID as “designing interactive products to support the way
people communicate and interact in their everyday and working lives.” ID relies on understand-
ing the people, i.e. users, what they desire to perform, i.e. tasks and goals, their characteristics
and capabilities, and the technology available. Moreover, it involves the knowledge of identifying
requirements and evolving them into a proper design solution [26]. The ID process involves
the following activities [26]:

- “Identifying needs and establishing requirements for the user experience”
- “Developing alternative designs that meet those requirements”
- “Building interactive versions of the design”
- “Evaluating what is being built throughout the process and the user experience it offers”

The heart of ID process is evaluation of the design solution and to ensure that the product is
usable. This is addressed via a user-centered design (UCD) approach [26].

2.2. User-centered Design

UCD means that in a development process, the real users of the product, their goals and not
just the technology should be considered as the driving forces. As it is suggested by its name,
UCD aims for involving users throughout the design process. There are various methods and
techniques that help to achieve this. Three principles are considered to be the basis for UCD.
These principles are:

- Early focus on users and tasks: understanding users and involving them in the design
  process (see Section 2.7 and Section 2.6).
- Empirical measurement: observing and measuring performance and reactions of users
  when they interact with the product (see Section 2.8).
- Iterative design: repeating the cycle of design, evaluate and redesign as often as required
  (see Section 2.4).

UCD principles appear to be obvious metrics but they are not easy to put into practice [26]. More
about the concepts related to ID and UCD can be found in the following sections.
2.3. The Life-cycle Model

To perform ID, two factors are important (i) understanding of the ID activities (ii) specifying the relation of activities to one another and the full development process [26]. The latter is called life-cycle model or process model. A life-cycle model may also include the when, and how to move from one activity to the next one, also the description of the deliverables of the activities [26].

2.4. Iterative Design

To design an interactive system, a clear understanding of the requirements is necessary. Nevertheless, it is observed that not all of the system requirements can be found before starting the design [27]. To overcome this problem, the idea of iterative design was introduced. The core idea of iterative design is to have a design process that tries to overcome the problem of incomplete requirements specification. This is realized by cycling through the process of design and incrementally improving the product produced in each pass.

Iterative design involves using prototypes. Prototypes are defined by Dix [27] as “artefacts that simulate or animate some but not all features of the intended system.” Prototypes are useful in discussing ideas with stakeholders and they can be used as a communication mean among the team members [26]. Prototyping provides cheaper and faster opportunities to evaluate a design solution. A prototype complexity can range from a simple paper-based simulation of the system to a complex piece of software [26].

2.5. Different Types of Requirements

Sharp [26] defines requirement as “a statement about an intended product that specifies what it should do or how it should perform”. Requirements should be specified as clearly as possible via the requirements gathering activities. There are different kinds of requirements such as functional requirements, environmental requirements, i.e. the circumstances in which the system will be used (context of use), usability requirements, and user characteristics [26]. Therefore, it is important to apply data gathering techniques in a way that this broad range of issues are covered.

2.6. Data gathering methods

Data gathering methods are used to collect sufficient, precise and relevant data with the aim of producing the requirements [26]. The users’ tasks, their related goals, the context in which the tasks are performed and the rationale for the current situation are the most important information that is needed to be collected via data gathering techniques. Data gathering techniques are also used in evaluation processes to collect users’ reaction and performance with the prototype of the intended system [26, 28]. Interview, questionnaire, observations, studying documentation, and researching similar products are some of the data gathering techniques [26]. Selection of the data gathering techniques should be based on the participants involved and the nature of the technique. In order to triangulate the results, usually, data gathering techniques are combined [26].

2.6.1. Interview

Interview is a friendly and flexible data gathering technique where a goal oriented conversation is conducted with the interviewee [28, 26, 27]. In evaluation, interviewing users about their interaction with the system provides an opportunity to gather information about the user’s experience. Various types of interviews are defined based on the amount of control the interviewer imposes on this conversation: structured, unstructured, semi-structured and group interview [26].
2.6.2. **Observation**

Observation is a popular data gathering technique that gathers information about how users achieve a task in the context and also the actual interaction of users with the system [26, 27]. One problem with simple observation is that it does not provide insight into the user’s decision process and attitude while interacting with the system [27]. One approach to overcome this problem is to ask users to verbalize their thoughts. This technique is called **think aloud** [26, 27].

2.6.3. **Questionnaire and Survey**

Questionnaires are a set of pre-designed questions that are used for collecting demographic data and users’ opinions [27, 26]. Questionnaires are less flexible than interviews but they can target a larger group of participants and they help in gathering more precise information [27, 28]. They need less administrative time, and the analysis of the gathered information can be done more rigorously [27].

2.6.4. **Usability Engineering**

Usability engineering is an approach to UCD where a **usability specification** is produced as a part of the requirements specification. This specification includes the exact criteria, i.e. usability goals, against which the system will be evaluated. In order to set up usability goals, there is a need to specify relevant measurable usability characteristics of the product, i.e. usability attributes [25] and to decide how they are going to be measured.

2.7. **Task Analysis**

In order to design interactive systems, it is crucial to have a clear understanding of the tasks the users want to perform [27]. Task analysis is focused on studying the user’s actions and and/or cognitive processes to achieve the tasks [29]. It deals with existing systems and procedures and investigates the existing situation [26, 27]. It also contributes to the new system requirements specification [27]. Task analysis involves using various data gathering techniques such as interviews and questionnaires [30].

2.8. **Design Evaluation**

Even in case of applying UCD, there is a need to assess the design solution and to make sure that the requirements are met [27]. This is the aim of evaluation. It is recommended not to consider evaluation as a single phase in the design process but to carry it out throughout the system life-cycle and to consider evaluation results in improving the design solution [27]. Evaluation should involve assessing not only the functional capabilities of the system, but also the users’ interaction with the system, their experience and the impact of the interaction on her/him. Therefore, various aspects such as learnability (how easy it is to learn the system), usability and the user’s satisfaction should be considered in evaluation.

Various categorizations of evaluation methods are documented in the literature [25, 26, 27]. Helander in [25] defines two main classes of methods. The first class includes those methods that rely on the users’ participation in the evaluation. This class of evaluations is called **empirical** evaluation methods [25]. The second class of methods does not rely on direct user involvement but on designers’ or usability experts’ judgment of the design. These methods are called **usability inspection** or non-empirical evaluation methods [25] (Dix [27] calls this class **expert analysis** methods). Another categorization of methods exists in [26] that divides methods into three categories of **usability testing**, **field study** and **analytical evaluation**. In this paper, the categorization made by Helander [25] is used for referring to methods.
2.8.1. Empirical Evaluation Methods

Usability testing and field studies are two empirical evaluation approaches. Both usability testing and field studies use basic data gathering techniques (observation and interview) to gather information on how users interact with a system or how they perform a task. Their main difference is in the settings the observation is performed in.

Usability test is a collection of methods used to evaluate the usability of a product. It is typically focused on how well a user can use the product to accomplish a specific task, and also errors that occur during this process [27]. Usability test [26] involves observing a user while the user is interacting with the system. It is performed in a controlled environment for instance in a laboratory setting. This means that in this type of observation the test users are isolated from the usual interruptions in their everyday work.

In contrast to usability testing, field study [26] involves observing users in their natural work settings. Field studies can be helpful in requirements gathering as well as evaluating a system.

2.8.2. Usability Inspection Methods

There are circumstances in which developers do not easily have access to users, user participation is too expensive or it takes too much time to involve them. In those situations, usability inspection methods can be used to discover design flaws since in contrast to empirical evaluation methods, in this category of evaluation methods users do not need to be present [26]. In addition, for empirical evaluation methods, normally a working prototype or implementation of the system is required while usability inspection methods can be performed on very early designs and prototypes. In the following, three main methods that belong to this category of evaluations are given.

Heuristic Evaluation

Dix defines heuristic [27] as “a guideline or general principle or rule of thumb that can guide a design decision or be used to critique a decision that has already been made.” Heuristic evaluation is a methods that applies a set of heuristics to discover the design flaws. Heuristic evaluation can be performed early in the project even on the design specification. This method is considered to be one of the cheapest evaluation methods [27]. It is also called a resource constraint method since running this method does not need a deep knowledge in usability and ID and it can be done by developers in case the project team does not have access to usability experts [25].

Walkthroughs

Walkthroughs are alternative approaches to heuristic evaluation. The same as heuristic evaluation, walkthroughs rely on predicting users’ problems without carrying out user tests [26]. Walkthroughs involve walking through a specific task and discovering the usability problems. The focus in walkthroughs is on learnability of the system, i.e. how easy the system is to learn [25, 26].

Usually, walkthroughs do not involve users, however, in a sub-class of walkthroughs named pluralistic walkthroughs [25, 26], users, developers and usability experts work together to find out usability problems of the design solution.

Usability-Expert Reviews

Usability-Expert review is an evaluation method when usability experts review a system design against standard and best practice design solutions in order to find out general design flaws
This method is very similar to heuristic evaluation. The main difference is that in this method, experts usually do not use heuristics to run the test. They actually rely on their own experience with system and users to identify the source of difficulties in the GUI design [25].

2.9. User-centered Design in Developing Clinical Decision Support Systems

Involvement of end users, i.e. clinicians, in the design process and adjustment of the design based on their feedback is one way to improve the acceptance of a CDSS. This is achieved by understanding clinicians, their characteristics, their goals and the tasks that they wish to perform, and consequently by producing a usable CDSS that fits to that specific clinical context.

As evident from the discussion in the previous sections, ID provides the knowledge required by CDSS developers (and generally developers of all types of products) in order to develop highly adoptable CDSSs. But the question is whether this knowledge is applied by the developers or not. This has been the motivation of conducting this systematic review.

3. Search Method

Systematic review is a research methodology that aims at summarizing the available literature on a topic and presenting an analysis based on that and providing a full picture on the topic [31]. In this study, a systematic review is used to analyze state of the art in CDSS developers’ attitude towards ID and ID activities.

The publications were selected from two databases namely ScicenDirect\(^1\) and PubMed\(^2\). These two databases cover the most important journals in medical informatics, ID and also well-known conferences in medical informatics.

The search was performed using various boolean combinations of these keywords: “medical decision support”, “clinical decision support”, “user-centered design”, usability, “user involvement”, “interaction design” and “human-computer interaction”. Later, in two steps, the abstracts and the contents of the returned results were studied and the most relevant papers were selected. The search strategy is depicted in Figure 1. Criteria for selection of the papers were positive answers to these questions:

- Is the study discussing development and or evaluation of a CDSS (i.e. practical science)?
- Are any of the ID concepts or activities considered in the study (i.e. ID consideration)?

The literature was reviewed to discover whether the ID related concepts, methods and approaches are documented by the authors. A list of related concepts and methods was incrementally created based on what was found in the literature (see Table 2 for the list).

4. Results

The literature was reviewed to find out which ID/HCI activities and concepts are documented by authors. An overview of the ID principles and methods presented in these studies is shown in Figure 4. The results from this review are presented in the following. More analysis of the results is given in the next section.

\(^1\)http://www.sciencedirect.com
\(^2\)http://www.pubmed.gov
4.0.1. Importance of the User Interface

The literature indicates a general consensus that usability of the user interface plays an important role in the system acceptance and reducing technology-induced errors [32, 33, 34, 35, 36, 15].

Figure 1: The search strategy

Figure 2: only in around 24% of cases the concept of life-cycle of the system, and/or consideration of user-centered design as a process is reported.
4.1. Evaluation Before or After Releasing the Application

Evaluation before releasing the application is typically conducted on a prototype of the system [33, 37, 23, 34, 38, 35, 39, 40, 36, 15, 41, 42, 43]. On the other hand, there are cases in which evaluation is done after releasing the system [32, 44, 45, 46]. In some cases authors do not make it clear whether the evaluation is made on the system after release or in early stages of the project before releasing the application [39].

4.1.1. User Involvement

Evident from the literature, involving users in evaluation (see Section 4.2) is more common than involving them in design. Very few of the studies have documented involvement of users in design (two studies [38, 35]).

4.1.2. Context of Use

Few studies documented efforts to understand clinicians, their characteristics and the context of use [41, 42].

4.1.3. The life-cycle model

In contrast to most of the literature, there are few studies that have presented a life-cycle view on UCD [35, 36, 42]. Some researchers have concluded that using UCD as a process throughout the whole life-cycle of the system is necessary to design a usable CDS [42].

4.2. Empirical Evaluation

As evident from Table 2, empirical evaluations such as observations [32, 47, 35, 41, 15, 42, 46, 43], interviews [32, 33, 38, 39, 42], questionnaires/surveys [48, 23, 38], field study [48, 49, 41, 42], usability tests [48, 33, 37, 34, 36, 15, 41, 42], and think aloud [33, 37, 38, 35, 15, 42] are the most popular evaluations documented in the literature.

4.3. Non-empirical Evaluation

Literature suggests that documented cases of applying non-empirical evaluation methods are much fewer than those of empirical methods. For instance, cognitive walkthrough and heuristic evaluation are applied only in two of the studies [37, 35]. Expert review is missing in the literature.
4.3.1. Challenges and Benefits

The literature indicates a general consensus that applying various ID methods, and the UCD process is effective; and results in more usable CDSSs and will eventually increase the usage of the system [37, 38, 36, 41]. Nevertheless, some of the studies have concluded that applying UCD and some of its methods is difficult and challenging [37, 50].

4.4. Summary of Findings

- The qualitative evaluation on the system was performed after releasing the system to the users in around 24% of the studies.
- Prototyping is used in 76% of the studies.
- The concept of iterative design is considered in 65% of the studies.
- Only in 24% of the studies the concept of life-cycle of the system, and/or consideration of user-centered as a process is reported (see Figure 2)
Evaluations based on “user participation” (i.e. empirical evaluations) are popular among developers of CDS (see Figure 3). As depicted in Figure 6, “interview” is used in 88%, “questionnaire” in 59%, “usability test” in 53% and “field study” in 25% of the studies.

- Only around 18% of the studies have applied non-empirical evaluations (heuristic evaluation, and cognitive walkthrough each in 12% of cases).

5. Discussion

As evident from Table 1, success factors of CDSSs can be divided into two main categories of technical and non-technical factors. The ID community specifies various methods that help developers assure these human-related aspects of the system. The aim of this literature review was to investigate whether existing knowledge in the ID field is applied properly by developers of CDSSs with the aim of developing more acceptable and adoptable CDS. In the following, a more detailed analysis of the literature is provided along with discussions to provide insight into the practical attitude towards ID in the CDS field.

5.1. Interaction Design in Practice

The search strategy in this review resulted in discovering only 17 studies which is a small number compared to the number of CDSSs being developed and evaluated. Only in one of the databases, ScienceDirect, around 100 studies were discovered that, according to their titles and abstracts, have documented developing and/or evaluating a CDSS.

Studies are distributed from 1997 to 2010\(^3\). More than half of the studies are published after 2006. This indicates that consideration of ID/HCI in developing CDSSs is becoming more popular in recent years.

5.1.1. Early focus on Users and Tasks

The first UCD principle is to have early focus on users and tasks (see Section 2.2). This means that users should be understood and involved in the full design process from the beginning. This however does not mean that users should be actively involved in design or act as

\(^3\)The search was carried out in October 2010. So it may not include all of the 2010 publications.
| Reference | [32] | [33] | [37] | [23] | [34] | [44] | [45] | [38] | [35] | [39] | [40] | [36] | [15] | [41] | [42] | [46] | [43] |
|-----------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Year      | 97   | 98   | 02   | 02   | 03   | 04   | 05   | 06   | 07   | 07   | 08   | 08   | 09   | 09   | 09   | 09   | 10   |
| UCD       | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    |
| Life-cycle| x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    |
| Cognitive aspects | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x |
| Eval. Before | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Eval After * | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Multi-disciplinary team | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x | x |
| Iterative design | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Usability | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    | x    |
| Usability test | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Usability engineering | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| User involvement | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Think aloud | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Prototyping | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Interview | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Questionnaire | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Survey | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Walkthrough | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Heuristic evaluation | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Field study | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Observation | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Task analysis | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Workflow | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Workflow integration | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Training | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Users involved | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

1 Evaluation before release
2 Evaluation after release
3 It is called problem
4 It is called interview
5 Not clear in the text, obtained from correspondence with the author.
6 It is mentioned in the paper but is not used practically

Table 2: Human Computer Interaction and Clinical Decision Support in practice (note that ✓ indicates the concept/method is applied in the study.)
designers. It is enough if users are consulted when making design decisions [26]. To support the importance of understanding the users, their goals and tasks, Sharp [26] indicates: “if something is designed to support an activity with little understanding of the real work involved, it is likely to be incompatible with current practice, and users do not like to deviate from their learned habits if operating a new device with similar properties.” Various data gathering techniques as well as task analysis can be used to support this principle.

Nonetheless, the review findings demonstrate that CDSS developers have not been widely upholding this principle. Data gathering methods applied in various studies have been mostly used in evaluations rather than gathering various types of requirements (including understanding users, and users’ characteristics and the context of use). Task analysis is used only in one study [36]. Finally, almost none of the studies have documented the usability requirements as a type of requirements used to motivate design and provide basis for evaluation.

All in all, it is evident that benefiting from various data gathering techniques in order to collect different types of requirements is not considered in many of the studies, and the knowledge on this needs to be improved in the field. It is important that those aspects of the clinical context that make it different from other domains in terms of collaborating with users and applying various evaluation or design methods be investigated carefully. Moreover, further investigation is needed to find out why task analysis, and also formal methods for understanding the context have not been popular in the CDS field.

5.1.2. Empirical measurement

The second UCD principle is to observe and measure performance and reactions of users when they interact with the system (see Section 2.2). This principle is satisfied in an acceptable level in the studies documented in the literature. Usability tests, and various data gathering techniques were used to gather users’ feedback and to observe and analyze users’ interaction with the CDSS to discover design problems.

5.1.3. Iterative Design

The third UCD principle is to have an iterative design process (see Section 2.2). Iterative design as mentioned in the results, has been considered in 65% of the studies. In some studies it is not clearly mentioned what has been the goal of evaluations and how or when the evaluation results would be used. Surely, getting users’ feedback and evaluations would be of no use if they do not inform the design. Considering the importance of iterative design in developing usable interactive systems (making informed design improvements based on evaluations), this is an indication of a need for improvement in this area.

5.1.4. Interaction Design versus Human-computer Interaction

As mentioned before, ID focuses on the whole design process but the focal point of most of the studies is on the evaluation. As evident from the reviewed literature, most of the works documented in the literature match the more traditional pattern of HCI rather than ID. The focus of traditional HCI has been mostly on evaluation and pointing out design flaws after design while ID and the UCD approach to ID emphasize not only on the evaluation but also the whole design process.

Moreover, in database searches, using the phrase “interaction design” did not result in any hits. None of the studies has actually used this term in the text. On the other hand, the phrase “human-computer interaction” is used in some of the studies. This is also in line with the aforementioned observation.
5.1.5. The Life-cycle Model

As mentioned in Section 2.3, it is important to specify how various ID activities are going to be carried out in the life-cycle of the system. Also, there is a need for an early planning of the UCD process in order to make various important decisions for instance how many users will be involved in the process and how their involvement is managed [29].

The literature contains very few studies that discuss the theoretical background of UCD as a design and development process that can be used in the life cycle of the project as a complementary process to existing software development methods [42, 36, 35]. In addition, the literature does not include discussions on the UCD planning. This is in line with our observation that the focus lies mostly on evaluation rather than the whole design process.

5.1.6. Design Evaluation

Evaluating design solutions before releasing the application is performed in many of the studies which shows an acceptable level of knowledge on this concept especially in recent years (since only one study [46] was found after 2006 in which evaluation was done after releasing the system). But still, not all of the evaluation methods, especially non-empirical evaluation methods have been applied so often in the field.

There are costs and benefits associated with each class of evaluations. To carry out empirical evaluations, developers should have access to users that are willing to participate in the evaluation process. To accomplish the non-empirical methods, access to usability experts or developers who are able to conduct evaluation is required. If usability experts are not available in the project, getting access to them might be costly for the project.

Regarding benefits linked to each type of evaluation, it is observed that on various occasions, especially in early stages of the project, non-empirical methods (or as it is called in some literature, usability inspection methods) can be used to identify general design flaws, discover the compliance to design standards or heuristics or even detailed qualities such as ease of learning [25]. On the other hand, these methods are not considered to be a replacement for the empirical methods especially since the general consensus is that some type of flaws in the system will be discovered only by having users interact with the system [25].

All in all, it is recommended that choice of evaluation methods be made considering the timing of evaluation, project progress, cost, and most importantly the goal of evaluation. This however is almost absent in the literature reviewed. Also, the goals of evaluation are not clearly specified. There is rare discussion of how various methods are chosen in the studies. For instant just few cases such as [50, 41] discuss benefits and costs associated with various methods. This would indicate the following:

- Users in this domain are easy to access and their involvement in evaluation is cheap.
- Usability experts have not been accessible in such projects and or their involvement is costly for the project.
- Even if the above statements are true, very few cases of applying heuristic evaluations (where even developers with little knowledge on usability can run the test to discover design flaws) suggests the lack of knowledge in this area among CDSS developers. Also, since not all of the design flaws can be discovered by users (especially being compatible by general design patterns) absence of non-empirical methods can be a sign of poor knowledge on ID in this domain.
5.1.7. General Discussion

The problem of low adoption rate of CDS has long been of concern to the researchers in this field. As a response to a need for answering the question of whether a CDSS will be used by users and how it will be used, researchers have previously done studies on various CDSS evaluation approaches [51, 52].

According to a literature review by Kaplan [51], very few evaluations of CDSSs can be found that focus on other aspects such as “why clinicians accept or do not accept a system” or “why they change their practice behavior after introducing the system”. In her literature review on the CDSS evaluation literature [51], Kaplan indicated that “in the evaluation literature, the main emphasis is on how clinical performance changes. Most studies use experimental methods or randomized controlled trials (RCT) to assess system performance or to focus on changes in clinical performance that could affect patient care.” She has profiled 34 CDSS evaluation studies in her review. Of those, only 12 studies had evaluated other aspects than performance using various qualitative evaluation techniques such as observations, interviews, field studies and so on [51].

In another related study [52], she puts steps further forward towards the general issue of evaluating clinical applications in an attempt to call for alternative approaches. She mentions that “unless evaluation approaches include social, organizational, cultural, cognitive, and contextual issues, they cannot answer key questions about why clinicians use or do not use an informatics application.”

While confirming Kaplan’s observations, we indicate that though qualitative evaluation methods may be able to answer the aforementioned questions, they cannot broaden the adoption rate of CDS and the problem of CDSSs not being used in practice, unless they are put together with a well-informed design and development process. This type of evaluation of course provides an opportunity to find out the reasons for low adoption. But to uphold the success factors of CDS documented by researchers in this field (see Section 2), there is a need for activities other than just evaluation. This would include understanding clinicians, their tasks and their goals, understanding their characteristics and the context of use of CDS as recommended in the ID filed.

The next step would be to investigate existing methods and approaches and identify how they fit into the clinical domain. For instance challenges in applying heuristic evaluation is discussed in [50] and is being related to various factors such as complexity of the context, and limitations of the method itself (for instance, the author mentions the existence of some collaborative tasks in the clinical domain in which more than one user is involved in task completion; while heuristic evaluation considers independent evaluators in the evaluation process). In addition, considering that this literature review shows lack of knowledge in some areas, there is a need to disseminate the existing ID knowledge and the knowledge gained by experiences in developing CDSSs among CDSS developers using UCD.
6. Conclusion

It is shown that in the clinical domain, taking human-related (ID-related) factors into consideration is highly recommended in theory especially in recent years.

Although compared to previous studies [51], this review suggests that qualitative evaluations of CDSSs are gaining more interest and attention, the rate of applying various ID methods and the UCD approach is still low among CDSS developers. Especially, compared to other domains such as aviation or automobiles in which usability engineering, and user-centered design is routine practice [47] and even compared to the clinical domain in general. Lastly, further investigations to discover reasons for this are required, also the knowledge on ID and UCD and success stories of applying them in various projects should be disseminated among developers of CDSSs to improve the general attitude towards ID.

7. Future Work

As a continuation to this study, this research question should be answered: What are the challenges in applying user-centered design in a clinical context and how to tackle these challenges?

In order to find an answer to this question, the following objectives should be accomplished:

1. conducting a literature review in order to identify “the state of the art in the intersection between ID and clinical application development” in general
2. gathering and investigating difficulties designers and developers of clinical applications have faced so far
3. gathering and investigating the point of view of a group of developers and clinicians who have been involved in any user-centered design process of a clinical application
4. providing a user-centered design guideline aimed at designers and developers of clinical applications

Acknowledgment

The author extends her gratitude to Olof Torgersson, who provided useful and detailed feedback on the paper.

References

[1] R. Greenes, Clinical decision support: the road ahead, Academic Press, 2007.
[2] T. Wendt, P. Knaup-Gregori, A, Decision Support in Medicine: A Survey of Problems of User Acceptance, Stud Health Technol Inform 77 (2000) 852–856.
[3] B. Chaudhry, J. Wang, S. Wu, M. Maglione, Systematic review: impact of health information technology on quality, efficiency, and costs of medical care, Annals of internal Med 144 (10) (2006) 742–752.
[4] A. Garg, N. Adhikari, H. McDonald, M. Rosas, Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review, JAMA 293 (10) (2005) 1223–1238.
[5] D. F. Sittig, A. Wright, J. a. Osheroff, B. Middleton, J. M. Teich, J. S. Ash, E. Campbell, D. W. Bates, Grand challenges in clinical decision support., Journal of biomedical informatics 41 (2) (2008) 387–92. doi:10.1016/j.jbi.2007.09.003.
[6] J. Osheroff, J. Teich, B. Middleton, E. Steen, A. Wright, D. Detmer, A roadmap for national action on clinical decision support, Journal of the American medical informatics association 14 (2) (2007) 141. doi:10.1197/jamia.M2334.Introduction.
[7] E. Berner, Clinical Decision Support Systems: Theory and Practice (Health Informatics), Springer, New York, NY 10013, USA, 2007.
[34] C. Ying-Jui, A. T. Chirh-Yun, B. Y. Min-Li, B. Yu-Chuan, Li, Assessing the Impact of User Interfaces to the Usability of a Clinical decision support system, in: AIMIA 2003 Symposium Proceedings, 2003, p. 808.

[35] K. 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) 760–768. doi:10.1016/j.ijmedinf.2006.07.011.

[36] A. Narasimhadhevara, 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. doi:10.1016/j.jbi.2007.03.006.

[37] C. Carroll, P. Marsden, P. Soden, E. Naylor, J. New, T. Dorman, Involving users in the design and usability evaluation of a clinical decision support system., Computer methods and programs in biomedicine 69 (2) (2002) 123–135.

[38] S. J. Leslie, M. Hartswood, C. Meurig, S. P. McKee, R. Slack, R. Procter, M. a. Denvir, Clinical decision support software for management of chronic heart failure: development and evaluation., Computers in biology and medicine 36 (5) (2006) 495–506. doi:10.1016/j.compbiomed.2005.02.002.

[39] A. Wilson, A. Duszynski, D. Turnbull, J, Investigating patients’ and general practitioners’ views of computerised decision support software for the assessment and management of cardiovascular risk, Informatics in Primary Care 15 (2007) 33–44.

[40] D. F. Lobach, K. Kawamoto, K. J. Anstrom, M. L. Russell, P. Woods, D. Smith, Development, deployment and usability of a point-of-care decision support system for chronic disease management using the recently-approved HL7 decision support service standard., Studies in health technology and informatics 129 (Pt 2) (2007) 861–5.

[41] T. W. Marcy, B. Kaplan, S. W. Connolly, G. Michel, R. N. Shiffman, B. S. Flynn, Developing a decision support system for tobacco use counselling using primary care physicians., Informatics in primary care 16 (2) (2008) 101–9.

[42] M. Peleg, A. Shachak, D. Wang, E. Karniel, Using multi-perspective methodologies to study users’ interactions with the prototype front end of a guideline-based decision support system for diabetic foot care., International journal of medical informatics 78 (7) (2009) 482–93. doi:10.1016/j.ijmedinf.2009.02.008.

[43] J. Trafton, S. Martins, M. Michel, E. Lewis, Evaluation of the Acceptability and Usability of a Decision Support System to Encourage Safe and Effective Use of Opioid Therapy for Chronic , Noncancer Pain by Primary Care Providers, Pain Medicine 11 (2010) 575–585.

[44] A. S. Young, J. Mintz, A. N. Cohen, M. J. Chinman, A network-based system to improve care for schizophrenia: the Medical Informatics Network Tool (MINT)., Journal of the American Medical Informatics Association : JAMIA 11 (5) (2004) 558–67. doi:10.1197/jamia.M1492.

[45] K. Zheng, R. Padman, M. P. Johnson, H. S. Diamond, Understanding technology adoption in clinical care: clinician adoption behavior of a point-of-care reminder system., International journal of medical informatics 74 (7-8) (2005) 535–43. doi:10.1016/j.ijmedinf.2005.03.007.

[46] J. Saleem, L. Militello, N. Arbuckle, M. Flanagan, Provider Perceptions of Colorectal Cancer Screening Clinical Decision Support at Three Benchmark Institutions, in: AIMIA Symposium Proceedings, 2009, pp. 558–562.

[47] J. Zhang, Human-centered computing in health information systems. Part 1: analysis and design., Journal of biomedical informatics 38 (1) (2005) 1–3. doi:10.1016/j.jbi.2004.12.002.

[48] A. Kushniruk, V. Patel, J. Cimino, Usability testing in medical informatics: cognitive approaches to evaluation of information, in: AMIA Annual Fall Symposium, 1997, pp. 218–222.

[49] M. Beuscart-Zephir, J. Breder, R. Beuscart, J. Menager-depriester, Cognitive evaluation: how to assess the usability of information technology in healthcare, Computer methods and programs in biomedicine 54 (1-2) (1997) 19–28.

[50] 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. doi:10.1016/j.ihcs.2008.06.002.

[51] B. Kaplan, Evaluating informatics applications–clinical decision support systems literature review. (November 2001).

[52] B. Kaplan, Evaluating informatics applications–some alternative approaches: theory, social interactionism, and call for methodological pluralism., International journal of medical informatics 64 (1) (2001) 39–56.
The Intersection of Clinical Decision Support and Electronic Health Record: A Literature Review

Hajar Kashfi

1st International Workshop on Interoperable Healthcare Systems (IHS2011) - Challenges, Technologies, and Trends, Szczecin, Poland, September 19-21, 2011. (manuscript submitted)
The Intersection of Clinical Decision Support and Electronic Health Record: A Literature Review

H. Kashfi

Abstract

Aim: It is observed that clinical decision support (CDS) and electronic health records (EHR) should be integrated so that their contribution to improving the quality of health care is enhanced. In this paper, we present results from a review on the related literature. The aim of this review was to find out to what extent CDS developers have actually considered EHR integration in developing CDS. We have also investigated how various clinical standards are taken into account by CDS developers. Methods: The ScienceDirect database was searched for related studies. The search yielded a final collection of 25 studies. Relevance criteria included (i) discussing development of CDS or an EHR with CDS services (ii) taking integration of CDS into EHRs into account. Results: It was observed that there are few CDS development projects where EHR integration is taken into account. Also, the number of studies where various clinical standards are taken into consideration in developing CDS is surprisingly low especially for openEHR, the EHR standard we aimed for. The reasons for low adoption of openEHR are issues such as complex and huge specifications, shortcomings in educational aspects, low empirical focus and low support for developers. Conclusion: There is a need for further investigation to discover the reasons why the rate of integration of EHRs and CDS is not at an optimum level and mostly to discover why CDS developers are not keen to adopt various clinical standards.

Keywords: Clinical decision support system, Electronic health record, clinical standards

1. Introduction

Even though more than 50 years of research have been put into the clinical decision support (CDS) field, the adoption rate of these systems is still low [1, 2, 3, 4, 5, 6]. Various researchers have investigated the factors that should be considered by developers of such systems in order to result in higher adoption. One of these factors is the integration of CDS into the electronic health record (EHR) systems. Different benefits are associated with the integration of CDS into EHRs. For instance, integration facilitates real time access to the knowledge provided by CDS at point
of care, it also eliminates tedious duplicate patient data entry since the preexisting digital patient data in the EHR system can be utilized for the purpose of providing decision support [1, 7, 8].

The aim of this study has been to answer this research question: *is integration of clinical decision support into electronic health record taken into consideration by developers of clinical decision support?* The practical science literature was reviewed not only to explore CDS developers’ attitude towards integration of EHR and CDS, but also to discover the status of EHR standards in this field.

The structure of the paper is as follows. We start with the background information including the motivation for integration of CDS and EHRs in Section 2. In Section 3 the literature review search strategy is given. The results of the review are presented in Section 4. Section 5 includes the discussion of the findings along with our reflection on the low adoption rate of the *open*EHR EHR standardization approach. Finally, we end with a conclusion and future directions of the study in Section 6.

2. Background

The idea of computerized medical records has been around as one of the key research areas in medical informatics for more than 20 years. Iakovidis defines EHR as “digitally stored health care information about an individual’s lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times” [9]. EHRs include the whole range of patient-related data such as demographic information, medical history, medication, and allergies [10].

The main aim of EHRs is to make distributed and cooperating health information system and health networks a reality [10]. The first benefit of deploying EHRs is that clinicians have access to all patient information, as and when required, and provided that they have authorization for that [1] since patient information is no longer on a piece of paper.

Several reasons have been identified for the low adoption rate of EHRs in small hospitals and office practices. This includes high implementation and maintenance costs, additional time and effort and finally the difficulty in choosing among available systems on the market due to a lack of standardization [1].

Improving the quality of health care is the ultimate goal of the EHR research domain, but it is in doubt whether EHRs have the ability to fulfill this goal [5]. EHRs need to be supported by other services in order to improve the quality of care [5, 11, 12, 13]. To reach the goal of improved health care quality, it is central to have CDS [5, 14, 3, 2, 6, 12, 15].

It has been observed that if there is no decision support service, the clinical knowledge needed for making a decision is not always available or applied [16]. Therefore, it is recommended that clinicians be automatically supported by timely access to clinical decision support tools [7, 8]. The emphasize in the current application of EHRs is on timely access to patient data, patient tracking and providing decision support with the aim of improving quality of care [13]. In spite of this fact, the usage of decision support among EHR users is still quite low and there are still many EHR systems that do not include any CDS features [5]. Nonetheless, interest in applying CDS in various health care organizations to improve quality of health care has recently shown an increase [17, 18]. The CDS these organizations are looking for should provide support in patient specific assessments [17, 1].
2.1. Low Adoption of Clinical Decision Support

Results from several studies that deal with the question: *which factors should be considered in the design and development of CDS to result in an acceptable and effective CDS?* are summarized in [19]. These studies focus on developing such systems that lead to wider adoption of CDS and consequent improvement in quality of health care. According to these studies and those reviewed in this section, two of the main challenges in design and development of CDS are:

- human-related factors that are related to the way CDS systems are designed, evaluated and introduced to the users
- technical factors that are mainly related to knowledge representation and reasoning in CDS systems
- Integration to the EHR systems available in health organizations

2.2. Integration of Clinical Decision Support into Electronic Health Records

It is recommended that CDS be integrated into other information systems in the clinical domain and it has been demonstrated that an integrated system has better effects on the care process [20]. Different clinical applications such as computerized physician order entry (CPOE), electronic prescribing, e-prescribing (eRX) and personal health records (PHR) are valuable underlying platforms for CDS [16, 1]. Several studies discuss how delivery of decision support through EHRs can improve the quality of care [4, 3, 21, 22]. Moreover, integration of CDS into EHR systems has been advocated in several studies as being helpful to the wider adoption of CDS [2, 1, 5, 4, 23, 16, 24]. Overall, EHR is considered as leverage for CDS [6, 1].

Several studies have observed that manual data entry into CDS acts as a barrier for broad adoption of CDS. It is recommended that the CDS be provided at the point of care and without any additional effort to invoke it or utilize it [1, 17]. Manual data entry which is a time consuming task and a burden for clinicians can be removed by integrating CDS into EHR systems and utilizing the data which is already in an electronic, computer-readable format. In this case, there is no need for duplicate data entry and the system can query related information from the EHR system [2, 1, 23, 25, 6]. Therefore, implementation of CDS is facilitated by EHRs. If there is no integration, data must be extracted from EHRs to be applied in the CDS. Moreover, if CDS is not integrated into EHRs, that part of the domain knowledge which is included in EHR is not applied properly [1].

2.3. Interoperability of EHR systems

EHR systems are being developed by various vendors, so they might be stored in different formats. This results in systems that are not interoperable, and makes sharing EHRs among different health organizations difficult. To overcome this problem, and to support secure and timely access to EHRs, national and international EHR standards are developed [26, 27]. openEHR [28] and health level 7 (HL7) [29] are two of the well-known interoperability standards. A description of these two standards is given in the following.
2.3.1. openEHR

openEHR is an open standard specification. The openEHR specification describes how EHRs are managed, stored, retrieved and exchanged [30]. Three main concepts defined in openEHR are (i) the two-level software architecture (ii) archetypes (iii) templates. The two-level architecture for clinical applications deals with separation of knowledge and information levels in order to overcome the problems caused by the ever-changing nature of clinical knowledge. This is realized by using openEHR archetypes. Archetypes and templates are used for data validation and sharing [28]. Beale et al. in [31] define archetype and template as follows:

- Archetype is “a computable expression of a domain content model in the form of structured constraint statements, based on a reference (information) model. openEHR archetypes are based on the openEHR reference model. Archetypes are all expressed in the same formalism. In general, they are defined for wide re-use, however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies.”

- Template is “a directly locally usable definition which composes archetypes into a larger structures often corresponding to a screen form, document, report or message. A template may add further local constraints on the archetypes it mentions, including removing or mandating optional sections, and may define default values.”

2.3.2. Health Level 7

HL7 is an EHR standard that focuses on communicating EHRs [10]. According to HL7 web-site¹: “Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services”. In HL7 version 3 a comprehensive Reference Information Model (RIM) is introduced [10]. HL7 clinical document architecture (CDA) templates are analogous to openEHR archetypes [32].

2.4. Other Standards in the Clinical Domain

There are different approaches to support the interoperability among heterogeneous clinical systems. Other than EHR interoperability standards that concentrate on standardizing the clinical information model, the initiative has been taken to standardize other concepts in the clinical domain such as clinical guidelines and clinical terminologies to improve shareability and reusability of them among health institutions.

2.4.1. Communicating The Clinical Terminology

The language is not uniform in the clinical domain and clinicians may use different terms to refer to the same concepts. Therefore, there is a need to standardize the clinical terminology to enable communicating it [33]. SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) is an advanced clinical terminology and coding system [33]. SNOMED CT concepts are usually referred to by an information model such as openEHR and HL7 [34].

¹http://www.hl7.org/
ICD (International Classification of Diseases) is a coding system that is designed to “promote international comparability in the collection, processing, classification, and presentation of mortality statistics” [35]. This classification standard is suitable for statistical reporting rather than clinical documentation as is supported by SNOMED CT. There is a map between SNOMED CT terms and the equivalent ICD codes [34].

2.4.2. Sharing Clinical Guidelines

Developing clinical guidelines involves a lot of effort. Therefore, there have been initiatives to enable reusability and shareability of clinical guidelines among various health organizations. The first step to support reusability and shareability of clinical guidelines is to define a common format for representing them [36]. One well-known language for this purpose is the one developed by the InterMed Collaboratory named GLIF (the GuideLine Interchange Format) [36].

3. Search Methodology

*Literature review* is a research methodology that aims at summarizing the available literature on a topic and presenting an analysis based on that and providing a full picture on the topic [37]. In this study, literature review is used to analyze state of the art in the intersection between CDS and EHRs.

The search was conducted in the ScienceDirect\(^2\) database that includes the major journals in medical informatics\(^3\). The queries and results were as follows:

- searching the combination of phrases “clinical decision support” and “electronic health record” returned 48 articles where 37 of them were selected for further studies.
- searching the combination of phrases “clinical decision support” and “medical health record” (excluding the papers that had the phrase “electronic health record”) returned 50 articles where 37 of them were selected for further studies.

Of these 74 studies, only 21 turned out to be relevant to the review based on their contents. In addition to these 21 studies, 4 more studies that the author had found were included in the review. The search strategy is depicted in Figure 1. Criteria for including the papers in the review were positive answers to these questions:

- Is the study discussing development and/or evaluation of a CDS system (i.e. practical science)? If yes, have the authors considered integration of the CDS into EHRs or a related application (i.e. integration)?
- Is the study discussing development and/or evaluation of an EHR system (i.e. practical science)? If yes, have the authors considered integration of a CDS feature into the system (i.e. integration)?

Since, we were particularly interested in openEHR, further searches were carried out in ScienceDirect and PubMed\(^4\) specifically on openEHR to find out if any development of an openEHR-based CDSS is documented in the literature:

\(^2\)http://sciencedirect.com
\(^3\)The search was done in mid 2010.
\(^4\)http://pubmed.org
4. Results

This section includes the preliminary findings from the literature review. Analysis of the findings are given in the next section.

The 25 selected articles were reviewed in order to find out whether they consider any of the clinical standards (i.e. EHR standards, guideline representation standards, and terminology or vocabulary standards).

As evident from Table 1, there are various studies that have applied EHR standards (not including openEHR) in developing EHRs with CDS functionalities. HL7 is used in 7 studies, GLIF in 1, and SNOMED CT/ICT in 2 studies. There are also studies in which local representations or terminologies were used for representing clinical guidelines or clinical terms [38, 39]. Most of the CDS services were documented to be integrated into a CPOE system. The summary of findings is presented in Figure 2.

- In ScienceDirect searching the combination of phrases “clinical decision support” and openEHR resulted in 1 article that was reviewed before (the study by Greenes [1]).
- In PubMed searching the combination of phrases “clinical decision support” and openEHR resulted in 2 articles by the author of this paper (these papers are not included in the review).
Table 1: The summary of the findings (Please note that √ is used when one item is considered in the study). - specifies that the item is not mentioned in the study.

| Who                  | Year | Integration Standards |
|----------------------|------|-----------------------|
| Gadd et al. [41]      | 1998 | √ √ √ √                 |
| Panzarasa et al. [39] | 2002 | √ √ √ √                 |
| Wright et al. [40]    | 2004 | √ √ √ √                 |
| Stuthe et al. [42]    | 2006 | √ HL7 √ √ √             |
| Rosebruck et al. [43] | 2006 | √ √ √ √                 |
| Stuthe et al. [44]    | 2006 | √ √ √ √                 |
| Stuthe et al. [45]    | 2006 | √ √ √ √                 |
| Stuthe et al. [46]    | 2007 | √ √ √ √                 |
| Stuthe et al. [47]    | 2007 | √ √ √ √                 |
| Stuthe et al. [48]    | 2007 | - HL7 √ √ √             |
| Stuthe et al. [49]    | 2007 | - HL7 √ √ √             |
| Stuthe et al. [50]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [51]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [52]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [53]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [54]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [55]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [56]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [57]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [58]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [59]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [60]    | 2008 | - HL7 √ √ √             |
| Stuthe et al. [61]    | 2008 | - HL7 √ √ √             |

4.1. HL7 versus openEHR

While searching the combination of phrases “clinical decision support” and HL7 resulted in 41 papers⁵, we did not find any study that reports on implementation of a CDS applying openEHR⁶.

![Figure 2: Various standards reported in the reviewed studies. All of the EHR standards that were applied in studies were HL7. openEHR was not adopted in any of the studies.](image)

5. Discussion

Theory supports the benefits offered by integrating CDS into EHR, but this concept is still appreciated more in theory than in practice. Only 25 related studies were discovered in this database while around 100 studies are documented in the literature that, based on their titles and abstracts, are about developing a CDSS. Nonetheless, the publication years of these 25 studies are an indication that in recent years, there has been an increase in consideration of EHR integration in development of CDS.

---

⁵Not all of these studies are included in the review.
⁶The search was done in mid 2010. However, in a new search in 2011, we found more new studies related to openEHR. These studies are discussed more in the discussion section.
Moreover, it is observed that taking standards into consideration in any clinical application (and generally any information system) is very important [11]. In case of CDSSs, since such systems operate by utilizing both patient/organizational-specific data and clinical knowledge, it is important to consider the standards that support each of these areas [11]. This however is observed to still be in need of further improvements. Of these 25 studies, only 6 had considered EHR standardization, and 3 had considered terminology standards which are both surprisingly small numbers.

Finally, one can conclude that based on the literature, HL7 has a higher level of adoption than openEHR and that applying openEHR in development of clinical applications specially CDS is yet rare. This brings the question that regardless of the advances in theory why is openEHR suffering from a low adoption rate in practice? This issue is discussed more in the following section.

5.1. Low Adoption of openEHR

Below is a list of problems that we or others have faced using openEHR. These issues are considered as barriers to higher adoption of openEHR:

5.1.1. Being huge and complex*

openEHR is naturally complex, and this complexity is not unexpected since openEHR is considered to be a solution for a complicated problem (i.e. interoperable future-proof EHR) in a complex domain (i.e. the clinical domain). For instance the powerful archetype model allows expressing complex clinical concepts, therefore, an inexperienced archetype developer should expect to spend some time on learning the openEHR concepts. Additionally, getting a grip on the current specifications (more than 1000 pages), UML diagrams and code documentation is challenging. At the same time, it is notable that this complexity is intensified by some other aspects such as improper educational support and limited internationalization.

5.1.2. Shortcoming in educational aspects*

Understanding a concept is the first step to be able to adopt it and this is even more valid for such complex concepts like those in openEHR. Unfortunately, no formal tutorial document exists for openEHR, formal training sessions are rare and even worse, not so many openEHR trainers exist around the world. Easy to understand tutorials are needed to help novice developers get a grip on openEHR.

5.1.3. Low government and industry penetration

Many of those who are interested in openEHR, in spending time on learning it or adopting it, are from the academic world (the main of which is University College London). So far, there are very few companies that are adopting openEHR and to our knowledge these companies are

---

7In November 2010, there was a discussion on openEHR mailing list with the same topic. This shows that even people in the openEHR community have noticed that the adoption rate is low and some actions should be taken in order to improve it. Especially, it is noticeable that the amount of attention to openEHR is much less than HL7 in various domains i.e. government, academy and industry.

8Some of the issues presented here are the result of investigating the discussions in the openEHR mailing list, even though some others had been experienced in this study. Those issues are marked with an asterisk.

9http://ucl.ac.uk
considered to be a part of the core openEHR community. The main companies are Oceaninformatics\(^{10}\), Cambio\(^{11}\), and Zilics\(^{12}\). But what about “ordinary audience”? On the other hand, low support from the governmental agencies lead to low industry penetration. Considering the complication and the cost imposed by the openEHR approach, and also limited documentations and guidelines, applying openEHR is not still cost-efficient and yet commercial companies show a lot of hesitation to accept risks imposed by adopting this immature standard.

5.1.4. Shortcoming in internationalization aspects

In order to reach an international-wide adoption, it is suggested that establishing regional communities would be helpful; nevertheless, there are other concerns in this regard. openEHR community should consider issues such as supporting and providing guidelines for regional communities all around the world. It is also beneficial to publish openEHR specifications in various languages in order to speed up the process of learning for various people. Regional events such as educational sessions, gatherings and so on are also valuable to influence collaboration. As an example, in Sweden, there are around 4 groups of people\(^{13}\) doing research on or adopting openEHR, but collaboration among them is at a very low level.

5.1.5. Low empirical focus*

openEHR should not just be about complex theoretical specifications and reference models, but also about implementation and practice. Semantic interoperability, two-level modeling and involving clinicians are interesting concepts, but so far these have been far from the practice. Currently, there are just a few empirical efforts on openEHR. Most of the focus of openEHR community has been on representation of domain concepts and theoretical aspects of the approach. Still, there is a huge need for supporting developers to make openEHR more practical.

5.1.6. Limited tools and implementations*

As mentioned above, developers needed to be supported in order to improve adoption of openEHR. One way of delivering this support is by providing frameworks and application programming interfaces (API). At this time, the openEHR reference model implementation is still immature and lacks important parts like templates, persistence, and services.

5.2. Recent Advances in The openEHR-based CDS

When it comes to CDS, there are a few studies that deal with how openEHR offers opportunities for CDS. Most of these efforts however, seem to be more focused on integrating clinical guidelines into openEHR archetypes or utilizing archetypes for representing clinical guidelines\(^{[62, 25, 63]}\) or to integrate reasoning and clinical archetypes (enhance archetypes by including knowledge representation capabilities to them)\(^{[64]}\). To our knowledge there is almost no study that has been focused on benefiting from the well-structured openEHR-based patient data for adopting data intensive reasoning methods in CDSSs or methods that rely on previous cases to carry out the reasoning process.

\(^{10}\)http://www.oceaninformatics.com

\(^{11}\)http://cambio.se

\(^{12}\)http://www.zilics.com.br

\(^{13}\)Chalmers university of technology, Linköping university, Cambio company and The Swedish NHS.
5.3. Why Are Clinical Standards Important for CDS?

According to the discussion in Section 2, enough motivation exists to integrate CDS into EHRs. There is still a question whether integration of CDS into EHRs can be done without taking EHR related standards into account. If EHR standards are not considered in CDS development, all clinical data should be translated to a format understandable for the CDS system. This is not an efficient way for CDS and the EHR system to communicate. Moreover, there is an increasing interest in the medical informatics community to share clinical knowledge. This can also be supported if CDS is developed based on EHR standards. For instance, by enriching standard compatible EHRs with the reasoning knowledge, EHR sharing will also result in sharing and reusing the embedded knowledge. In cases where general domain knowledge including clinical guidelines are integrated into EHRs, the reusability and sharing of knowledge can be achieved as well.

6. Conclusion

Researchers in the area of CDS and also EHR have motivated that by integrating CDS into EHRs, the improvement in the quality of health care would be higher than when the systems operate separately. The integration will be more efficient if the standards related to EHRs are considered in developing CDS. The possibility to share the domain knowledge, especially the reasoning knowledge, in decision making is another motivation for taking standards into account in developing CDS.

Nevertheless, a review of the related literature indicates that not all of CDS developers take integration into account, also there are very few of them who consider standards in developing CDS. Discovering the reasons for this however needs further investigation and has not been in the scope of this review.

Acknowledgment

I would like to give thanks to Olof Torgersson who provided helpful suggestions to improve the paper.

References

[1] R. Greenes, Clinical decision support: the road ahead, Academic Press, 2007.
[2] T. Wendt, P. Knaup-Gregori, A, Decision Support in Medicine: A Survey of Problems of User Acceptance, Stud Health Technol Inform 77 (2000) 852–856.
[3] B. Chaudhry, J. Wang, S. Wu, M. Maglione, Systematic review: impact of health information technology on quality, efficiency, and costs of medical care, Annals of internal Med 144 (10) (2006) 742–752.
[4] A. Garg, N. Adhikari, H. McDonald, M. Rosas, Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review, JAMA 293 (10) (2005) 1223–1238.
[5] D. F. Sittig, A. Wright, J. a. Osheroff, B. Middleton, J. M. Teich, J. S. Ash, E. Campbell, D. W. Bates, Grand challenges in clinical decision support, Journal of biomedical informatics 41 (2) (2008) 387–92. doi:10.1016/j.jbi.2007.09.003.
[6] J. Osheroff, J. Teich, B. Middleton, E. Steen, A. Wright, D. Detmer, A roadmap for national action on clinical decision support, Journal of the American medical informatics association 14 (2) (2007) 141. doi:10.1197/jamia.M2334.Introduction.
[7] Patient Safety: Achieving a New Standard of Care (2003).
[8] Crossing the Quality Chasm: A New Health System for the 21st Century, Website, http://journals.lww.com/qmhcjournal/Abstract/2002/10040/Crossing_The_Quality_Chasm_A_New_Health_System.10.aspx (2001).
[9] I. Iakovidis, Towards personal health record: current situation, obstacles and trends in implementation of electronic healthcare record in Europe., International journal of medical informatics 52 (1-3) (1998) 105–15.

[10] B. Blobel, Advanced and secure architectural EHR approaches., International journal of medical informatics 75 (3-4) (2006) 185–90. doi:10.1016/j.ijmedinf.2005.07.017.

[11] J. Osheroff, E. Pifer, J. Teich, D. Sittig, R. Jenders, Improving outcomes with clinical decision support: An implementer’s guide., HIMSS, 2005.

[12] R. Greens, M. Sordo, D. Zaccagnini, M. Meyer, GJ. Design of a standards-based external rules engine for decision support in a variety of application contexts: report of a feasibility study at Partners HealthCare System, MedInfo.

[13] L. Zhou, C. a. Soran, C. a. Jenter, L. a. Volk, E. J. Orav, D. W. Bates, S. R. Simon, The relationship between electronic health record use and quality of care over time., Journal of the American Medical Informatics Association: JAMIA 16 (4) (2009) 457–64. doi:10.1197/jamia.M3128.

[14] J. Anderson, Increasing the acceptance of clinical Information, MD computing: computers in medical practice 16 (1) (1999) 62.

[15] K. Kawamoto, D. Lobach, Proposal for fulfilling strategic objectives of the US roadmap for national action on decision support through a service-oriented architecture leveraging HL7 services, Journal of the American medical (2007) 146–155doi:10.1197/jamia.M2298.Introduction.

[16] I. Cho, J. Kim, J. H. Kim, H. Y. Kim, Y. Kim, Design and implementation of a standards-based interoperable clinical decision support architecture in the context of the Korean EHR., International journal of medical informatics 9 (2010) 611–622. doi:10.1016/j.ijmedinf.2010.06.002.

[17] K. Kawamoto, C. A. Houlihan, E. A. Balas, D. F. Lobach, Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success., BMJ (Clinical research ed.) 330 (7494) (2005) 765. doi:10.1136/bmj.38398.500764.8F.

[18] M. Trivedi, J. Kern, A. Marce, B. Grannemann, B. Kleiber, T. Bettinger, K. Althsuler, A. McClelland, Development and Implementation of Computerized Clinical Guidelines: Barriers and Solutions, Methods of information in medicine 41 (5) (2002) 435–442.

[19] H. Khashi, Towards Interaction Design in Clinical Decision Support Development, manuscript submitted to International Journal of Medical Informatics, Elsevier (2011).

[20] R. A. K. Horasan, M. I. T. Anasijevic, B. L. M. Iddleton, M. S. C, Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality, Journal of the American Medical Informatics Association 10 (2003) 523–530. doi:10.1197/jamia.M1370.Although.

[21] D. Hunt, R. Haynes, S. Hanna, K. Smith, Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review, Jama 280 (15) (1998) 1339. doi:10.1001/jama.280.15.1339.

[22] M. Johnston, K. Langton, R. Haynes, Effects of computer-based clinical decision support systems on clinician performance and patient outcome. A critical appraisal of research, Ann Intern Med 120 (2) (1994) 135–142.

[23] E. Berner, Clinical Decision Support Systems: Theory and Practice (Health Informatics), Springer, New York, NY (2003), USA, 2007.

[24] A. Wilson, A. Duszynski, D. Turnbull, J. Investigating patients’ and general practitioners’ views of computerised decision support software for the assessment and management of cardiovascular risk, Informatics in Primary Care 15 (2007) 33–44.

[25] R. Chen, P. Georgii-Hemming, H. Ahlfeldt, Representing a chemotherapy guideline using openEHR and rules., Studies in health technology and informatics 150 (2009) 653–7. doi:10.3233/978-1-60750-044-5-653.

[26] V. Stroetmann, D. Kalra, P. Lewalle, J. Rodrigues, KA, Semantic Interoperability for Better Health and Safer Health Care, Deployment and Research (January). doi:10.2759/38514.

[27] P. Schloeffel, T. Beale, G. Hayworth, S. Heard, H. Leslie, The relationship between CEN 13606, HL7, and SNOMED CT, The advances in terminology and coding system for eHealth, Studies in health technology and informatics 121 (2006) 279–90.

[28] T. Beale, S. Heard, openehr architecture overview, Website, http://www.openehr.org/releases/1.0. 2/architecture/overview.pdf (2008).

[29] T. Beale, S. Heard, openehr architecture overview, Website, http://www.openehr.org/releases/1.0.2/architecture/overview.pdf (2008).

[30] openEHR, Website, http://en.wikipedia.org/wiki/openEHR (2010).

[31] Teale, S. Heard, Archetype Definitions and Principles, Website, http://www.openehr.org/releases/ 1.0.2/architecture/am/archetype_principles.pdf (2007).

[32] M. Eichelberg, T. Aden, J. Riesmeier, A. Dogac, G. B. Laleci, A survey and analysis of Electronic Healthcare Record standards, ACM Computing Surveys 37 (4) (2005) 277–315. doi:10.1145/1118090.1118891.

[33] K. Donnelly, SNOMED-CT: The advanced terminology and coding system for eHealth, Studies in health technology and informatics 121 (2006) 279–90.

[34] SNOMED CT, Website, http://en.wikipedia.org/wiki/SNOMED_CT (2010).

[35] ICD, Website, http://www.cdc.gov/nchs/icd.htm (2010).
[36] L. Ohno-Machado, J. H. Gennari, S. N. Murphy, N. L. Jain, S. W. Tu, D. E. Oliver, E. Pattison-Gordon, R. a. Groenes, E. H. Shorliffe, G. O. Barnett, The guideline interchange format: a model for representing guidelines., Journal of the American Medical Informatics Association: JAMIA 5 (4) (1998) 357–72.

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

[38] S. F. Noormohammad, B. W. Mamlin, P. G. Biondich, B. McKown, S. N. Kimaiyo, M. C. Were, Changing course to make clinical decision support work in an HIV clinic in Kenya., International journal of medical informatics 79 (3) (2010) 204–10. doi:10.1016/j.ijmedinf.2010.01.002.

[39] S. Panzarasa, S. Madda, S. Quaglino, Evidence-based careflow management systems: the case of post-stroke rehabilitation, Journal of Biomedical 35 (2) (2002) 123–139. doi:10.1016/S1532-0464(02)00505-1.

[40] T. Stair, REDUCTION OF REDUNDANT LABORATORY ORDERS BY ACCESS TO COMPUTERIZED PATIENT RECORDS, The Journal of emergency medicine 16 (6) (1998) 895–897.

[41] C. Gadd, P. Baskaran, D. Lobach, Identification of design features to enhance utilization and acceptance of systems for Internet-based decision support at the point of care., in: Proceedings of the AMIA, 1998, pp. 91–5.

[42] A. S. Young, J. Mintz, A. N. Cohen, M. J. Chinman, A network-based system to improve care for schizophrenia: the Medical Informatics Network Tool (MINT),. Journal of the American Medical Informatics Association: JAMIA 11 (5) (2004) 558–67. doi:10.1197/jamia.M1492.

[43] R. N. Shiffman, G. Michel, A. Essahui, E. Thornquist, Bridging the guideline implementation gap: a systematic, document-centered approach to guideline implementation., Journal of the American Medical Informatics Association: JAMIA 11 (5) (2004) 418–26. doi:10.1197/jamia.M1444.

[44] S. T. Rosenbloom, D. Talbert, D. Aronsky, Clinicians’ perceptions of clinical decision support integrated into computerized provider order entry., International journal of medical informatics 73 (5) (2004) 433–41. doi:10.1016/j.ijmedinf.2004.04.001.

[45] W. L. Galanter, R. J. Didomenico, A. Polikaitis, A trial of automated decision support alerts for contraindicated medications using computerized physician order entry., Journal of the American Medical Informatics Association: JAMIA 12 (3) (2005) 269–74. doi:10.1197/jamia.M1727.

[46] G. Haller, P. S. Myles, J. Stoelwinder, M. Langley, H. Anderson, J. McNeil, Integrating incident reporting into an electronic patient record system., Journal of the American Medical Informatics Association: JAMIA 14 (2) (2007) 175–81. doi:10.1197/jamia.M196.

[47] H. Stutman, R. Fineman, K. Meyer, Optimizing the acceptance of medication-based alerts by physicians during CPOE implementation in a community hospital environment, in: AMIA Annual Symposium, 2007, pp. 701–705.

[48] D. F. Lobach, K. Kawamoto, K. J. Anstrom, M. L. Russell, P. Woods, D. Smith, Development, deployment and usability of a point-of-care decision support system for chronic disease management using the recently-approved HL7 decision support service standard., Studies in health technology and informatics 129 (Pt 2) (2007) 861–5.

[49] T. Graham, A. Kushniruk, M. Bullard, B. Holroyd, D. Meurer, B. Rowe, How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events, in: AMIA Annual Symposium Proceedings, Vol. 2008, American Medical Informatics Association, 2008, p. 257.

[50] T. W. Marcy, B. Kaplan, S. W. Connolly, G. Michel, R. N. Shiffman, B. S. Flynn, Developing a decision support system for tobacco use counselling using primary care physicians., Informatics in primary care 16 (2) (2008) 101–9.

[51] A. Wright, D. F. Sittig, SANDS: a service-oriented architecture for clinical decision support in a National Health Information Network., Journal of biomedical informatics 41 (6) (2008) 962–81. doi:10.1016/j.jbi.2008.03.001.

[52] M. N. Gerard, W. E. Trick, K. Das, M. Charles-Damte, G. A. Murphy, I. M. Benson, Use of clinical decision support to increase influenza vaccination: multi-year evolution of the system., Journal of the American Medical Informatics Association: JAMIA 15 (6) (2008) 776–9. doi:10.1197/jamia.M2698.

[53] T. S. Field, P. Rochon, M. Lee, L. Gavendo, S. Subramanian, S. Hoover, J. Baril, J. Gurwitz, Costs associated with developing and implementing a computerized clinical decision support system for medication dosing for patients with renal insufficiency in the long-term care setting., Journal of the American Medical Informatics Association: JAMIA 15 (4) (2008) 466–72. doi:10.1197/jamia.M2589.

[54] J. L. Schnipper, J. A. Linder, M. B. Palchuk, J. S. Einbinder, Q. Li, A. Postilnik, B. Middleton, “Smart Forms” in an Electronic Medical Record: documentation-based clinical decision support to improve disease management., Journal of the American Medical Informatics Association: JAMIA 15 (4) (2008) 513–23. doi:10.1197/jamia.M2501.

[55] M. Peleg, A. Shachak, D. Wang, E. Karnieli, Using multi-perspective methodologies to study users’ interactions with the prototype front end of a guideline-based decision support system for diabetic foot care., International journal of medical informatics 78 (7) (2009) 482–93. doi:10.1016/j.ijmedinf.2009.02.008.

[56] J. Saleem, L. Miliotello, N. Ar buckle, M. Flanagan, Provider Perceptions of Colorectal Cancer Screening Clinical Decision Support at Three Benchmark Institutions, in: AIMIA Symposium Proceedings, 2009, pp. 558–562.

[57] T. S. Field, P. Rochon, M. Lee, L. Gavendo, S. Subramanian, S. Hoover, J. Baril, J. H. Gurwitz, Computerized clinical decision support during medication ordering for long-term care residents with renal insufficiency., Journal of the American Medical Informatics Association: JAMIA 16 (4) (2009) 480–5. doi:10.1197/jamia.M2981.

[58] C. C. Chen, K. Chen, C.-y. Hsu, Y.-c. J. Li, Developing guideline-based decision support systems using protégé
and jess., Computer methods and programs in biomedicine in print (2010) 1–7. doi:10.1016/j.cmpb.2010.05.010.

[59] W. L. Galanter, D. B. Hier, C. Jao, D. Sarne, Computerized physician order entry of medications and clinical decision support can improve problem list documentation compliance., International journal of medical informatics 79 (5) (2010) 332–8. doi:10.1016/j.ijmedinf.2008.05.005.

[60] J. Trafton, S. Martins, M. Michel, E. Lewis, Evaluation of the Acceptability and Usability of a Decision Support System to Encourage Safe and Effective Use of Opioid Therapy for Chronic, Noncancer Pain by Primary Care Providers, Pain Medicine 11 (2010) 575–585.

[61] M. C. Were, C. Shen, M. Bwana, N. Emenyonu, N. Musinguzi, F. Nkuyahaga, A. Kembabazi, W. M. Tierney, Creation and evaluation of EMR-based paper clinical summaries to support HIV-care in Uganda, Africa., International journal of medical informatics 79 (2) (2010) 90–6. doi:10.1016/j.ijmedinf.2009.11.006.

[62] M. Marcos, B. n. Martínez-Salvador, Towards the interoperability of computerized guidelines and electronic health records: an experiment with openEHR archetypes and a chronic heart failure guideline, in: Proceedings of the ECAI 2010 conference on Knowledge representation for health-care, KR4HC’10, Springer-Verlag, Berlin, Heidelberg, 2011, pp. 101–113.

[63] L. Xiao, G. Cousins, L. Hederman, T. Fahey, B. Dimitrov, The design of an EHR for clinical decision support, no. Bmei, IEEE, 2010. doi:10.1109/BMEI.2010.5639694.

[64] L. Lezcano, M.-A. Sicilia, C. Rodríguez-Solano, Integrating reasoning and clinical archetypes using OWL ontologies and SWRL rules., Journal of biomedical informatics 44 (2) (2011) 343–53. doi:10.1016/j.jbi.2010.11.005.
Applying a User-centered Design Methodology in a Clinical Context

Hajar Kashfi

The 13th International Congress on Medical Informatics (MedInfo2010), Studies in health technology and informatics, 2010 Jan ;160(Pt 2):927-31.
(reprinted with an updated layout)
Applying a User Centered Design Methodology in a Clinical Context

Hajar Kashfi

Division of Interaction Design, Department of Computer Science and Engineering, Chalmers University of Technology, Gothenburg, Sweden.

Abstract

A clinical decision support system (CDSS) is an interactive application that is used to facilitate the process of decision-making in a clinical context. Developing a usable CDSS is a challenging process; mostly because of the complex nature of domain knowledge and the context of use of those systems. This paper describes how a user centered design (UCD) approach can be used in a clinical context for developing a CDSS. In our effort, a design-based research methodology has been used. The outcomes of this work are as follow; a customized UCD approach is suggested that combines UCD and openEHR. Moreover, the GUI developed in the design phase and the result of the GUI evaluation is briefly presented.

Keywords:
Clinical Decision Support System, User Centered Design, Usability, UCD, Prototype, Design and Development process, Iterative design, openEHR.

Introduction

Errors that occur in a clinical process are mostly due to cognitive limitations of humans, the potential to forget knowledge in the health care flow. Information systems have the ability to decrease such errors by supporting clinicians in this process e.g. by reminding them of important factors to be considered for the current case or to alert them of adverse drug-drug interactions [1]. A Decision Support System (DSS) is an interactive application that is supposed to facilitate the process of decision making for decision makers. This support is done by mapping or compiling existing data to useful information that can be used as a clue for making the best decision [2]. Clinical Decision Support Systems are those DSS:s that are used in the clinical do-
main. CDSS:s are intended to help clinicians in the process of decision making. Services supported by CDSS:s include diagnosis, alerting, reminding, treatment suggestions, and patient education. Based on a thorough literature review done on around 140 papers about CDSS, it is clear that CDSS:s have the potential to improve care [3].

**Usability of CDSS**

ISO 9421 [4] defines usability as the “Extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.” Poor usability is the one of the reasons for why CDSS:s have not yet gained a broad acceptance. While there have been many efforts in developing CDSS:s, very few of those systems have been accepted in real clinical environments. Studies show that user interfaces have an impact on acceptability of CDSS:s in a clinical context. The success of a CDSS has a direct relation to the way its graphic user interface (GUI) has been designed [5].

CDSS:s are meant to reduce clinical errors, nevertheless, because of improper design of those systems, other kinds of errors may occur by using them [1,6]. Studies reveal that clinical information systems with low usability not only do not improve patient care and reduce clinical errors, but also may have the opposite effect [7-8].

**Involving Clinicians in the Design Process of CDSS:s**

Not just in the clinical domain, but in every other domain experiences show that by involving users in the design and development process of a system, the system will be more usable for the intended users [9-12]. The design approach which emphasizes on involving users in the design is called User Centered Design process (UCD) [9-10]. Accordingly, one can not develop a CDSS which addresses clinicians’ needs in a clinical context without a design process in which end users, clinicians, are involved actively [13]. To make a CDSS a usable product, we should consider not only user needs that reveal functional requirements of the system, but also non-functional or usability requirements as well as characteristics of the clinical environment in which the system will finally be applied.

In this paper, we present issues related to user-centered design of a CDSS for Dry Mouth, an oral disease. The main reason for selecting Dry Mouth is that our end users expressed a need for a CDSS for this disease.
Methods

The research method we applied in our work is a design-based research method [14]. For this purpose, our collaborators in Sahlgrenska Academy¹ suggested the design and development of a CDSS for an oral disease named Dry Mouth. “Dry mouth or Xerostomia is the abnormal reduction of saliva and can be a symptom of certain diseases or be an adverse effect of certain medications”[15]. Treatment of Xerostomia is related to finding its cause(s). There are five main categories for Xerostomia: Drug-induced, Disease-induced, Radiation-induced, Chemotherapy-Induced, and cGVHD-induced [15].

The reason for suggesting Dry Mouth was that the dentists and dental hygienists are commonly the first clinicians to face the complaints by patients regarding this disease; hence, they should be aware of it and its problems to prevent the deleterious consequences of this disorder. However, according to our expert panel, finding cause(s) of Dry Mouth is a challenge for dentist and dental hygienists, and needs to be supported by a clinical application. The decision support process we aim for includes these two main steps (1) finding the cause(s) of disease based on the patient’s medical records (2) suggesting related materials and treatment options, based on results from the first step. Since this system is intended to be used integrated with an existing Clinical Data Entry application [16], data entry forms are not part of the Graphical User Interface (GUI), however we have to provide users with options to edit existing data. Finally, users need to be able to enter their own comments; including diagnosis or treatments to the system.

The Design Process

The approach we use in this design process is UCD. UCD focuses on the end users, their needs and the context in which the system will be used. The main goal in this method is user satisfaction. UCD has an iterative nature. It means that during the design and development process, at several points, prototypes are delivered to users for evaluation and improvement.

As depicted in Figure 1, the idea of UCD is a circular design process including analysis, design, prototyping and getting user feedback. End users are in the heart of this design process and should be involved in all steps. Users are asked about what they expect the application to do for them and what priorities they have in doing their tasks using the intended application. Users have the chance to specify their needs as detailed as possible e.g. which colors do they prefer or what are their time limits running a specific task using the application.

On the other hand, informaticians can communicate with users to extract vital information about their current situation and their future needs e.g. what users like

¹ http://www.sahlgrenska.gu.se/english
about the way they are currently doing their tasks or what would they like to be changed [11]. Finally, task analysis and evaluation [9-10] should be done based on the gathered information.

**The Importance of Involving Clinicians in the design**

Domain knowledge plays the main role in complexity of clinical applications. Clinical tasks may not be complex by themselves but what makes the clinical application development so complicated is that most of the clinical processes are unstructured. They are done in clinicians’ mind and based on their expertise. Moreover, clinical knowledge is ever-changing.

Hundreds of data items are involved in a clinical decision making process. After all, concepts in clinical domain are not easy to understand for informaticians and they face difficulties communicating with clinicians or studying literature to get enough domain knowledge to be able to model it and to develop an application.

Extracting domain knowledge in the clinical domain has always been a bottleneck in the development process of such systems and a challenge for informaticians. Therefore, in the clinical domain, we need to involve clinicians in designing the Information model or more precisely domain concept models to be used for information modeling. One of the recent approaches that focuses on involving users in domain concept modeling is openEHR [17].

![Figure 1- User Centered Design Process](image)

**The openEHR Approach**

openEHR is an open standard specification that emphasizes on the role of clinicians in organizing domain knowledge in form of different clinical concepts such as observation, evaluation, instruction and action [17].

---

2 Copyright 2009, Kevin Bury Design
In the openEHR approach, clinicians are in charge of defining the specification of clinical knowledge to be used in information modeling. This approach suggests a two-level architecture for clinical applications to separate knowledge and information levels in order to overcome the problems caused by the ever-changing nature of clinical knowledge.

While the main emphasis of openEHR is on semantic interoperability of medical records, we found the approach highly compatible with UCD. Therefore, we applied openEHR to facilitate involving clinicians in the design and to ease domain concept modeling and communicating with our end users.

From an UCD point of view, openEHR is very helpful. This approach recommends the utilization of expert knowledge not only just by consulting clinicians but also by letting them design concept models based on what they have in mind. By applying openEHR, we can communicate better with our end users since clinical concepts recommended by openEHR are understandable for clinicians.

**UCD Principles Applied in The Project**

There are number of principles that are recommended in UCD [18]: Multidisciplinary design team, Understanding users and context, Active user participation, Early prototyping, Continuous evaluation, and Holistic design. Besides Holistic design, we have been concerned about the other principles, as explained below.

**Project Team**

Our development team is a multidisciplinary team consisting of an interaction design expert, two computer scientists with different backgrounds (AI, Software Engineering), a domain expert (specialist in dentistry), a programmer, and a nurse. However, more end users and experts are involved in different steps in various time periods.

**Intended Users, Tasks and Context of Use**

One of the main principles in UCD is to define users and the context of use [10].

**Users:** In this project, direct users are dentists who work in an oral medicine clinic. We used narrative explanation of some typical end users, personas, [7] to find more about our end users’ characteristics. Since the output of the CDSS will be a treatment decision, patients are our indirect users. Nonetheless, patients will not use the system directly.

**Tasks:** Based on literature review and interviews with end users and domain experts, we defined the tasks listed below as the main tasks that dentists carry out with regard to Dry Mouth: (1) Information Overview (2) Information manipulation, (3)
Requesting related actions like laboratory tests, (4) Diagnosis, (5) Referring to guidelines and other clinical evidence, (6) Recording the results.

Context of use: Dentists will use the application while they are visiting a patient in the clinic. They will use it in presence of the patient, at the same time they are communicating with the patient and in a setting with a limited amount of time.

Users’ priorities/Usability goals: The goal is to develop a system, which fits to the dentists’ workflow as much as possible; experiences show that clinicians should not need to change their clinical workflow while using a CDSS [18]. It is also important to consider that not all clinicians are experienced in using information systems. On the other hand, because of their occupations, they do not manage to spend much time on learning a new application. Based on this information, we set up our usability goals such as: Effectiveness, Efficiency, Safety, Learnability, etc.

Iterative GUI Design and Evaluation

During the design, we have been using both low fidelity and high fidelity prototypes. From those, we can name sketches designed and improved during brain storming sessions for collecting functional requirements and usability requirements together with our expert panel. In this step, conceptual design of the application was done. These sketches were later translated to some power point prototypes. Afterwards, low fidelity prototyping tools were used to visualize the design solutions. Finally, a Java based GUI has been developed to make the final usability tests more realistic and reliable.
Iterative Domain Concept Model Design

The domain concept modeling started with brainstorming sessions in which our expert panel (experts in Dry Mouth) were asked to think about Dry Mouth and its related concepts based on this question: What do you want to know about a patient who visits you because he/she suffers from Dry Mouth?; and to put as much information as possible on a paper. Later, our expert panel has been asked to prepare a questionnaire based on this question: What do you ask from a patient who visits you because he/she suffers from Dry Mouth?

Questions on the questionnaire were then categorized based on openEHR concepts; in other words, their logical relation e.g. is the question related to patient history or is it a lab result? In the next step, simple diagrams were created based on the questionnaire. For this purpose, a mind-map application\(^3\) was used to make it possible for our expert panel to simply understand and edit the created diagrams.

\(^3\) http://www.xmind.net/
GUI and Domain Concept Model Evaluation

For the GUI evaluation, we used the evaluation methods applicable in early stages of the project. Two main methods we have been utilizing so far are Heuristic Evaluation and Usability Tests [9]. Based on the results from the evaluations we improved the GUI in several stages. One of the resulting GUI screens is showed in Figure 2.

Iterative design of the domain concept model includes evaluations of the current model based on the literature and experts’ opinions, and story-based assessment. Information modeling diagrams were improved several times based on the experts’ opinions. Several experts were involved in this process to minimize the subjectivity of the design and to be as broad as possible in collecting knowledge. A sample mind map is depicted in Figure 3.

Figure 3- Information modeling
Discussion and Results

UCD emphasizes that users’ needs should be reflected in the GUI design and that the GUI design should influence the design of the rest of the system [12]. On the other hand, openEHR emphasizes the domain concept modeling as the starting point. But how much does the domain model reflect the end users’ needs? By using the openEHR approach without considering other aspects like usability issues, we may end up developing highly adaptable systems with comprehensive information models, which are not usable.

In this project, we tried to benefit from the strengths of the two of approaches and to introduce an adaptation of UCD in a clinical concept keeping an eye on the openEHR approach.

The Customized UCD Approach for openEHR Based CDSS Development

As references suggest “The actual contents of the UCD process, the methods used, the order of activities, etc, must be customized and adapted to the particular organization and project based on their particular needs” [19]. So it was not a surprise to see that we need to apply a customized version of UCD in this project.

As shown in Figure 4, the main idea of UCD is used in the process but in three different cycles. One is a general cycle to develop the whole application. This main cycle contains a cycle to develop the Domain Concept Model; and a cycle to develop the GUI. So the process includes two main steps in parallel (1) Iterative development of the domain concept model (2) Iterative development of the GUI. For the first step, several specialists in dentistry (expert panel) and for the second step, both domain experts and general dentists (end user panel) were involved.

GUI vs. Domain Concept Model

During the iterative design process we noticed that the impact of the domain concept model on the GUI is inevitable. Decision about the components to be shown on the GUI is directly related to the output from the domain concept modeling. Any changes in the domain concept model should be checked from the GUI point of view. Therefore, as depicted in Figure 3, in each iteration, there should be an input from the left hand side process (domain concept model) to the right hand one (GUI). In other words, after each domain concept modeling iteration, the necessity of a new iteration for GUI design should be checked.

Characteristics of the Customized Approach and problems

The recommended approach has several characteristics:

- This approach considers active involvement of the end users and domain experts in designing and evaluating the domain concept model and the GUI
• In the suggested approach new GUI and Domain Concept modeling iterations will be performed until the end users are satisfied with the results.

• In this approach, the effect of the domain concept model on the GUI has been considered as explained before.

• The approach helps overcoming the knowledge extraction bottleneck by applying clinical concepts suggested by openEHR for communicating with clinicians and providing an opportunity for them to model domain knowledge based on their expertise.

• This approach inherits the idea of the knowledge and the information level separation suggested by openEHR in order to make developed applications highly adaptable.

• Finally, the approach is applicable for developing not only openEHR-based applications but also all kinds of clinical applications e.g. OWL based ones. Important issues to be considered while applying the approach are (I) the parallel iterative UCD of the domain concept model and the GUI, and (II) the effect of the domain concept models on the GUI.

We also faced some problems during the design phase. In design and implementation of CDSS:s a big challenge is choosing a knowledge representation and reasoning. Our experience showed that, selecting the representation and reasoning method have to be done in parallel with the information modeling and the GUI design, oth-
erwise, the changes forced by this selection causes modifications in the GUI design which is more cost effective to be known in the early stages of the GUI design. Secondary, the classical bottleneck of knowledge acquisition in clinical domain still exists. While applying the suggested methodology decreases difficulties in mutual understanding of clinicians and designers, it cannot eliminate the bottleneck problem totally, especially for the cases that reasoning should be done by applying knowledge intensive methods.

References

[1] Graham Ta, Kushniruk AW, Bullard MJ, Holroyd BR, Meurer DP, Rowe BH. How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events. AMIA Symposium, 2008 ;257-61.

[2] Vikram K, Karjodkar FR. Decision support systems in dental decision making: an introduction. The journal of evidence-based dental practice, 2009 ;9(2):73-6.

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

[4] Organization IS. ISO 9421-11. Standard on Display Screen (VDU) Regulations, Use of Ergonomics for Procurement and Design. Geneva, Swiss, 1998.

[5] Ying-Jui C, Chirh-Yun AT, Min-Li BY, Yu-Chuan BA. Assessing the Impact of User Interfaces to the Usability of a Clinical decision support system. AIMIA Symposium, 2003;808.

[6] Saleem JJ, Patterson ES, Militello L, Render ML, Orshansky G, Asch SM. Exploring barriers and facilitators to the use of computerized clinical reminders. JAMIA, 2005 ;438-47.

[7] Han YY, Carcillo JA, Venkataraman ST, Clark RS, Watson RS, Nguyen TC, Bayir H, Orr RA. Unexpected Increased Mortality After Implementation of a Commercially Sold Computerized Physician Order Entry System. Pediatrics, 2005 ;116(6):1506-12.

[8] Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL. Role of computerized physician order entry systems in facilitating medication errors. JAMA, 2005 ;293(10):1197-1203.

[9] Vredenburg K, Isensee S, Righi C. User-Centered Design: An Integrated Approach. Prentice Hall PTR, Upper Saddle River, NJ, 2002.

[10] Organization IS. ISO 13407. Human Centered Design Process for Interactive Systems. Geneva, Swiss, 1999.
[11] User-Centered Design. IBM. Available from: https://www-01.ibm.com/software/ucd/ucd.html

[12] Norman DA, Draper SW. User Centered System Design: New perspectives in Human-computer Interaction. L. Erlbaum Associates Inc. Hillsdale, NJ, USA, 1986.

[13] Marcy TW, Kaplan B, Connolly SW, Michel G, Shiffman RN, Flynn BS. Developing a decision support system for tobacco use counselling using primary care physicians. Informatics in primary care, 2008;16(2):101-9.

[14] Wang F, Hannafin MJ. Design-based research and technology-enhanced learning environments. Educational Technology Research and Development, 2005;53(4): 5-23.

[15] Porter SR, Rcs FD, Rcse FD, Scully C, Rcps FD. Etiology and management of Xerostomia. AJP, 2004;97(1):28-46.

[16] Jontell M, Mattsson U, Torgersson O. MedView: an instrument for clinical research and education in oral medicine. Oral surgery, oral medicine, oral pathology, oral radiology, and endodonlogy, 2005;99(1):55-63.

[17] Beale T, Heard S. openEHR Architecture Overview. Available from: http://www.openehr.org

[18] Gulliksen J, Gőransson B, Boivie I, Blomkvist S, Persson J, Cajander A. Key principles for user-centred systems design. Behaviour & Information Technology, 2003;22(6):397-409.

[19] Horasani RA, Anasijevic MI, Iddleton BL, C MS. Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality. JAMIA, 2003;10(6):523-30.

Acknowledgements

Scincere thanks go to Ian McNicoll, Soren Lauesen, and Dowen Birkheld for evaluating domain concept models and the GUI. Many thanks also go to Mats Jontell, Marie Lindgren and Göran Falkman, our team members; and to my love Mohsen Nosratinia, and to Anna Gryszkiewicz for proofreading this paper. The author would also like to express her gratitude to Olof Torgersson under whose supervision this work has been done as a part of the author’s PhD study. The project was funded by the Swedish Governmental Agency for Innovation Systems (VINNOVA), grant 2006-02792, as a joint project between Chalmers University of Technology and Sahlgrenska Academy, and is in progress at the time of writing this paper.

Address for correspondence

Department of Computer Science and Engineering, Chalmers University of Technology, SE-412 96 Gothenburg, Sweden. Email: hajar.kashfi@chalmers.se
Paper IV

Applying a User-centered Approach in Designing a Clinical Decision Support System

Hajar Kashfi

*Computer Methods and Programs in Biomedicine, Elsevier.*

(manuscript submitted)
Applying a User-centered Approach in Designing a Clinical Decision Support System

H.Kashfi

Department of Applied Information Technology
Chalmers University of Technology
SE–412 96 Gothenburg, Sweden

Abstract

Aim: To design a clinical decision support system (CDSS) by applying a user-centered design (UCD) process with the aim of learning from applying UCD in a clinical context. Methods: A UCD process has been applied in this study. To support this UCD process, several methods were utilized such as prototyping, usability test, usability expert review and interview. Several usability experts, users and domain experts were involved in this process. The work presented in this paper is the outcome of the first three iterations of the project. Results: Several user interface prototypes were developed, evaluated and improved iteratively. Characteristics of the clinical context that may have an effect on applying a UCD process were detected and analyzed. Conclusion: Applying a UCD process for designing this CDSS was very helpful and resulted in various improvements in the design that would otherwise remain undetected until the application is implemented and released to the users. The experience showed that UCD is considered to be helpful but challenging in this context. There are characteristics of the users, the tasks and the context to be aware of while applying a UCD process in a clinical context.

Keywords: clinical decision support system, user-centered design, human-centered design, usability, design evaluation, interactive system design, user interface evaluation, qualitative evaluation, clinical application, empirical usability evaluation method, non-empirical usability evaluation method, usability test, usability evaluation

1. Introduction

The history of applying computers in the clinical domain goes back to the 50s. Since then, there have been continuous efforts to benefit from computers in the care process specially diagnosis and treatment of patients to reduce preventable clinical errors (mostly human errors) and to improve quality of care in general. A clinical decision support system (CDSS) is a computer system that is used to facilitate the process of decision making for clinicians. This support is provided by mapping or compiling existing data to useful information that can be used as a clue for making the best decision [1]. Studies have demonstrated that CDSSs can be helpful in various ways such as improving prescribing practice [2, 3, 4, 5], reducing or preventing errors [6, 5, 7, 8],

*Corresponding author
Email address: hajar.kashfi@chalmers.se (H.Kashfi)

Preprint submitted to Computer Methods and Programs in Biomedicine May 18, 2011
steering up best practices in medicine or encouraging evidence-based medicine [4, 9, 5, 6] and finally decreasing cost [6, 5].

More than 40 years have been spent on studying CDSS development. Nevertheless, the theoretical advances have been ahead of practice so far [6, 10] and it is observed that CDSSs suffer from a low adoption rate in spite of advances in research [6, 10, 11].

Various researchers have carried out studies to discover the reasons for low adoption of CDSSs and to identify success and failure factors of these system. According to these studies, success factors of CDSSs can be divided in two main categories of technical and non-technical factors. Non-technical factors documented in these studies, in their general form, have been the focus of the human-computer interaction (HCI) research field for years. To address such issues, HCI recommends applying a process named user-centered design (UCD).

Taking HCI into consideration has become a routine in domains such as aviation and automotive industry [12], nevertheless this is not the case in the clinical domain. Therefore, applying such methods that are demonstrated to be helpful in other domains, disseminating the knowledge gained by experience, and learning from successes and failures can be of great help in this domain, specially since it is observed that these types of success factors of CDSSs are more appreciated in theory than in practice.

1.1. Aim of the Paper

The aim of this paper is to improve the reader’s knowledge on the UCD process, and methods to support UCD. The hope is to achieve this by discussing our experience in applying UCD in a clinical context and presenting the process, phases, and methods carried out in this study1. So far, three iterations of the project are gone through. Each iteration includes different phases and various methods in each phase to support UCD. Several prototypes were created and evaluated using a number of qualitative evaluation methods.

The paper starts with some background information on the importance of HCI in developing CDSSs. Afterwards, details of three iterations of the UCD process and methods applied in each iteration are discussed. Lastly, findings and limitations of the study are discussed.

2. Background

2.1. Human-computer Interaction

HCI is defined as “a discipline concerned with the design, evaluation and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them” [15]. The heart of HCI is the concept of usability which is a very important factor in designing an interactive system [16]. Usability is defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” [17].

Low usability can result in underuse (the system is not used so often and users stick to their current methods for accomplishing the tasks) or misuse (the system is used improperly) of the

\footnote{Investigation of openEHR [13] as one of the electronic health record (EHR) interoperability standards, was another aim of this study. UCD was applied to develop not only the user interface of the CDSS but also the domain models. Domain models were developed iteratively and by involving domain experts as suggested by both UCD and openEHR. The details about development of an openEHR-based CDSS is out of the focus of this paper, hence is skipped here. More information about this aspect of the project can be found in [14].}
system. Underuse and misuse of the system both bring costs to the organization or ruin the reputation of the team or the company that developed the system [18]. There are a number of benefits associated with designing a usable system such as increased productivity, reduced errors, reduced training and support, improved acceptance and enhanced reputation [18].

To develop a usable interactive system, both functional requirements and non-functional requirements, including usability requirements, should be considered by developers. Traditionally, the focus of software design processes have been on functional requirements. As mentioned by Seffah [19] “the importance is given to the functionality, and the interface is really a small issue to be subordinated”. Nevertheless, nowadays there are design frameworks integrating functional and non-functional requirements [18].

To develop systems with higher usability, the HCI community suggests a user-centered design (UCD) (or human-centered design (HCD)) process [20] and various methods to support this process [18]. These methods cover different phases of the system development. The UCD process is based on the idea that by involving users in the design and development process of a system, the system will be more usable for the users in the intended context [20, 21, 22].

2.2. Importance of Human-computer Interaction in Developing Clinical Decision Support Systems

There are various studies that deal with the question of which factors should be considered in design and development of a CDSS to result in an acceptable and effective system and to reach a higher adoption rate? According to these studies, success factors of CDSSs can be divided in two main categories of technical and non-technical factors. Non-technical factors are mostly human-related issues such as: users’ interaction with the system, users’ workflow, users’ training, and users’ satisfaction and acceptance. Moreover, as observed by Kaplan [23], to evaluate a CDSS not only “quantitative” but also “qualitative” evaluation methods are required to answer the questions of “why clinicians accept or do not accept a system” or “why they change their practice behavior after introducing the system”.

Existence of such studies shows that there is motivation in applying qualitative evaluation methods and consideration of HCI and usability in CDSS design. It is also evident from the literature that developers of CDSSs are being informed about these matters. Nonetheless, the published practical studies suggest that neither all of the methods, nor all aspects of UCD are put into practice by developers of CDSSs. For instance, most of the studies report the application of individual methods rather than UCD as a process to be applied in the whole life-cycle of systems. Additionally, not much theoretical discussion of methods and costs and benefits associated with them are documented in the related literature.

This suggests that there is a need to disseminate the benefits of applying UCD and its recommended standard methods that cover not only the user interface evaluation but also various phases of the project such as planning, requirements gathering, and designing. In addition, spreading the knowledge of how to apply UCD in the clinical context for developing systems such as CDSSs, and publishing success and failure stories of applying UCD in this context would be beneficial to improve the practical attitude of CDSS developers towards HCI, usability and UCD.

2.3. The Project Background

In 2007, a team of computer scientists from two universities in Sweden started a joint project with the clinical of oral medicine at Sahlgrenska University Hospital with the aim of developing a CDSS for an oral disease named dry mouth. Dry mouth or xerostomia is “the abnormal reduction
of saliva and can be a symptom of certain diseases or be an adverse effect of certain medications” [24]. There are various different factors dentists or dental hygienists should remember (e.g. related diseases and drugs) therefore management of the disease is not always easy and some information may be unwittingly omitted in the process and this may result in a lower quality of diagnosis and treatment of the patient. The need for a CDSS for this oral disease was brought up by specialists in Dentistry in the Clinic of Oral Medicine.

3. User-centered Design Iterations, Phases and Methods

The UCD process (depicted in Figure 1) starts with a planning phase and continues with a cycle including four phases, namely understanding and specifying the context of use, requirements, design, and evaluation. The UCD cycle will be repeated until the requirements are met and users are satisfied with the design. End users are at the heart of this process and involvement of users in all UCD phases is recommended. The HCI community have suggestions for the methods that one may apply in different phases of the UCD cycle (see Table 1) [18].

Each iteration of the project may include all or some of the UCD phases. In each phase, a collection of recommended methods is selected, based on the characteristics of the project and the development team. For instance, in this project, iteration one included all of the five phases while iteration three included only two of them. Three iterations of the project along with phases and methods carried out in each iteration are discussed in Section 4, Section 6, and Section 8. A summary of these three iterations, phases and methods is shown in Table 2.

In the following, definitions of the five UCD phases are given along with examples of the methods suggested for each phase. Not all of these methods are defined in this paper. Nevertheless, the definitions of those methods that were applied in this study can be found in Section 4, Section 6, and Section 8. For definitions of the other methods the reader can refer to the related literature [18, 25, 26, 27, 28].

| Planning | Context of use | Requirements | Design | Evaluation |
|----------|---------------|--------------|--------|------------|
| ◦ Usability planning and scoping | ◦ Identify stakeholders | ◦ Stakeholder analysis | ◦ Brainstorming | ◦ Participatory evaluation |
| ◦ Usability cost benefit analysis | ◦ Context of use analysis | ◦ User cost-benefit analysis | ◦ Parallel design | ◦ Assisted evaluation |
| o ◦ Survey of existing users | ◦ User requirements interview | ◦ Design guidelines and standards | ◦ Heuristic or expert evaluation |
| o ◦ Focus groups | ◦ Affinity diagram | ◦ Storyboarding | ◦ Controlled user testing |
| o ◦ Scenarios of use | ◦ Card sorting | ◦ Affinity diagram | ◦ Satisfaction questionnaires |
| o ◦ Persons | ◦ Paper prototyping | ◦ Storyboarding | ◦ Assessing cognitive workload |
| o ◦ Existing system or competitor analysis | ◦ Software prototyping | ◦ Heuristic or expert evaluation | ◦ Critical incidents |
| o ◦ Task or function mapping | ◦ Wizard-of-Oz prototyping | ◦ Controlled user testing | ◦ Post-experience interviews |
| o ◦ Allocation of function | ◦ Organizational prototyping | ◦ Satisfaction questionnaires | |
| o ◦ User, usability and organizational requirements | | | |

Table 1: Methods of the user-centered design (UCD) process. For more details about each method refer to [18].
3.1. The Planning Phase

In this phase, planning of the process is done. Stakeholders (those who may be affected by the system), users, project team members and users who will participate in evaluations are specified. High level information about users, users’ needs, and the environment (context of use) is also gathered in the planning phase. Usability planning and scoping and usability cost benefit analysis are two of the activities suggested to be carried out in this phase [18].

3.2. The Context of Use Phase

The focus of this phase is on understanding the technical, physical and organizational aspects of the context, the user population, and users’ goals and tasks. Various methods can be used to gather this information such as context of use analysis [18], task analysis [28, 18] and field study [18, 25, 28, 27]. Information gathered in this phase is used as a basis for system design and evaluation.

3.3. The Requirements Phase

The Requirements phase is considered to be one of the most important phases in software development. In this phase, users and organizational requirements are gathered and documented.

In addition to functional requirements of the system, usability requirements are identified in this phase in order to set objectives and priorities for the design team [18]. Effectiveness, efficiency, learnability and satisfaction are some of the general usability requirements [18, 25]. The design should be evaluated against some usability objectives, i.e. usability goals, throughout the iterative design process. In order to set up usability goals, one needs to specify relevant measurable usability characteristics of the system, i.e. usability attributes [26] and to decide how these are going to be measured. Interview (see Section 4.3.2) and existing systems analysis are the methods suggested for this phase [18].
Table 2: Summary of the iterations, phases and methods. Each column corresponds to one of the three iterations of the project. In each column, various phases that have been carried out in that iteration are shown. Under each phase, there is a list of methods applied in that phase.

3.4. The Design Phase

In this phase, based on the results from previous phases, design solutions are created. In order to decrease costs, it is recommended to apply prototyping techniques such as sketching (see Section 4.4.2) and paper prototyping (see Section 6.3.2) in this phase in early iterations of the project [25].

3.5. The Evaluation Phase

Evaluation of design solutions against requirements gathered in the requirements phase (and considering information gathered in the context of use phase) is carried out in the evaluation phase. Two classes of evaluation methods can be applied in this phase. The first class is empirical evaluation methods [26] (evaluations based on user participation) such as interview (see Section 4.3.2) and usability test (see Section 6.4.1). The second class is non-empirical evaluation methods [26] (evaluations based on developers or usability experts participation) such as usability expert review (see Section 6.4.4), heuristic evaluation and cognitive walkthrough.

4. Methods Applied in Iteration One

In the first iteration of the project, all of the five UCD phases were gone through. Explanation of the methods applied in these phases is presented in the following.
4.1. Methods Applied in the Planning Phase

Planning for the project was brief and included specifying the team, stakeholders (including a specialist in dentistry who was going to be involved in all stages of the project. This person is referred to as our main clinical partner in this paper). Planning was done in a group meeting held at the Clinic of Oral Medicine at Sahlgrenska University Hospital.

4.2. Methods Applied in the Context of Use Phase

To understand the context of use and to identify stakeholders, meetings were held with the Project Manager, and our main clinical partner in the Clinic of Oral Medicine.

4.3. Methods Applied in the Requirements Phase

Literature review, interview [25, 18], and multi-disciplinary group sessions were carried out in the requirements phase in the first iteration. More about these methods is given in the following.

4.3.1. Literature Review

This included studying articles in which the characteristics of dry mouth were explained, and those that discussed success factors of CDSSs. Moreover, some existing CDSSs were studied.

4.3.2. Interview

Interview is a data gathering method in which a goal oriented conversation is performed with the interviewee [25]. Based on the amount of control the interviewer imposes on this conversation, four types of interviews can be defined: structured, unstructured, semi-structured and group interview. Interviews in this phase were unstructured interviews with our main clinical partner that were held at the Clinic of Oral Medicine. The aim of these interviews was to gather information about the functionalities users expect from the system.

4.3.3. Multi Disciplinary Group Sessions

Every second week, a meeting was held at the Clinic of Oral Medicine to share the project progress with some of the stakeholders and to get their opinion on different issues such as graphical user interface (GUI) design, and decisions about user representatives and domain experts (dentists and dental hygienists) to be interviewed.

4.4. Methods Applied in the Design Phase

Brainstorming [18] and low fidelity prototyping techniques [25] were applied in this phase to produce design solutions based on the information gathered in the previous phases.

4.4.1. Brainstorming Sessions

To produce design solutions, brainstorming sessions [18] were held at Sahlgrenska together with our main clinical partner. At the beginning of the first session, our main clinical partner was introduced to some existing CDSSs in order to get a better idea about functionalities a CDSS may provide.
4.4.2. Low Fidelity Prototyping: Sketches and PowerPoint Prototyping

To realize the produced designs, prototypes of the GUI were developed in this phase. The prototypes developed in this phase were low fidelity prototypes [25]. Low fidelity prototypes are not much like the final prototype. The materials used for creating such prototypes (e.g. paper and pen) are different from the material in the final product. Low fidelity prototypes can be developed very cheaply, quickly and simply.

In this phase, two low fidelity prototypes of the system were developed with a close collaboration with our main clinical partner. These included sketches drawn in the brainstorming sessions, and a more interactive Powerpoint prototype, which was later used for evaluations.

Sketching relies on simple drawings of the design ideas [25] and is a low fidelity prototyping technique. The Powerpoint prototype was the realization of the same design solution as in the sketches but in a more interactive manner.

4.5. Methods Applied in the Evaluation Phase

In this phase, both empirical and non-empirical evaluations were carried out to evaluate the Powerpoint prototype created in the previous phase.

4.5.1. Informal User Evaluations

In two meetings, the prototype was shown to our main clinical partner. His comments about the design were recorded on paper and discussed. In these sessions, the test person was supported with explanations whenever he did not understand something on the GUI. The meetings were held at the Clinic of Oral Medicine.

4.5.2. Informal Expert Reviews

In several informal meetings with some usability experts and user interface design experts, the prototype was evaluated and alternative designs were suggested and discussed\(^2\). The meetings were held at the Chalmers University of Technology.

5. Results from Iteration One

Activities in the first iteration of the project resulted in a basic understanding of the system requirements and the context of use, i.e. the Clinic of Oral Medicine. As suggested by the UCD process, this iteration also included the development of early prototypes of the system and prototype evaluations. In the following, the details of the results are given.

5.1. Results from the Planning Phase

A multidisciplinary team was set up to handle the development of the project. The team included the following members: our main clinical partner, three computer scientists (for simplicity they are called designers), and one programmer. It was decided to monitor the progress through regular meetings in the Clinic of Oral Medicine. No clear decision about how and when to involve more domain experts and tests users were made at this stage.

\(^2\)the term “usability expert review” is not used since one of the experts was not a usability expert but a person with experience in user interface design.
5.2. Results from the Context of Use Phase

The system is intended to be used in the Clinic of Oral Medicine at Sahlgrenska. Information technology (IT) has been around in this clinic for at least 12 years. People in this clinic work with T4 [29] and MedView [30], two clinical applications for data gathering and information visualization. Specialists in dentistry and dental hygienists at this clinic are users of the system. Patients are also affected by the system.

5.3. Results from the Requirements Phase

The data entry for dry mouth would be partially done by patients via the touch screen GUIs available at the clinic, and partially by clinicians via the MedView application [30]. Afterwards, if the patient is likely to have dry mouth, the clinician decides whether to use the CDSS. Therefore, the CDSS is not aimed at data entry, but presentation of patient data in a way that makes diagnosis easier.

5.3.1. Functional Requirements

System requirements gathered in this phase included: (i) partial data entry (the possibility to edit patient information if required) (ii) providing an overview of the patient information (iii) providing hints on the information (e.g. using colors to indicate risky items) to make diagnosis easier (iv) providing diagnostic suggestions (v) providing related clinical evidences

5.3.2. Usability Requirements

As suggested by Helander [26], based on categorization of the users, the context of use, and the tasks to be performed by users, a set of usability attributes were defined for the application. Three categories of users were specified: (i) general dentists (ii) specialists in dentistry (iii) dental hygienists. The characteristics of the environment in which these users would apply the system were gathered. Four types of usability requirements suggested by Shneiderman [25] were considered to be relevant to this system. The main tasks to be undertaken by users were specified. Finally, measurable usability attributes and their measuring methods were set. A summary of the aforementioned information gathered in this phase is presented in Table 3. Based on the usability attributes, and by specifying usability goals a usability specification was prepared for the project (see Table 4).

| User Characteristics | User Environment | User Tasks | Usability Attributes | Measuring Instrument | Metrics |
|----------------------|------------------|------------|----------------------|----------------------|---------|
| General dentists     | No time for learning | Partial data entry | Stasisfaction | Questionnaire | Time to complete a task |
| Specialists in dentistry | High pressure | Patients’ record overview | Error rates | Bench mark tasks | Number of errors in a specified time period |
| Dental hygienist     | Technical support | Get support for dry mouth | Efficiency | Data log | Number of steps per task |
|                      | Many interruptions | Overview articles | Ease of learn |                     |         |
|                      | Many patient visits during the day |                     |                     |                     |         |

Table 3: The usability attributes.

9
| Attribute                              | Measuring instrument | Measuring method | Planned level |
|---------------------------------------|----------------------|-----------------|---------------|
| Ease of locating info                 | Difficult 1 2 3 4 5  | Easy            | >4            |
| Ease of understanding colors           | Difficult 1 2 3 4 5  | Average rating  | ≥4            |
| Ease of understanding the decision     | Difficult 1 2 3 4 5  | Average rating  | >4            |
| support part                          |                      |                 |               |
| General satisfaction                  | Low 1 2 3 4 5 High   | Average rating  | >4            |

Table 4: The usability specification

5.4. Results from the Design Phase

Based on basic understanding of the users, tasks and context acquired in the previous phases, an initial design of the system was created for further development. The suggested design solution was based on the idea of clinical questionnaires. In other words, a list of related questions were provided together with our main clinical partner to be used for data gathering (using existing applications) and for data representation in the CDSS being developed. This design idea, however refined in various steps, remained as the core design idea throughout these three iterations.

To realize the design solution, some sketches and a power point prototype were produced in this phase. One of the prototypes generated in the first iteration is depicted in Figure 2.

5.5. Results from the Evaluation Phase

The user evaluations on the first prototype revealed some minor changes in the design while the informal expert reviews resulted in major changes.

5.5.1. Results from the User Evaluations

Informal user evaluations in this iteration did not cause major changes. The design solutions were developed together with our main clinical partner, hence the evaluation with the same user did not result in major improvements. In the following, some of the comments given on the design are presented:

- Navigation:
  To improve navigation and to make the design more compatible with the user workflow, a change in the order of items was suggested. For instance, it was suggested that chemotherapy related questions be moved under the “Drugs” section.

- Color coding:
  It was suggested that suitable colors to indicate missing information be applied.

- Visual clarity:
  It was suggested that unnecessary items be removed in order to improve visual clarity of the GUI. For instance, removal of the risk bar was suggested.

---

3This questionnaire was also used as a basis for developing openEHR domain models named archetypes [14]
Figure 2: The GUI prototype created in the first iteration. This design solution included three collapsible horizontal sections. Each section included various questions to be filled in or reviewed. On top of the first section there existed two progress bars that were meant to show how much of the information is missing, and how much dry mouth risk is calculated based on answers to the questions. To get the diagnostic suggestions and review related clinical documents, users needed to navigate among screens.
5.5.2. Results from the Expert Reviews

Informal expert review sessions held in the first iteration resulted in major changes in the design. As illustrated in Figure 2, in the first iteration, designers and our main clinical partner, came to a design solution in which users needed to navigate among various screens. This design solution was highly objected to by the experts involved in the evaluation. One suggestion was to reduce the number of screens by applying the tree table design pattern [31].

6. Methods Applied in Iteration Two

Analysis of the evaluation results in the first iteration revealed that the design solution did not still meet all the requirements. Therefore, as recommended in the UCD process, it was decided to go through another cycle of UCD, i.e. the second iteration. The second iteration of the project included four phases namely planning, requirements, design and evaluation. Various methods were carried out in these phases as presented more in detail in the following.

6.1. Methods Applied in the Planning Phase

At this stage, more time was spent on planning to get more interviewees and test users for requirements gathering and running usability tests. To motivate involving more users, in a short presentation, stakeholders (including our main clinical partner) were informed about the benefits associated with UCD and involving more users in the UCD process.

6.2. Methods Applied in the Requirements Phase

Interview is the method used in this phase to gather more information about the disease, and the workflow. The interviews held in this phase were all semi-structured interviews in which users were asked questions with a specific set of answers and also open questions that enabled them to share their opinions more easily. Four domain experts, three specialists in dentistry and one dental hygienist, were interviewed in this phase. The interviews were held at different hospitals and clinics where the interviewees worked.

6.3. Methods Applied in the Design Phase

Based on the evaluation results from the first iteration and the discovered design flaws, a new design solution was developed in the second iteration. Design guidelines and two different prototyping techniques were applied in this phase as discussed in the following.

6.3.1. Design Guidelines

In this phase of the project, some design patterns and guidelines were considered in developing the new design solution. One of them was the Microsoft health common user interface⁴ that provides some design guidelines for designing GUIs for clinical applications. Various guidelines in the area of clinical noting and terminology, consistent navigation, medication, patient identification and miscellaneous are provided by Microsoft.

One other known design solution that was applied in this project was tree table [31]. Tree table is a GUI design pattern that is suggested for application when hierarchical information is to be presented in columns.

---

⁴http://www.mscui.net
6.3.2. Low Fidelity Prototyping: Paper Prototyping

Paper prototyping is a low fidelity prototyping technique (see Section 4.4.2) by which a paper-based simulation of the GUI is developed [25]. A paper prototype of the system was created in this phase. Paper prototyping was selected since it is easy, time efficient and cost effective [25].

6.3.3. High Fidelity Prototyping: Software Prototyping

High fidelity Prototypes [25] consist of the materials one expects in the final product. These prototypes are much like the final product. Also, it takes more time, effort and money to create such prototypes. The high fidelity prototypes are strong in testing technical functionalities and also selling the design idea to stakeholders.

In addition to the paper prototype, a Java-based prototype of the system was also developed in this phase. One motivation for creating a Java-based prototype was that by having a more interactive prototype, and a prototype which is more similar to the final product, the results of the user tests would be more reliable. However, this turned out to be an improper decision (see sec:pro). One other motivation for creating a Java-based prototype was to create an opportunity to investigate the openEHR related functionalities of the system and to investigate the development of an openEHR-based application in more detail.

6.4. Methods Applied in the Evaluation Phase

Three empirical evaluation methods namely usability test [28], think aloud protocol [28], and interview, together with a non-empirical evaluation method namely usability expert review [16] were carried out in this phase. Details about each method are as follows.

6.4.1. Usability Test

Usability test is a collection of methods used to evaluate the usability of a product. It is typically focused on how well a user can use the product to accomplish a specific task, and also errors that occur during this process [28].

Usability tests were conducted in the Clinic of Oral Medicine at Sahlgrenska. Before each test, the test person was verbally informed about the test procedure, goals of the test and how she/he can be more helpful e.g. by being honest about the design flaws.

Two persons were responsible for running the test. Four usability tests were run on three specialists in dentistry and one dental hygienist. Each test session took around two hours. Users were given 10 tasks to accomplish. Tasks were selected to cover all elements in the design. The list of tasks was printed and one of the test leaders read each task for the test user. Hints were given just if the user was not able to proceed.

In the usability test sessions, users were asked to verbalize what they thought while they interacted with the system (see Section 6.4.2). Moreover, after each session, users were interviewed about their background also their experience of using the system. More about the interviews is given in the following.

6.4.2. Thinking Aloud Protocol

Thinking aloud is a simple observation method in which the user is asked to verbalize what she/he thinks and performs during the observation [28]. This method is used in usability test to gather more information about how a user interacts with the GUI.

In the usability tests carried out in this phase, test users were asked to think aloud. Their comments were recorded on paper during the test session and analyzed afterwards.
6.4.3. Interview

After each usability test, the test user was interviewed about their experience of using the system, also their background. The interviews were semi-structured (see 4.3.2) and consisted of 44 questions, and around 10 background questions such as personal information and information about other applications the user works with.

In addition, three specialists in dentistry and one dental hygienist (referred to as domain experts) were interviewed about the disease and the workflow. Also, by presenting the GUI prototype to the interviewees and letting them reviewing the design, their opinions about the prototype were gathered in this stage.

6.4.4. Usability Expert Review

One way to evaluate a GUI against standard and best practice design solutions is to ask usability experts to review the design [16]. In this phase, three usability experts reviewed the prototype. The reviews were conducted at Chalmers University of Technology. In each review session, one usability expert was asked to review the prototype, i.e. the Java-based prototype. One of the designers was also present at the review sessions that provided an opportunity to discuss design flaws and suggestions to improve them. Comments and suggestions given by the experts were recorded on paper for further analysis.

7. Results from Iteration Two

7.1. Results from the Planning Phase

Besides our main clinical partner, who was involved in the project from the beginning, three more specialists in dentistry and one dental hygienist were selected to be interviewed. Another group of three specialists in dentistry and one dental hygienist were also specified to participate in the project as test users for user interface evaluations.

7.2. Results from the Design Phase

Based on analysis of the evaluation results in the previous iteration, also studying some design guidelines, a new design was produced in this phase. Figure 3 depicts the prototype developed in this phase. This prototype was later translated to a Java-based prototype to be used in the usability tests. The design was based on the first developed idea of clinical questionnaires (see Section 5.4) and the tree table design pattern (see 6.3). As illustrated in Figure 3, the new GUI consisted of three different collapsible sections that are explained in the following.

In the GUI, different colors (green, gray, orange) were used to indicate different conditions of the patient data. Orange was used to indicate “risk”, green to show “no risk”, gray to show “missing information” as a background color for unanswered questions.

7.2.1. Symptoms and Signs

This section included three main categories of information: (i) a tree structure of symptoms reported by the patient or signs observed by the clinician (marked as A in the figure). This was in form of a set of questions and answers (see Section 5.4) (ii) details about the total number of questions, the number of answered questions, and potential dry mouth risk based on the answers to the questions (marked as B in the figure) (iii) a user interface input component for each question e.g. radio buttons for yes/no questions.
Figure 3: The GUI prototype, the second iteration
The tree structure of questions which represented symptoms and signs for each patient included information about general and local symptoms, i.e., oral symptoms. It also included information about previous treatments (labeled as “iatrogenic”) and related diseases. Users might browse the tree structure from more abstract concepts to detailed patient information. For instance under the “Oral symptoms” heading, users could see if the patient had noticed any decrease in her/his amount of saliva. The progress bars and the numbers in front of it (marked as C in the figure) indicated the total number of questions and answered questions. Based on answers to the questions, the color of the progress bar indicated if that specific category of items contributed to the patient’s disease. If the bar was orange it indicated contribution.

7.2.2. Decision Support

This section included: (i) an overview of the diagnostic suggestions (contributing factors) by the system (marked as D in the figure). The pie chart in this section was designed for showing the proportion of causes (ii) related clinical documents (marked as E in the figure). Abstracts of the relevant papers were presented in text format in this section.

7.2.3. Event Details

This section consisted of two tabs: Drug and Lab Value. In the drug tab (marked as F in the figure), users could view: (i) a list of drugs that the patient took (ii) details about each drug e.g. if the drug had a dry mouth side effect and a link to a website named Fass. Fass includes a comprehensive database of the existing drugs in the market, their characteristics and their side effects (iii) a possibility to prescribe a new drug.

In the lab value tab, there was: (i) results of previous lab tests (marked as G in the figure) (ii) details about the results for instance if the results indicated any risk of having dry mouth using icons (marked as H in the figure) (iii) a possibility to order a lab test (marked as I in the figure).

7.3. Results from the Evaluation Phase

According to the UCD process used in this project, the new design solutions were evaluated by users and usability experts, in order to find out whether all the requirements are satisfied, and to discover design flaws.

7.3.1. Results from the Expert Evaluations

The three expert evaluations resulted in discovering various general design flaws regarding navigation, feedback, pliancy and hinting, consistency, color coding and icons. Experts also provided suggestions for most of the flaws. Some examples of these flaws are summarized in Table 5.

7.3.2. Results from the Usability Tests and Interviews

Usability tests were carried out on the Java-based prototype of the system. In addition, more information about the data to be presented on the GUI, the structure of items and also the workflow was gathered in interviews with end users and domain experts. Users also had some opinion about how the GUI can be improved.

More details about the results are presented in the following. Some of these design flaws are also summarized in Table 6.

5http://fass.se
| Flaw               | Example and details                                                                 | Recommendation                                                                 |
|-------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Navigation        | The nested structure of the sections and trees, including more than 2 levels, is difficult to navigate and find information | The collapsible sections should be replaced with tabs |
| Functionality     | The pie chart is not easy to understand for users, also users needs to navigate in the small area provided for related articles in order to find an article. Also it should be possible for users to sort questions | A list of contributing factors should be provided, the articles should be listed in a larger area or in a pop-up window. A sorting functionality should be provided |
| Visual clarity    | Distinguishing questions and their answers is not visually easy                       | A stripped background for questions is needed                                  |
| Consistency       | On top of the screen, various collapsible horizontal sections are presented while at the bottom, there exists a tabular table area | A consistent design solution should be used for representing information (all tabs or all collapsible sections) |
| Pliancy and hinting | Some of the buttons are small, and not easily detectable, also no pliancy response is provided so that users find out that the button is click-able | Pliancy and hinting is required for various items on the screen |
| Icons             | Some icons are not easy to understand for instance the icon used for indicating the risky items in the tree | New icons should be designed                                                  |
| Color coding      | The green color in icons and in the bars are not the same however they have the same meaning, it is also better to use more than just one color in each bar to provide more information | The same colors for bars and icons should be included in the bars to show unanswered questions, and risky and safe answers |

Table 5: The design flaws detected by the usability experts in the second prototype.

| Flaw               | Example and details                                                                 | Recommendation                                                                 |
|-------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Navigation        | The nested structure of the sections and trees was difficult to navigate for users specially since the structure and order of some items was not based on the user workflow model | The collapsible sections should be replaced with tabs and arranged according to the user workflow model |
| Functionality     | The pie chart was not easy to understand, also some functionalities such as suggesting products to users or sending referral was not included in the design | A list of contributing factors should be provided, also new functionalities: writing a comment, suggesting products, sending referral, etc. should be included |
| Pliancy and hinting | Users did not detect some of the clickable areas                                        | Pliancy and hinting for various items on the screen should be provided |
| Color coding      | The users complained about the yellow color used in the design, they were expecting a combination of red, yellow, green | The new colors : red, blue and green should be used in the design to indicate risky, unanswered and safe items |
| Language          | Some of the terms such as “iatrogenic” was confusing for users                         | Based on users’ feedback new terms would be used in the design                |

Table 6: The design flaws detected in usability tests of the second prototype
Navigation

The order of sections, also the possibility to collapse them totally, resulted in confusion for all of the test users. Half of the test users, stuck to the first section (symptoms and signs) which made it impossible or challenging for them to find the information located in other sections.

The user workflow model

All of the test users reacted to the order of headings and some of them to the order of sections. One of the complaints was about oral symptoms being located before general symptoms in the tree.

According to the users and domain experts interviewed, diagnosis and management of dry mouth (the users workflow model) was a bit different to what was gained in the previous iteration. According to them, management of a dry mouth patient starts by general anamnesis. After general anamnesis, information related to local symptoms and examination is gathered. The next phase would be to do some tests if needed; including saliva mirror test and biopsy test. This workflow model affected the users’ interaction with the system.

Even though the system is not going to be used for data entry (but for presenting data), users had a problem locating information when they found the organization of information on the screen not compatible with their workflow.

Color coding

Surprisingly, all of the test users either misunderstood the colors or did not pay attention to them. Part of that might be because they were new to the system. They admitted that if they learned the meaning of colors they would pay more attention to them. Three out of four test users suggested applying red, yellow and green colors, the same as traffic light colors, that everyone is familiar with.

Language

Most of the headings used in the user interface were familiar to the test users. However, some of them e.g. “Iatrogenic” were confusing since they normally would not use that word to indicate previous treatments on users. “General Symptoms” is another heading which should be changed to the term “Anamnisis” which exists in other applications and users were familiar with. “Oral Symptoms” should also be replaced with the term “Local Symptoms and Examinations”.

Visual clarity

Having duplicate headings made users confused. For instance, in the “Symptoms and Signs” tree there was a sub-tree including information about current drugs the patient took. Users could not however edit that information. On the other hand, in the last section named “Event Details”, information about current drugs with more details and a possibility to prescribe new drugs was provided (“Drug” tab). When test users were asked to prescribe a drug, they were confused about choosing the right section. This therefore resulted in a number of errors for related tasks.

In addition, all of the users misunderstood the meaning of the pie chart (in the “Decision Support” section) and the information presented there. The usability tests, revealed that the i.e. users’ perception of the pie chart (a presentation of the risks percentage, or the percentage of contributing causes) was obviously wrong.
Table 7: The results of the usability tests in iteration two

| Attribute                        | Number of related questions | Reached level | Is the goal satisfied? |
|----------------------------------|----------------------------|---------------|------------------------|
| Ease of locating info            | 11                         | 3             | No                     |
| Ease of understanding colors     | 3                          | 1             | No                     |
| Ease of understanding the decision support section | 1 | 1 | No |
| General satisfaction             | 5                          | 3             | No                     |

○ Functionality

During usability tests, it was noticed that some functionalities provided in the prototype, would not be used by users. For instance, all of the test users admitted that they would not prescribe a drug most of the time, and they would never change ordination of a drug which was prescribed by another physician.

On the contrary, it was discovered that there were some functionalities not considered in the design, for instance the possibility to send a referral to a colleague (in most cases a specialist. e.g. a Sjögren’s syndrome specialist)

8. Methods Applied in Iteration Three

As presented in Table 7, usability tests and interviews with end users revealed that the usability goals were not satisfied. Moreover, various general design flaws were detected by usability experts that needed to be removed. This motivated the decision of going through another cycle of the UCD process, i.e. the third iteration.

Based on the results from the previous evaluations, the designer realized that the new design should lead to improvements in navigation, visual clarity, consistency, language, icons and color coding. Therefore, changes in colors, icons, labels, and the order of sections should be considered in the new design.

8.1. Methods Applied in the Design Phase

Analyzing the evaluation results and comparing them to the usability goals (see Table 4), led to designing two parallel design solutions. By producing parallel designs [18], there was a chance to evaluate two designs at the same stage and to choose the best design solution for further development. In this phase, a low fidelity prototyping tool was used to develop two prototypes of the system.

8.2. Methods Applied in the Evaluation Phase

In this phase, the same three usability experts reviewed the two new prototypes. One of the designs was selected for further development. Various general design flaws were detected in the selected design and suggestions were made to improve the selected design. The review sessions were carried out in the same manner as the reviews in the second iteration (see Section 6.3).
9. Results from Iteration Three

9.1. Results from the Design Phase

Considering the evaluation results from the previous iteration, as suggested in UCD, new design solutions were created. As mentioned before, two parallel designs were developed in this phase.

In the third prototype (Figure 4), the horizontal sections were replaced with tabs to improve navigation. The order of tabs was changed to be more compatible with the user workflow to improve navigation. Some headings were updated based on the users’ language. The four tabs on top (marked as A in the figure) covered information to be gathered for performing the diagnosis (symptoms and signs together with previous lab test results). At the bottom (marked as B in the figure), there were seven tabs that included the diagnostic suggestions and various actions clinicians might perform after diagnosis. The order of tabs was based on their priority in the user workflow model.

The fourth prototype (Figure 4) was quite similar to the third one. The main difference between these two prototypes was that the items presented at the bottom of the screen (actions) in the third prototype (marked as B in Figure 4) were located on the right side of the screen (marked as A in Figure 5) in the fourth one.

9.1.1. Results from the Evaluation Phase

According to UCD, there was a need to evaluate the improved design solutions developed in the previous phase. The two new prototypes were reviewed by the three usability experts. Usability experts approved the fourth prototype since the fourth prototype was observed to be better in visual clarity and navigation.

In addition, suggestions were given by the usability experts to improve the design and remove the remaining minor design flaws. Some examples of the flaws detected by experts in this prototype are summarized in Table 8.

| Flaw             | Example and details                                                                 | Recommendation                        |
|------------------|------------------------------------------------------------------------------------|---------------------------------------|
| Functionality    | The users should be able to see the history of actions (comments, referrals, etc.) | A history tab should be added to the screen |
| Icons            | Some icons are not easy to understand, for instance the icons used for “sending referral” or “ordering a lab test” | New icons were suggested to be used |
| Visual clarity   | Some of the icons were duplicated (for instance the icon used for referral was used in three locations on the screen) | Duplicated icons should be removed when not required |
| Feedback         | Proper feedback does not exist for some actions. For instance in case of ordering a lab test users should be informed clearly that the action is done | Feedback in form of pop-up windows should be provided for various functionalities |
| Control          | Users may not clearly see what information is being saved or transferred. For instance while sending a message to a colleague the automatically generated part of the message is not presented to the user | All the related information should clearly be shown to the user, and suitable feedback should be provided |

Table 8: The design flaws detected by HCI experts in the fourth prototype
Figure 4: The GUI prototype, the third iteration

Diagnosis

The patient is diagnosed with Disease-induced dry mouth

Contributing factors

Age
Taking 3 drugs or more
Sjogren's syndrome
Figure 5: The GUI prototype, the fourth iteration
9.1.2. The Final User Interface Design

Finally, based on usability expert reviews and recommendations provided by them, a final prototype of the system was created. This prototype is depicted in Figure 6.

In this prototype, four tabs on the left side of the screen included a tree structure of different categories of the patient’s health information (anamnesis, local symptoms, etc.) (marked as A in the figure). In each tab, and for each sub-category of information a progress bar was presented (marked as B in the figure). The bars included various colors and numbers to indicate the number of unanswered, risky and safe items. Three colors (blue, red and green) indicated the unanswered, risky and safe items (for each category of information/question). Moreover, three different icons were used next to each item/question to convey the same information (marked as C in the figure).

On the right side of the screen, the tabs were included (marked as D in the figure). The first tab, “Take an action”, included the information related to the actions users could take (e.g. writing a comment). On the second tab, “Previous actions”, users could overview the previous actions on the patient case (e.g. previous comments).

10. Discussion

UCD is a design and development process which is supported with a collection of standard methods [18]. These methods cover different phases of the application development process. UCD is more than just involving users in evaluations. It focuses also on understanding the users, the users’ tasks, the users’ goals, and the context in which the system will be used.

In this study so far, three iterations of the UCD process were carried out. A collection of recommended methods were selected to be conducted in various phases of the iterations. Some of the lessons learned in relation to various UCD phases and methods are discussed in the following.

10.1. Regarding the Planning Phase

It is recommended to have the UCD planning early in the project [32, 18]. The planning includes decisions about the users to be involved, and how and when they participate in the process. Moreover, in the planning phase, user representatives should be selected carefully to cover all of the user types [18].

Improper UCD planning is one of the shortcomings of this study. While active user involvement was considered in the project, it was not clearly specified where, when, and how the users should participate in the process. We had no agreement about the users and domain experts to be involved in requirements gathering, design and evaluations.

In the first iteration of this project, only one user, i.e. our main clinical partner, was involved in the UCD process. Our main clinical partner of course cannot be the representative of all of the user types of the system.

In the second iteration, the stakeholders were persuaded to involve more users and domain experts in the UCD process. Consequently, several test users were introduced to the development team. After interviewing all of the test users (in usability tests), it was revealed that all of them were dental PhD students. Obviously, these users were not representatives of the all user groups either. This could have had an effect on our evaluation results. Selection of this group of user representatives by people at the Clinic of Oral Medicine could have been due to the fact that, as researchers, they had more flexible schedules. Therefore, without any cost to the clinic, they could be asked to act as test users in the project. On the other hand, other specialists in dentistry and dental hygienists were booked for patient visits. This made it more difficult to book them for usability tests, and surely using their time for usability tests could be more costly for the clinic.
Figure 6: The GUI prototype, the last iteration
By a proper planning early in the process, number and types of the users to be involved in requirements gathering, design and evaluations can be discussed and finalized. With timely planning, in case of facing the aforementioned issues, the project team will have enough time to motivate and support involving a wide category of users. Although it sounds costly to involve more users in the process at first glance, it has of course a return of investment in the long run when a usable system for all types of users is developed.

10.2. Regarding the Requirements Phase

10.2.1. The User Workflow Model

It is demonstrated how the clinical workflow plays an important role in developing usable and acceptable clinical applications [33, 34, 35, 36]. Researchers in the clinical domain recommend conducting workflow analysis in order to prevent failures of clinical applications and reducing clinicians’ frustration while applying the system [36]. It is reported how changes in clinical workflow, or alternation of clinicians’ interaction to each other, among other reasons, can result in increased patient mortality after installing a clinical application [35].

Users in the clinical context are known to resist changes in their everyday workflow [33], therefore, to develop a usable clinical application, it is vital to understand the workflow and suggest design solutions based on this workflow. All in all, UCD helps to understand the users’ requirements, the user workflow and design a system according to this information.

In this project also, it was experienced how minor changes in the workflow can affect the users’ reaction to the system. Based on the clinical literature and also interviews with domain experts, it was concluded that “oral symptoms” or “local symptoms” are of more importance in patient health information related to dry mouth. Therefore, as general design patterns suggest, this information preceded other categories of information such as “general health information” or “anamnesis” in the prototype. However, all of the tests users reacted to this structure of information and this had negative effects on the GUI navigation. Users commented that in their everyday workflow, the process starts with “anamnesis” so they expect that category of information be located first on the GUI as well.

10.2.2. Understanding Users’ Requirements

As it is expected from an iterative design process, functional requirements of the system were updated as well as the GUI design in these iterations. Some functionalities were removed and some were added to the requirements specification of the system. For instance, prescribing was removed since users indicated that they would never use this feature due to the organizational rules. Sending referrals was an example of functionalities that were added to the system, as a result of usability tests and interviews.

10.3. Regarding the Design Phase

10.3.1. Low Fidelity versus High Fidelity Prototypes

Both low fidelity and high fidelity prototypes were developed in this UCD process. Low fidelity prototypes are those prototypes that are thrown away after evaluation, from those paper prototypes are common. On the contrary, high fidelity prototypes are much more like the final product and use materials to make this possible. For instance, a Java-based user interface is a high fidelity prototype. Surely, more time and effort is needed to produce high fidelity prototypes. Such prototypes are more suitable for evaluating technical issues [25]. It should be noted that
inertia to bad design is more likely in cases that high fidelity prototypes are used. This is mainly because of more time and effort that designers and developers put into such prototypes. For complicated user interfaces such as ours, it is better to run the usability tests on low fidelity prototypes so that any changes in design can be made more easily and without high cost. In this project, around five months were spent on developing the Java-based user interface, and this means that part of this work should be repeated since some changes should be made in the prototype based on evaluation results (see Section 6.3). Moreover, since the goal of evaluations was not to measure technical qualities of the system, paper prototyping or other types of low fidelity prototypes would be sufficient in these three iterations [25]. This is also evident from the nature of flaws detected in evaluations that could have been detected by using paper prototypes as well.

One other motivation for creating a high fidelity prototype of the system was to have an opportunity to investigate the openEHR related functionalities of the system, this could also be postponed until the low fidelity prototype of the GUI was evaluated and finalized.

10.3.2. Navigation Improvement

According to Cooper [37] navigation is “any action that takes a user to a new part of the interface or which requires him to locate objects, tools or data”. Poorly designed navigation is one of the typical flaws in the usability of interactive applications [37]. More importantly, it is observed how navigation problems in clinical applications can facilitate clinical errors [38]. As a result of applying UCD and various empirical and non-empirical evaluation methods, the navigation was improved in the prototypes during the three iterations of the project. At first, usability experts noticed that there were too many screens to be navigated by users. Therefore, screens in the prototype were converted to different collapsible sections in the new design as noticeable in Figure 3. Later on, the usability tests, revealed that users still had problems navigating and locating information. Therefore, in the new design different tabs substituted the horizontal collapsible sections.

10.4. Regarding the Evaluation Phase

Usability evaluation methods are divided into two main classes namely empirical methods and non-empirical or usability inspection methods [16]. Interviews [25, 27, 28], field studies [25, 27, 28], questionnaires [25, 27, 28], usability tests and think aloud methods are some of the methods that belong to the first category. Usability expert reviews, cognitive walkthrough [16, 25, 28] and heuristic evaluation [16, 25, 28] are examples of the methods that belong to the second class. Each of these evaluation methods has strengths and weaknesses. For instance, expert reviews are suitable for detecting general design flaws and one of their strengths is that experts will provide alternative design solutions to remove detected flaws [16]. In contrast, empirical methods are strong in discovering detailed design flaws that even the most competent usability experts may not detect, especially in cases when the flaws are domain specific [16].

There is no need to apply all methods in an individual project. It is, however, recommended that suitable methods be selected by the development team based on the understanding of trade-offs associated with each method [16]. Surely, by combining methods from these two categories a project can benefit from the strengths of each method, as is the case in this study.

The studies in the area of CDSS development suggest that empirical evaluations, i.e. evaluations through user participation, are much more popular among the CDSS developers compared to the non-empirical methods, i.e. evaluations through expert analysis. Non-empirical methods
have been applied in very few studies [39, 40, 41]. Rare application of evaluations through expert analysis can be due to insufficient knowledge of developers on such methods or inaccessibility to experts who are capable of carrying out such methods. Identifying the reasons for such distribution of methods in CDSS development projects needs further investigation and is not within the scope of this paper.

In this project, both empirical and non-empirical evaluations were applied, and resulted in improvements in the design. Results detected in usability expert reviews were all general design flaws (see Table 5, 8), on the other hand, the flaws detected in usability tests were much more domain-specific including the language and workflow related issues (compare Table 5 and Table 6). It is evident from the tables, how applying both classes of methods can be beneficial in discovering different types of design flaws in a project.

10.5. The Context, Users and Tasks: What Clinical UCD Practitioners Should be Aware of

Based on this study and results reported by other researchers [5, 33, 42, 43], there are characteristics of the users, tasks and the context that developers of clinical applications should take into consideration in order to design a more usable clinical system. These characteristics are explained more in detail in the following and summarized in Table 9.

10.5.1. Context

A clinical context is a safety-critical context in which errors may lead to patient death. The context, is a highly interactive context. Interactions such as interactions between clinicians, clinicians and devices, and finally clinicians and patients exist in this context.

The context is a complex context in which domain-specific knowledge is not easily understandable to outsiders such as clinical application developers. Therefore, to understand the context, the concepts in the context and also the clinicians’ workflow, a close collaboration between developers and domain experts is inevitable in the process of developing a clinical system.

10.5.2. Users’ characteristics

UCD practitioners should be aware of the users’ characteristics in this domain. Clinicians are non-tech-savvy users of the software systems. These users (especially physicians and specialists) are very self-confident when it comes to their work knowledge. Also, as mentioned in the previous section, these users are resistant to changes in their everyday workflow. In addition, they would like to be in charge of the process of interacting with the computer system in contrast to the cases in which the system is in charge [5, 33]. For instance, clinicians prefer to make the final decisions themselves and do not like the system to force an option (e.g. a diagnosis). Clinicians’ experiences have significant effects on how they work, reflect on patient cases, make decisions and so on. Another characteristic of clinicians is that they are trained and are asked to be highly respectful to their colleagues [44]. Finally, there is a hierarchy in the clinical domain, and power relations among clinicians [44].

All of the aforementioned characteristics should be considered in developing a clinical application and in applying a UCD process in this context. For instance, it is very important that clinicians have high self-esteem regarding their work knowledge. But when it comes to UCD this may be problematic in getting more users to be involved in the process.

Clinicians wonder “why should other clinicians be involved while we know everything about our job?”. The second aspect, being respectful to colleagues, can result in evaluation sessions in which clinicians tend not to talk about the GUI problems, since they want to be respectful to other
Table 9: The characteristics of the users, tasks and context in the clinical domain that may have effect on the UCD process and design.

| Users                      | Tasks                  | Context               |
|----------------------------|------------------------|-----------------------|
| Not tech-savvy             | Several actors         | Safety-critical       |
| Self-confident             | Interruptions          | Highly interactive    |
| Resistant to change        | Dependency             | Workflow              |
| In charge                  | Time constraints       | Domain specific knowledge |
| Experience                 |                        | Complex               |
| Booked schedule            |                        |                       |
| In clinical hierarchy      |                        |                       |
| In power relation          |                        |                       |
| Respectful                 |                        |                       |

people involved in the design process specially their colleagues. The clinical hierarchy can also affect user involvement and evaluations. There are questions regarding UCD to be answered: how many clinicians should be involved, and who are they? Who should specify them and what if a clinician at a higher level says “no” to involving more clinicians in the UCD process? Moreover, there may be cases where since a colleague from a higher level has been involved in the design, test users hide their real opinion about the GUI design. Finally, clinicians are usually booked for patient visits which makes their involvement not straightforward and of course costly for the clinic.

10.5.3. Tasks

When it comes to the tasks, it should be taken into consideration that there are cases in which more than one actor is involved in a clinical task [42] for instance a nurse and a physician may collaborate to accomplish one specific task. Also, there are usually various interruptions while a clinician is accomplishing a task, the interruptions can be as easy as leaving the computer in order to examine the patient (in case of this project, to examine the patient’s mouth).

There are other aspects of the clinical tasks that are not directly related to our study but are worth mentioning here. For instance, there are cases in which time is critical for treating the patient or even saving his/her life. As another example, some clinical tasks may have inter-dependency. This means that starting one task may trigger establishing a second task or canceling one may result in abandoning the second task.

Regarding qualitative evaluations recommended to support UCD, the main question is whether existing evaluation methods are suitable for measuring qualities of a system including such tasks [42, 43]. For instance, is the result of usability tests reliable when a real clinical setting cannot be simulated? Are usability tests and other methods able to evaluate a system with time-critical, or collaborative tasks? Of course, finding a proper answer to these questions needs a broader investigation of the methods and their application in the clinical context.

11. Conclusion

In theory, human-related factors and issues that are the focus of the HCI research field are considered to be a main class of success factors in developing CDSSs. Nonetheless, in prac-
tice, methods and processes suggested by HCI to develop more usable systems are not a routine practice in designing and developing CDSSs.

In this project, besides designing a CDSS, the aim was to learn from the experience of applying a UCD process in a clinical context, and to detect and analyze challenges associated with it.

As expected from a UCD process, this study also demonstrated that involving users in the design makes early detection of flaws possible. Even for a team with experiences in developing clinical applications and usability, evaluations resulted in various changes, and an improved (more usable) user interface. Without knowing about users and the context of use, and without involving users it was not easy or even possible to find some flaws before implementing the system, especially those flaws that are related to the domain concepts.

UCD is not a methodology. It does not propose step by step methods, rather it is a process which is supported by a collection of suggested methods. UCD can be customized and applied freely to be made more compatible with the project and the team. Not all phases of the UCD cycle are required to be carried out in each iteration. Moreover, not all of the methods suggested in the literature should be applied for an individual project. The choice of methods depends on the nature of the project and decisions made by the team members.

Finally, we observed that there are characteristics of the context, tasks and users that developers should be aware of when developing a CDSS by applying a UCD approach (Table 9).

12. Future Work

As a continuation to this study, an empirical evaluation should be performed on the last prototype of the system to make sure that all of the usability goals are satisfied. Afterwards, more technical focus is required to implement the CDSS including the knowledge representation and reasoning aspect of the CDSS. After deployment of the system, quantitative methods should be applied to evaluate the effectiveness of the system and other qualities such as performance.

The findings and discussions presented in this paper are based on only one experience of applying UCD in a clinical context, and collaborating with one specific group of clinicians. Surely, the findings can be a starting point for further investigation of the clinical context, its characteristics and the effects of these characteristics on UCD. Therefore, there is an interest to pursue a wider investigation of the characteristics of the context, tasks and users, also to identify their effects on UCD, and finally provide guidelines and suggest improvements to the existing methods in order to make them more suitable for the clinical context.

Acknowledgment

The author would like to convey her gratitude towards all the following people who participated in this project either as reviewers, evaluators or test users: Sus Lundgren, Erik Fagerholt, Martin G E Hjulström, Soren Lauesen, Dowen Brikheld, Mike Brennan, Johan Blomgren, Mia Zellmer, Maria Westin, Jenny Ohman, Gita Gale and Jessica Skoogh.

Sincere thanks go to Mats Jontell, Marie Lindgren, Göran Falkman and Marita Nilsson, the team members. The author would also like to express her gratitude to Olof Torgerson for his valuable comments on this paper. This work has been done as a part of the author’s PhD study under Olof Torgerson’s supervision.

The project was funded by the Swedish Governmental Agency for Innovation Systems (VINNOVA), grant 2006-02792 and is in progress at the time of writing this paper.
References

[1] K. Vikram, F. R. Karjodkar, Decision support systems in dental decision making: an introduction., The journal of evidence-based dental practice 9 (2) (2009) 73–6. doi:10.1016/j.jebdp.2009.03.003.
[2] J. Bennett, P. Glasziou, Computerised reminders and feedback in medication management: a systematic review of randomised controlled trials, Medical Journal of Australia 178 (5) (2003) 217–222.
[3] R. Walton, S. Dovey, E. Harvey, N. Freemantle, Computer support for determining drug dose: systematic review and meta-analysis, British Medical Journal 318 (7189) (1999) 984.
[4] D. Hunt, R. Haynes, S. Hanna, K. Smith, Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review, Jama 280 (15) (1998) 1339. doi:10.1001/jama.280.15.1339.
[5] E. Berner, Clinical Decision Support Systems: Theory and Practice (Health Informatics), Springer, New York, NY 10013, USA, 2007.
[6] R. Greenes, Clinical decision support: the road ahead, Academic Press, 2007.
[7] R. Kaushal, K. Shoania, D. Bates, Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review, Archives of Internal Medicine 163 (12) (2003) 1409.
[8] D. Bates, J. Teich, J. Lee, D. Seger, G. Kuperman, N. Ma’Luf, D. Boyle, L. Leape, The impact of computerized physician order entry on medication error prevention, Journal of the American Medical Informatics Association 6 (4) (1999) 313.
[9] R. N. Shiffman, Y. Liaw, C. a. Brandt, G. J. Corb, Computer-based guideline implementation systems: a systematic review of functionality and effectiveness., Journal of the American Medical Informatics Association : JAMIA 6 (2) (1999) 104–14.
[10] T. Wendt, P. Knaup-Gregori, A, Decision Support in Medicine: A Survey of Problems of User Acceptance, Stud Health Technol Inform 77 (2000) 852–856.
[11] J. Osheroff, J. Teich, B. Middleton, E. Steen, A. Wright, D. Detmer, A roadmap for national action on clinical decision support, Journal of the American medical informatics association 14 (2) (2007) 141. doi:10.1197/jamia.M2334.Introduction.
[12] J. Zhang, Human-centered computing in health information systems. Part 1: analysis and design., Journal of biomedical informatics 38 (1) (2005) 1–3. doi:10.1016/j.jbi.2004.12.002.
[13] T. Beale, S. Heard, openehr architecture overview, http://www.openehr.org/ (2009).
[14] H. Kashfi, Applying a user centered design methodology in a clinical context., Studies in health technology and informatics.
[15] T. Hewett, R. Baecker, S. Card, T. Carey, ACM SIGCHI Curricula for Human-Computer Interaction (1996).
[16] M. G. Helander, T. K. Landauer, P. V. Prabhu, Handbook of Human-Computer Interaction, Elsevier Science Pub Co, 1998.
[17] ISO 9241-11, Ergonomic requirements for office work with visual display terminals (VDTs)Part 11: Guidance on usability, International Organization for Standardization, Geneva, Swiss, 1998.
[18] M. Maguire, Methods to support human-centred design, International Journal of Human-Computer Studies 55 (4) (2001) 587–634. doi:10.1006/ijhc.2001.0503.
[19] A. Seffah, E. Metzker, The obstacles and myths of usability and software engineering, Communications of the ACM 47 (12) (2004) 71–76.
[20] K. Vredenburg, S. Isensee, C. Righi, User-Centered Design: An Integrated Approach, Prentice Hall PTR, Upper Saddle River, NJ, 2002.
[21] ISO 13407, Human-Centred Design Process for Interactive Systems, International Organization for Standardization, Geneva, Swiss, 1999.
[22] User-Centered Design, Website, https://www-01.ibm.com/software/ucd/ucd.html (2010).
[23] B. Kaplan, Evaluating informatics applications–clinical decision support systems literature review. (November 2001).
[24] S. Porter, An update of the etiology and management of xerostomia, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology & Endodontics 97 (1) (2004) 28–46.
[25] H. Sharp, Y. Rogers, J. Preece, Interaction Design: Beyond Human-Computer Interaction, Wiley, 2007.
[26] M. G. Helander, T. K. Landauer, P. V. Prabhu (Eds.), Handbook of Human-Computer Interaction, Elsevier Science Inc., New York, NY, USA, 1997.
[27] J. Preece, Y. Rogers, D. Benyon, S. Holland, T. Carey, Human-computer Interaction, Addison-Wesley, 1994.
[28] A. Dix, J. Finlay, G. Abowd, R. Beale, Human-computer interaction, Prentice-Hall, Inc., Upper Saddle River, NJ, USA, 1997.
[29] T4 practice management software . Website, http://eamer.carestreamdental.com/en-gb/sweden/practice-management-systems/1kodak-t4.aspx (2010).
[30] M. Joniell, U. Mattsson, O. Torgerssen, MedView: an instrument for clinical research and education in oral
medicine., Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics 99 (2005) 55–63. doi:10.1016/j.tripleo.2004.01.009.

[31] J. Tidwell, Designing Interfaces, O’Reilly, Beijing, 2006.

[32] J. Gulliksen, B. Göransson, I. Boivie, S. Blomkvist, J. Persson, A. s. Cajander, Key principles for user-centred systems design, Behaviour & Information Technology 22 (2003) 397–409. doi:10.1080/01449290310001624329.

[33] R. A. K. Horasani, M. I. T. Anasijevic, B. L. M. Iddleton, M. S. C, Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality, Journal of the American Medical Informatics Association 10 (2003) 523–530. doi:10.1197/jamia.M1370.

[34] A. Garg, N. Adhikari, H. McDonald, M. Rosas, Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review, JAMA 293 (10) (2005) 1223–1238.

[35] Y. Y. Han, J. a. Carcillo, S. T. Venkataraman, R. S. B. Clark, R. S. Watson, T. C. Nguyen, H. Bayir, R. a. Orr, Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system., Pediatrics 116 (6) (2005) 1506–12. doi:10.1542/peds.2005-1287.

[36] S. T. Rosenbloom, F. E. Harrell, C. I. Lehmann, J. H. Schneider, S. A. Spooner, K. B. Johnson, Perceived increase in mortality after process and policy changes implemented with computerized physician order entry., Pediatrics 117 (4) (2006) 1452–5; author reply 1455–6. doi:10.1542/peds.2005-3163.

[37] A. Cooper, R. Reimann, D. Cronin, About Face 3: The Essentials of Interaction Design, Wiley, Indianapolis, IN, USA, 2007.

[38] R. Koppel, J. P. Metlay, A. Cohen, B. Abaluck, R. S. L. S. E. Kimmel, B. L. Strom, Role of computerized physician order entry systems in facilitating medication errors., JAMA : the journal of the American Medical Association 293 (10) (2005) 1197–203. doi:10.1001/jama.293.10.1197.

[39] C. Gadd, P. Baskaran, D. Lobach, Identification of design features to enhance utilization and acceptance of systems for Internet-based decision support at the point of care., in: Proceedings of the AMIA, 1998, pp. 91–5.

[40] M. Peleg, A. Shachak, D. Wang, E. Karnieli, Using multi-perspective methodologies to study users’ interactions with the prototype front end of a guideline-based decision support system for diabetic foot care., International journal of medical informatics 78 (7) (2009) 482–93. doi:10.1016/j.ijmedinf.2009.02.008.

[41] 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. doi:10.1016/j.jbi.2007.03.006.

[42] P. Edwards, K. Moloney, J. Jacko, F. Sanfort, Evaluating usability of a commercial electronic health record: A case study, International Journal of Human-Computer Studies 66 (10) (2008) 718–728. doi:10.1016/j.ijhc.2008.06.002.

[43] M. W. M. Jaspers, A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence., International journal of medical informatics 78 (5) (2009) 340–53. doi:10.1016/j.ijmedinf.2008.10.002.

[44] C. Delany, D. Watkin, A study of critical reflection in health professional education: ‘learning where others are coming from’., Advances in health sciences education : theory and practice 14 (3) (2009) 411–29. doi:10.1007/s10459-008-9128-0.
Paper V

Supporting openEHR Java Desktop Application Developers

Hajar Kashfi, Olof Torgersson

The XXIII International Conference of the European Federation for Medical Informatics, Proceedings of Medical Informatics in a United and Healthy Europe (MIE2011), Oslo, Norway, 28-31 August, 2011.
(in print)
Supporting openEHR Java Desktop Application Developers

Hajar KASHFI1 and Olof TORGERSSON

Department of Applied Information Technology, Chalmers University of Technology and University of Gothenburg, SE–412 96, Gothenburg, Sweden

Abstract. The openEHR community suggests that an appropriate approach for creating a graphical user interface for an openEHR-based application is to generate forms from the underlying archetypes and templates. However, current generation techniques are not mature enough to be able to produce high quality interfaces with good usability. Therefore, developing efficient ways to combine manually designed and developed interfaces to openEHR backends is an interesting alternative. In this study, a framework for binding a pre-designed graphical user interface to an openEHR-based backend is proposed. The proposed framework contributes to the set of options available for developers. In particular we believe that the approach of combining user interface components with an openEHR backend in the proposed way might be useful in situations where the quality of the user interface is essential and for creating small scale and experimental systems.

Keywords. openEHR, clinical application, opereffa, application development framework, data binding.

Introduction

With the growing presence of electronic healthcare record (EHR) systems developed by various vendors, it becomes increasingly important to agree upon standards that can overcome the resulting interoperability problems [1]. The goal of the openEHR initiative is to develop an open standard that can serve as the basis for both developing EHR systems and to guarantee semantic interoperability between systems [2]. openEHR suggests a two-level architecture for managing data in clinical applications. The top-level is made up of archetypes, which are domain specific models that should be developed by domain experts. The lower level is the openEHR reference model (RM), which is a very generic model for managing clinical data [2].

Regardless of the advantages offered by openEHR, the standard suffers from a rather low adoption rate. While this is not the place to make a proper analysis of the reasons for this, some possible reasons are the complexity of the standard, lack of documentation and training for developers, and a limited set of tools and frameworks available to ease application development. Most of the focus of the community seems to have gone into representing and modelling domain concepts and perfecting the specifications. However, to make openEHR more practical, application developers need to be supported with APIs, frameworks and tools. Of course, a number of application development projects exist. Some of the more mature are: the open source health information platform [3] (OSHIP), the open EHR-Gen framework [4], GastrOS [5],

1 Hajar Kashfi, Department of Applied Information Technology, Chalmers University of Technology, SE–412 96 Gothenburg, Sweden; E-mail: hajar.kashfi@chalmers.se.
Different approaches can be used to develop openEHR applications. The typical approach is to automatically generate the graphical user interface (GUI) from openEHR archetypes/templates. To our knowledge, current openEHR frameworks and tools are compatible with this model (depicted in Figure 1-A). The idea is that clinicians design and create archetypes (and templates) using existing tools. Based on these, a GUI or GUI artefacts are generated from the given archetypes/templates. To improve the GUI design, manual adjustment of the GUI or its style files is often required. The typical openEHR application is web based.

In contrast, there is an approach in which no generation of GUI based on archetypes is done but instead the interface is designed by experts based on the demands of the users of the application. There is then a need to connect this user interface to the archetypes designed in parallel by domain experts. Unfortunately, the current frameworks do not provide enough support for this type of application development. To fill this gap, we have developed an extension to one of the existing openEHR frameworks to help developers easily connect a user interface created by a GUI-designer to an openEHR based backend.

![Figure 1. The two development models. The left side model is supported by opereffa.](image-url)

### 1. Methods and Tools

As mentioned in the previous section, in contrast to the automatic or semi-automatic approach to creating GUIs to openEHR-based applications, there is an alternative illustrated in Figure 1-B. To support this approach, there is a need for a simple and efficient data-binding framework connecting an application’s frontend to its backend (or the business logic). Usually, the idea of data binding is that when the data changes, the changes are reflected automatically by the bound elements on the user interface. In the same manner, if the “outer representation” of data changes, then the
corresponding data in backend should be automatically updated as well to reflect the change [7].

We have developed an extension, a Java desktop user interface data-binding layer, to one of the openEHR application development frameworks namely opereffa (compare the left and right sides of the Figure 2). opereffa is an initiative for creating an open source clinical application and is built on top of a Java-based open source framework. Services such as GUI generation, and persistence are supported in opereffa. opereffa generates web-based user interface artefacts using Java Server Faces (JSF) [8] and also makes use of the data binding capabilities of JSF.

![Figure 2. The proposed architecture.](image)

2. Results

The new data-binding layer on top of opereffa provides a single entry point for connecting Java desktop GUIs to an archetype-enabled backend. To make the desktop connection framework as easy to use as possible for application developers, it is designed using a facade pattern [9]. This means that there is only one single class, ArchetypeDataHandler, which hides all the details of archetype-based data management and therefore is the only class someone using the framework needs to know anything about. To further improve ease of use in applications, the ArchetypeDataHandler is a singleton, meaning that there is only one instance of it in an application and it can easily be accessed anywhere. To connect a preDesigned GUI to the openEHR backend the only steps required are: (i) creating an xml-file specifying the connection between GUI components and archetypes (ii) adding each component in the GUI to the ArchetypeDataHandler, i.e. calling the method `add (JComponent c)` on the ArchetypeDataHandler.

Underlying the implementation is the assumption that each GUI component is logically in relation to one and only one item in an archetype (an item in an archetype can be visually presented in several places on a screen though). This means that for each component there exists an archetype name, and a unique path for the item in that archetype. This information is stored in an xml file, which is used by the
ArchetypeDataHandler to decide to which data item a certain GUI component should be connected. A sample of entries in the xml file is shown in Figure 3.

Internally, a class named GUIMapper with support from other mapper classes provides the actual functionality. The role of this class is to keep track of all GUI components, their archetypeWrappers and the path of the item in the archetype to which each component is mapped. The synchronization of data shown in the GUI and what is stored in the GUIMapper is realized using various listeners. If data changes on the GUI this change is reflected in the GUIMapper in the backend. On the other hand, if data is loaded from the DB, the GUIMapper updates the GUI as well. All data is kept in memory to be persisted at the right time using opereffa persistence services.

To evaluate the functionality of the data-binding framework, a demo application was created using the graphical GUI-editor of NetBeans. In the demo application, four different archetypes are used and connected to 39 GUI components. The archetypes are both special archetypes developed for a decision support system for Xerostomia [10] and adaptations of common archetypes such as openEHR-EHR-OBSERVATION.lab_ test.v1. A snapshot of the demo application is depicted in Figure 4. The screen shows a field where one can search for a patient, a list where one can select one of the patient’s recent sessions and the data recorded at that session. The part of the code that enables it to load and store archetyped data is only a few lines that add components to the ArchetypeDataHandler. The framework provides the rest.

Figure 3. Sample entries showing the connection between GUI components and archetypes

3. Discussion and Conclusion

The proposed framework for binding a pre-designed GUI to an openEHR-based backend contributes to the set of options available for developers. We particularly believe that the approach of combining GUI components with an openEHR backend in the proposed way might be useful for various small scale and experimental systems as well as systems where the quality of the user interface is of great importance.

The generic proposed model for building openEHR applications was illustrated in Figure 1-A. While generating GUIs from archetypes and templates has advantages when it comes to maintenance of large-scale systems, creating good, and not just mediocre, user interfaces from underlying domain models is a non-trivial problem. During the time mature generation techniques are being developed, hooking up designed GUIs to openEHR backends is an interesting alternative. The use of designed GUIs is also interesting from another point of view. GUIs based on a domain model are by necessity rather close to the implementation model of the system. However, when a GUI is designed, the goal of the developers should always be to have an on-screen representation that is as close as possible to the users’ mental model [11]. Therefore, having a simple way of replacing parts of a system with GUIs designed by hand in accordance with the users’ mental models is valuable to handle the situations where generation cannot produce an appropriate solution.
The main disadvantage of the approach used in this paper is maintenance. A generated GUI can change automatically if the underlying archetypes/templates change whereas a manually created GUI has to be updated manually. A related problem is that in complex systems the number of GUI components that need to be connected to the backend will be very large. The current implementation is rather limited since it only supports a small number of GUI components. A more complete implementation must of course support all commonly used standard components and perhaps even provide some special controls tailored towards clinical applications. This however is work for the future.

![Xerostomia Data](image)

**Figure 4.** The demo application

References

[1] Schloeffel P, Beale T, Hayworth G, Heard S, Leslie H. The relationship between CEN 13606, HL7, and openEHR. In: HIC (2006). Health Informatics Society of Australia; 2006. p. 24.
[2] Beale T, Heard S. openEHR Architecture Overview [published on the Internet]. openEHR Foundation; 2009 [cited 2011 April 20]. Available from: http://www.openehr.org
[3] Open Source Health Information Platform (OSHIP) [homepage on the Internet]. Multi Level Healthcare Information Modelling - MLHIM [cited 2011 April 20]. Available from: http://www.oship.org
[4] Open-EHR-Gen [homepage on the Internet]. Available from: http://code.google.com/p/open-ehr-gen-framework
[5] GastrOS [homepage on the Internet]. The University of Auckland [cited 2011 April 20]. Available from: http://sourceforge.net/projects/gastros
[6] openEHR REFerence Framework and Application (Opereffa) [homepage on the Internet]. UCL [cited 2011 April 20]. Available from: http://opereffa.chime.ucl.ac.uk/introduction.jsp
[7] Data Binding Overview [webpage on the Internet]. Microsoft Corporation [cited 2011 April 20]. Available from: 2010. http://msdn.microsoft.com/en-us/library/ms752347.aspx
[8] Burns E, Griffin N, Schalk C. JavaServer faces 2.0: the complete reference. McGraw-Hill Professional; 2009.
[9] Stelting S, Maassen O. Applied Java patterns. USA: Sun Microsystems Inc.; 2002.
[10] Kashfi H. Applying a user centered design methodology in a clinical context. Studies in health technology and informatics. 2010 Jan ;160(Pt 2):927-31.
[11] Cooper A, Reimann R, Cronin D. About face 3: the essentials of interaction design. Wiley-India; 2007.
Paper VI

Towards a Case-Based Reasoning Method for openEHR-Based Clinical Decision Support

Hajar Kashfi, Jairo Robledo Jr.

Proceedings of The 3rd International Workshop on Knowledge Representation for Health Care (KR4HC’11), Bled, Slovenia, 6 July, 2011.
(in print)
Towards a Case-Based Reasoning Method for openEHR-Based Clinical Decision Support

Hajar Kashfi and Jairo Robledo Jr.

1 Department of Applied Information Technology
Chalmers University of Technology
SE–412 96, Gothenburg, Sweden
hajar.kashfi@chalmers.se

2 Department of Oral Medicine and Pathology
Institute of Odontology
Sahlgrenska Academy
University of Gothenburg
SE–405 30, Gothenburg, Sweden
jrobledo@uces.edu.co

Abstract. In 2007, a team of informaticians and specialists in dentistry in Sweden started a project to develop a CDSS based on openEHR for an oral disease named dry mouth. Since openEHR is an emerging standard, designing a CDSS based on it is an unexplored research area. According to our findings, so far, very rare (almost none) openEHR-based CDSS has been released. The methodological approach applied in developing an openEHR-based CDSS is presented in this paper. This includes typical activities in developing CDSSs in addition to the activities one needs to carry out in order to develop an openEHR-based system. In the first phase of this project, the focus has been on openEHR archetype design, knowledge acquisition, and choosing a suitable KRR method based on the available legacy patient records, i.e. a knowledge intensive case-based reasoning method, and the extracted general domain knowledge. We also propose an architecture for such a system with the aim of benefiting from the structured openEHR-based patient data in reasoning.

Key words: Clinical decision support, openEHR, archetype, Case-based reasoning

1 Introduction

Presently, the use of computerized approaches to improve quality of health care is widespread in the clinical domain. Electronic health records (EHR) and clinical decision support systems (CDSS) are two complementary approaches to improve quality of health care. One of the success factors of CDSSs is observed to be their integration into EHRs [1–5] and since there are various international EHR standards (such as openEHR) being developed, it is important to take these standards into consideration while developing CDSSs [6].
Developing CDSSs involves challenges such as representing clinical knowledge, keeping it updated and performing the reasoning [6, 4, 3, 5]. At the time of introducing various EHR standards and calls for moving from standalone CDSSs towards CDSSs that are integrated into EHR system [6, 4, 3, 5], developers should adopt new approaches in developing such systems. This is of course an interesting research problem to see how the presence of these standards may influence developing CDSSs.

The paper is structured as follows. The background information about openEHR and the oral disease for which the CDSS is going to be developed is given in Section 2. Methods and materials applied in this study for designing an openEHR-based CDSS are presented in Section 3. This includes the activities carried out in this methodological approach. Results of the activities are given in Section 4. A discussion is provided in Section 5. Finally, we end with a conclusion and the future directions of the study in Section 6.

2 Background

2.1 The openEHR Approach

openEHR is a an open specification standard for managing electronic health records (EHR) so that the problem of shareability and computability of information in the clinical domain is overcome [7].

The openEHR approach emphasizes the role of clinicians in organizing domain knowledge in the form of different clinical concepts such as observation, evaluation, instruction and action [7]. This approach suggests a two layer architecture for clinical applications to separate knowledge and information layers in order to overcome the ever-changing nature of clinical knowledge. Patient data is stored in a generic form which is retrievable in heterogeneous clinical applications based on some constraints named archetype. An archetype which is designed by domain experts defines some constraints on data in terms of types, values, relation of different items and so on [7]. Archetypes are used for data validation and sharing [7].

Very few methodological approaches are documented to guide developing archetypes or openEHR-based applications. A well-known methodological approach for developing archetypes is the one presented by Leslie et al. [8] which includes these steps: (i) Identifying clinical concepts (ii) Identifying existing archetypes (iii) Creating new archetypes if necessary.

2.2 Dry Mouth

Dry mouth is “the abnormal reduction of saliva and can be a symptom of certain diseases or be an adverse effect of certain medications” [9]. There are various causes for dry mouth from, of which certain previous treatments on the patient, drugs and diseases can be mentioned. Dry mouth is typically managed with saliva substitutes, yet these days, clinicians can find more systematic treatments for this
Towards a CBR Method for an openEHR-Based CDSS

disease [9]. A number of specialists in dentistry from The Sahlgrenska Academy at Gothenburg University\(^3\) proposed a need for getting an automatic support for diagnosis and treatment of this disease. In their opinion, many general dentists are not aware of systematic therapies available for dry mouth, and it is not so easy for them to find potential causes for the disease in order to administer the optimal treatment.

3 Methods and Materials

In this phase of the project, the focus has been on openEHR archetype design, knowledge acquisition, and choosing a suitable knowledge representation and reasoning (KRR) method, based on the available legacy patient records and the available external domain knowledge. Details of the activities and their outputs are discussed below.

3.1 Preparing the Assessment Questionnaire

Our domain experts were not able to independently develop the archetypes as suggested by Leslie et al. [8], especially since they were new to openEHR. Hence, we decided to use a different approach that suited our domain experts. As part of their everyday work, specialists in dentistry at Sahlgrenska have access to an online application named mForm which provides them with facilities to develop their own examination forms (assessment questionnaires). These forms act as data entry interfaces for the clinical system available for patient data gathering in Sahlgrenska. Hence, our domain experts were already familiar with the concept of independently developing their own examination forms. This fact, initiated our approach for developing openEHR archetypes based on clinical questionnaires.

3.2 Domain Concept Modeling and Designing openEHR archetypes

The questionnaire created in the previous step, was used as a basis to produce domain concept models and finally archetypes. Domain concept diagrams were used mainly for communicating the concepts and the relation between them. These models were created using a mind-mapping tool\(^4\) in collaboration between domain experts and informaticians. In our approach, brainstorming sessions were held with domain experts to iteratively prepare the domain concept diagrams. Finally the domain concept models were used by informaticians to create archetypes. This was done using the available openEHR tools.

3.3 Domain Knowledge Gathering and Related Patient Data

At first, we held interviews with domain experts and also studied the related material to find out more about dry mouth, and related concepts. However, we

\(^3\) [http://www.sahlgrenska.gu.se/english](http://www.sahlgrenska.gu.se/english)

\(^4\) [http://xmind.org](http://xmind.org)
soon found out that, as informaticians, we would not be able to efficiently extract knowledge from existing evidences. Therefore, in parallel to domain concept modeling and archetype creation, a domain expert, was asked to gather such information.

For this purpose, PubMed\(^5\) was searched for the following terms: ("xerostomia" OR "dry mouth" OR "Sjögren's Syndrome") AND ("therapy" OR "treatment"). Also individual terms were combined, e.g. "xerostomia" AND "treatment"; "xerostomia" AND "therapy"; etc.

Moreover, the main dentistry database at Sahlgenska was also searched by domain experts to find dry mouth related patient cases.

3.4 Selecting the KRR Method

In this project, based on the amount of legacy patient records and domain knowledge available, and some other motivations (see Section 4.4), we chose a knowledge intensive case-based reasoning (CBR) as the knowledge representation and reasoning method for the CDSS.

**Case-based Reasoning** One of the reasoning methods which has been used in the clinical domain is case-based reasoning (CBR)\(^1\). Begum et al.\(^1\) explain CBR and its application in the clinical domain as follows: “The CBR is inspired by human reasoning, i.e., solving a new problem by applying previous experiences adapted to the current situation. A case (an episodic experience) normally contains a problem, a solution, and its result. The CBR is an appropriate method to explore in a medical context where symptoms represent the...
problem, and diagnosis and treatment represent the solution”. The CBR cycle that includes retrieve, reuse, revise and retain [12] is depicted in Figure 2.

In this method, the solution to previous problems is adapted to the new problem. Cases and indexing information are stored in the knowledge-base and reasoning is carried out by doing indexing, matching and adapting and storing new cases. Indexing efficiency is a key issue in this reasoning method [3, 13].

Case-based reasoning may be considered to be a data intensive method, since it starts with a set of cases for training. However, it is very different from other data intensive approaches. The knowledge that is extracted from experts in knowledge-intensive methods, can be subjective. On the other hand, if one only relied on objective knowledge e.g. the knowledge extracted from evidence, the valuable experience of experts in domain is not used. CBR uses both objective and subjective knowledge for reasoning. In other words, reasoning from previous cases (in our project patient data) is done in this method. Knowledge is recorded in form of cases. In the cased-based knowledge-base, cases and indexing information are recorded [3].

CBR is considered to be a suitable method to be used in CDSSs specially in the clinical domain [10, 11]. The concept of case is a concept that is used in medicine as well as for training and discussing treatment of an individual patient, moreover clinical guidelines include practice cases [10].

One class of CBR methods is a hybrid approach called knowledge intensive-CBR where the reasoning process is enhanced by benefiting from reasoning on the existing general knowledge. (note the “general knowledge” close to the “previous cases” in Figure 2).

Fig. 2. The knowledge intensive-CBR cycle, taken from [12].
3.5 Creating Artificial Cases

In a need for generating some dry mouth patient cases, we used the assessment questionnaires generated before, to develop data entry forms using the mForm application. Manual patient entry was done by one domain expert with the aim of creating some cases to be used in the reasoning process.

3.6 Proposing an Architecture Based on Two Existing Frameworks

A framework is a set of classes and design solutions and one can see it as a partial design and implementation of an application [14]. Using a framework, a huge amount of development time can be saved in a project. For developing an openEHR-base CDSS it is most efficient to use the existing frameworks to benefit from the services provided for managing the openEHR-based patient records. This is the same for CBR. Therefore, this CDSS is going to be built on top of two frameworks namely opereffa (an openEHR application development framework) and JColibri (a CBR application development framework).

opereffa [15] is one of the existing frameworks for developing openEHR-based applications. The framework manages tasks needed for loading archetypes, validating them and storing data, based on the openEHR reference model. JColibri [14] is a framework for developing CBR applications. It includes basic functions and algorithms needed in a CBR application.

4 Results

The workflow of the activities in the first phase of the project are depicted in Figure 4. As shown in this Figure, the outputs of the activities are: the questionnaire, the domain concept models, the archetypes, general domain knowledge, and artificial dry mouth patient cases. Also, based on the gathered information (general domain knowledge, and the available legacy patient records) a KRR method was selected for the CDSS namely knowledge-intensive CBR.

4.1 The Questionnaire, Concept Models and Archetypes

The questions covered various aspects of patient data including history of other diseases and drugs, related lab results, diet habits, age and sex. The questionnaire consisted of 6 main sections and a total of 41 questions and 15 related laboratory tests. The questionnaire was created by one domain expert and shared with 4 more domain experts to be revised and approved.

Based on the generated questionnaire a domain concept model was created. The model was created in close collaboration with clinicians. Various concepts/sections in the questionnaire were mapped to the related openEHR general classes such as observation and evaluation. A sample of the domain concept model is depicted in Figure 1.

The model was later translated to 23 openEHR archetypes by informaticians. Before creating the archetypes, the existing shared openEHR archetypes were
searched to find reusable archetypes. Around 10 archetypes were reused and almost all were modified for this purpose.

In addition, having a close collaboration with clinicians while developing these models, the interviews we held with some external domain experts provided an opportunity for us to gather some basic knowledge that a clinician uses in diagnosis and treatment of dry mouth. Furthermore, some external resources were also studies to gather more general information regarding dry mouth.

### 4.2 General Domain Knowledge

More than 6000 references were obtained from the searches; only review articles were used due to their scientific evidence level. From a list of around 1000 articles, 71 were selected. Papers describing treatment strategies in xerostomia, dry mouth or Sjögren’s Syndrome were the main objective of the search.

No guidelines for the treatment of any of these diseases were found after this search. This suggests that there is no global agreement about treatment strategies in xerostomia, dry mouth, or oral manifestations of Sjögren’s Syndrome. However, there are several papers with a high level of scientific evidence about
different therapy methods for patients with these diseases, such as systematic reviews or meta-analysis, where some statements can be drawn from.

In contrast to dry mouth and Sjögren’s Syndrome, several treatment guidelines and global treatment consensuses can be found for many other medical conditions. Generally speaking, it can be said that even if there are a lot of papers in the literature about treatment or therapies in xerostomia, dry mouth or oral manifestations of Sjögren’s Syndrome, this information is far less compared to other common diseases.

There is a global agreement in the literature that xerostomia is a common and significant (or maybe the most common) side effect of many commonly prescribed drugs. However, according to the literature, it is difficult to establish relative incidence rates for xerostomia for a particular medication. This happens because reported rates depend on how the professional collects the information from the patient, how patients react to a specific kind of drug, the type of drugs being taken, the cause for which the drug is being taken, the possible presence of contributing factors (such as Sjögren’s Syndrome, radiation therapy, or other immunological diseases) to the disease, the dose of the medication, etc. So, as an example, it is not possible to say that xerostomia will be present if a patient is taking 3 drugs or a specific amount of drugs; neither about the percentage of patients who will present with xerostomia if taking 3 or more drugs. Nevertheless, the risk for xerostomia increases with the number of drugs being taken. Some studies describe a list of medicaments (over 500) that may cause xerostomia, and those drugs listed have been reported to cause xerostomia in 10% or more of patients.

4.3 Legacy Patient Records

The main dentistry database at Sahlgrenska contains more than 20 000 patient records and images. Nevertheless, there are only around 100 dry mouth related cases in the database. According to our domain experts, the information related to dry mouth is missing for most of the patient cases, especially information related to diagnosis and treatment of the disease. One might be able to extract most of the historical information of patients from the available repositories but still other vital information is still missing. In other words, there are not a reasonable number of high quality (complete) dry mouth cases in the repository.

As a solution to this problem, a number of artificial cases were created by the domain experts to improve the process of CBR.

4.4 Knowledge Representation and Reasoning

There are two main classes of choices for selecting a KRR methods, i.e. data intensive methods and knowledge intensive methods. Answers to the following questions would help in choosing the suitable method in a specific project.

– Do we have enough data to be used in data intensive methods?
Towards a CBR Method for an openEHR-Based CDSS

Do we have enough domain experts to extract the knowledge or sufficient structured domain knowledge in order to adopt a knowledge intensive method?

Unfortunately in this project, the answer to both the questions was “no”. Yet, as a result of previous activities we had some basic knowledge that, though not sufficient for adopting knowledge intensive method, could be used for simple rule-based reasoning. Additionally, the domain experts involved in the project indicated that, while they are not able to provide us with probability numbers or exact rules in how to treat dry mouth, they can create some dry mouth patient cases. This yielded in a decision for adopting a knowledge intensive-CBR for the dry mouth CDSS.

Applying a hybrid KRR method is recommended in CDSSs, and for this project at the moment, the only other approach that is possible to be applied along with the CBR method, is a rule-based approach. As illustrated in Figure 2, general knowledge is used in CBR to improve the reasoning process. This general knowledge can be represented in many ways, one of which is a set of rules. With a rather small set of rules (general domain knowledge) generated as a result of previous activities, we can support the CBR method we selected and benefit from a hybrid method. The reasons for selecting the knowledge-intensive CBR method is summarized in table 1.

Two domain experts were responsible for creating the cases. For this purpose the aforementioned questionnaire was used to create an online data entry form using the tools available at the clinic. Total of 14 cases were created at this stage.

4.5 Archetypes s versus Domain Knowledge

In the dry mouth domain, a sample of general knowledge would be: People who use 3 or more drugs at the same time usually get dry mouth. This kind of information cannot be extracted from archetypes, but can be extracted from literature, or gained from the clinicians’ mind, that is why as result of domain knowledge gathering and domain concept modeling activities we generated some general domain knowledge.

Based on the openEHR approach, clinicians would be responsible for creating archetypes even though our experience revealed that sometimes it is too optimistic to think that this task is done only by a group of clinicians. Especially in cases where we plan to use archetype data for clinical decision support. This means that one should be aware of the fact, that beside attributes (items in archetypes) one needs some knowledge to be used in the CBR. As shown in Figure 4, the general knowledge was extracted from literature and from the meetings with the domain experts (the meetings were basically held for designing the archetypes). This information was added to the models that were created for domain knowledge as descriptions for each item.

4.6 The software architecture proposal

A layered architecture is proposed for this application. As depicted in Figure 5, the top layer is the view layer or in other words the user interface. Below that,
Fig. 4. A screen shot from the online form for case creation.

there is a mapper layer which is responsible for mapping the GUI components to the opereffa framework classes, also to connect them to the JColibri framework. Automatic generation of cases out of archetypes will be done in this layer. JColibri manages the CBR process and will have access to patient data repository. This repository will be shared between JColibri and opereffa. Patient data is stored in the database based on openEHR reference model. Each case/patient data will be stored using the related archetype that acts as a constraint on data. All the processes related to openEHR is managed by opereffa. JColibri and opereffa layers are not aware of each other, and everything between them is managed via the mapper layer. So far, part of the mapper layer which is responsible for mapping the view layer to the openEHR underlying framework is implemented and tested. The implementation of the whole application is still in progress.

5 Discussion

As mentioned before, there are very few documented methodological approaches to guide developing archetypes or openEHR-based applications. This includes those published by Marcos et al. [16] and Leslie et al. [8]. The most well-known methodological approach for developing archetypes is the one presented by Leslie
Towards a CBR Method for an openEHR-Based CDSS

et. al. [8]. This approach however emphasizes the role of clinicians and how they may apply existing openEHR tools to browse existing archetypes or developing new ones. Our approach is different in its view on adopting more traditional clinical approaches for gathering information such as clinical questionnaires.

Additionally, when it comes to CDSSs, there are a few studies that deal with how openEHR offers opportunities for CDS. Most of these efforts however seem to be more focused on integrating clinical guidelines into openEHR archetypes or utilizing archetypes for representing clinical guidelines [16–18] or to integrate reasoning and clinical archetypes (enhance archetypes by including knowledge representation capabilities to them) [19]. To our knowledge there is almost no study that has been focused on benefiting from the well-structured openEHR-based patient data for adopting data intensive reasoning methods in CDSSs or methods such as CBR that rely on previous cases to carry out the reasoning process.

As this study shows, because of the openEHR novelty, it is likely that in many projects, clinicians are more familiar with the traditional clinical concepts such as clinical questionnaires compared to the new and complex openEHR concepts such as archetypes. Therefore, other approaches for developing archetypes can be applied that are more compatible with the capabilities of the clinicians involved in the project.

Moreover in case of developing a CDSS, the activities in developing archetypes can be in form of more informed interviews and/or brainstorming sessions with domain experts where not only domain concept models and eventually archetypes are generated but also the available general domain can be extracted from clinicians’ minds. The well-defined concepts in openEHR help provide opportunities for informaticians to use these concepts for knowledge extraction in this manner.

5.1 Why Case-based Reasoning?

As mentioned in previous sections, based on our investigation, CBR is the most suitable KRR method to be used for this CDSS not only because of the advantages and practicability of this method for this project considering the amount of data and knowledge available, but also for the similarity found between openEHR archetypes and cases in CBR.
Towards a CBR Method for an openEHR-Based CDSS

Case description is analogous to archetypes in openEHR as discussed in Section 5.2. This approach did not require explicit knowledge to be represented and also the reasoning process is not a black box and can be understood by users. Therefore, the developed system can be used for training dentistry students as mentioned before.

The Table 1 shows a brief comparison between the selected method and other existing approaches.

| Criteria                          | Method                  | Data Intensive | Knowledge Intensive | Knowledge intensive-CBR |
|----------------------------------|-------------------------|----------------|---------------------|-------------------------|
| No need for deep domain knowledge | Yes                     | ✓              | ✓                   |
| No need for huge data volume     | Yes                     | ✓              | ✓                   |
| Easy Knowledge Acquisition       | ✓                       | ✓              | ✓                   |
| Objective Knowledge              | ✓                       | ✓              | ✓                   |
| Subjective Knowledge             | ✓                       | ✓              | ✓                   |
| Easy to maintain                 | ✓                       | ✓              | ✓                   |
| Use of past experiences          | ✓                       | ✓              | ✓                   |
| Suitable for Education           | ✓                       | ✓              | ✓                   |

Table 1. Motivations for selecting the knowledge intensive-CBR method.

5.2 openEHR archetypes and cases in CBR

As depicted in Figure 2, two types of knowledge are applied in a CBR cycle, domain-dependent knowledge or general knowledge, and specific knowledge which is encapsulated in cases. Archetypes provide us with all the specific knowledge we need for CBR. It is natural to see that no reasoning knowledge is included in the concept models or archetypes, but they could be used for extracting general knowledge of the domain for instance for extracting basic rules that are applied for diagnosis.

openEHR defines different classes of patient data. These classes are observation, evaluation, instruction and action. In openEHR observation is a structure to record any information which is extracted from the world outside the clinician’s mind [7]. This includes patient history of diseases and other treatments and symptoms and signs of the disease. In contrast, evaluation type is used to store the decision made by the clinician which is done in her/his mind. Instruction is a set of tasks that should be done on a patient; for instance prescription or orders. Action is used to record information about the action taken on the patient based on the instructions. Figure 6 illustrates how an openEHR-based patient record can be mapped to a case in CBR.

On the other hand, representation of the cases in CBR includes Description of the problem and the Solution. Description of the problem is analogous to the observation part of the patient data, including information about clinical history, symptoms and signs, and also lab values. Each case in CBR should include information about the solution to the specified problem (query) in that case. This solution in CBR is analogous to the openEHR evaluation, instruction and action in openEHR-based patient data.
6 Conclusion and Future Work

To develop an openEHR-based CDSS, one should carry out not only the typical CDSS development activities but also activities suggested by openEHR community for providing a solid underlying layer for storing and retrieving sharable clinical data. The openEHR activities start with designing archetypes by involving domain experts. In this study, we found out that the approach suggested by the openEHR community [8] is not applicable because of the capabilities of the clinicians involved and we needed to apply our own approach, which was designing archetypes based on clinical questionnaires.

Moreover, as in all CDSSs, a knowledge representation and reasoning method should be selected. There are some criteria for selecting a KRR method for a CDSS which we applied for selecting CBR for this project. CBR is a suitable reasoning method for clinical domain since it is analogous to the concept of individual patients, known as cases, which are also used for training medical students. Clinicians see each patient as a case and even use this term for sharing patient data among colleagues. Additionally, CBR applications can be used for education in clinical domain.

Applying a CBR method in an openEHR-based CDSS is an interesting open research direction, but needs connecting two different frameworks. Cases have similarities to archetypes, therefore they can be generated automatically from them and be used for reasoning purposes. openEHR archetypes help in the knowl-
edge extraction process, but the classical bottleneck of knowledge acquisition in 
clinical domain still exists.

The next phase of the project is to implement the rest of the mapper layer 
and investigate the reasoning functionality.

References

1. Sittig, D.F., Wright, A., Osheroff, J.a., Middleton, B., Teich, J.M., Ash, J.S., Camp-
bell, E., Bates, D.W.: Grand challenges in clinical decision support. Journal of 
bio medical informatics 41(2) (April 2008) 387–92
2. Garg, A., Adhikari, N., McDonald, H., Rosas, M.: Effects of computerized clinical 
decision support systems on practitioner performance and patient outcomes: a 
 systematic review. JAMA 293(10) (2005) 1223–1238
3. Berner, E.: Clinical Decision Support Systems: Theory and Practice (Health In-
formatics). Springer, New York, NY 10013, USA (2007)
4. Osheroff, J., Teich, J., Middleton, B., Steen, E., Wright, A., Detmer, D.: A roadmap 
for national action on clinical decision support. Journal of the American medical 
informatics association 14(2) (2007) 141
5. Greenes, R.: Clinical decision support: the road ahead. Academic Press (2005)
6. Osheroff, J., Pifer, E., Teich, J., Sittig, D., Jenders, R.: Improving outcomes with 
clinical decision support: An implementer’s guide. HIMSS (2005)
7. Beale, T., Heard, S.: The openEHR Architecture Overview. Website (2009) http: 
//www.openehr.org.
8. Leslie, H., Heard, S.: Ocean Informatics. Website (2008) http://www.oceanin-
formatics.com/ocean-informatics-resources/Tutorials.html.
9. Porter, S.: An update of the etiology and management of xerostomia. Oral Surgery, 
Oral Medicine, Oral Pathology, Oral Radiology & Endodontics 97(1) (Jan 2004) 
28–46
10. Bichindaritz, I., Marling, C.: Case-based reasoning in the health sciences: Whats 
next? Artificial Intelligence in Medicine 36(2) (Feb 2006) 127–135
11. Begum, S., Ahmed, M.U., Funk, P., Xiong, N., Folke, M.: Case-Based Reasoning 
Systems in the Health Sciences: A Survey of Recent Trends and Developments. IEEE 
Transactions on Systems, Man, and Cybernetics, Part C 7(1) (2010) 39–59
12. Aamodt, A., Plaza, E.: Case-based reasoning: Foundational issues, methodological 
variations, and system approaches. Artificial Intelligence Communications, IOS 
Press 7(1) (1994) 39–59
13. Pandey, B., Mishra, R.B.: Knowledge and intelligent computing system in 
medicine. Computers in biology and medicine 39(3) (Mar 2009) 215–230
14. Bello-Tomas J, Gonzalez-Calero P, D.A.B.: JColibri: an object-oriented frame-
work for building CBR systems. in Proc. ECCBR 2004, advances in case-based 
reasoning, Berlin, Heidelberg (2004) 3246
15. UCL: The openEHR Reference Framework and Application. Website (2011) http: 
//opereffa.chime.ucl.ac.uk:80/introduction.jsf.
16. Marcos, M., Martinez-Salvador, B.n.: Towards the interoperability of computerized 
guidelines and electronic health records: an experiment with openEHR archetypes 
and a chronic heart failure guideline. In: Proceedings of the ECAI 2010 confer-
ence on Knowledge representation for health-care. KR4HC’10, Berlin, Heidelberg, 
Springer-Verlag (2011) 101–113
17. Chen, R., Georgii-Hemming, P., Ahlfeldt, H.: Representing a chemotherapy guideline using openEHR and rules. Studies in health technology and informatics 150 (January 2009) 653–7
18. Xiao, L., Cousins, G., Hederman, L., Fahey, T., Dimitrov, B.: The design of an EHR for clinical decision support. Number Bmei. IEEE (October 2010)
19. Lezcano, L., Sicilia, M.A., Rodríguez-Solano, C.: Integrating reasoning and clinical archetypes using OWL ontologies and SWRL rules. Journal of biomedical informatics 44(2) (April 2011) 343–53
