Faculty of Information and Communication Technology

A CLINICAL FUNCTIONAL REQUIREMENTS (CFR) DOMAIN LIBRARY FOR ELICIT CORRECT CLINICAL REQUIREMENTS

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DECLARATION

I declare that this thesis entitle “Clinical Functional Requirements (CFR) Domain Library Using Key Structural Pattern for Correct Elicitation of Clinical Requirements” is the result of my own research except as cited in the references. The thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degree.

Signature :

Name : Nadiah binti Daud

Date :

APPROVAL

I hereby declare that I have read this thesis and in my opinion this thesis is sufficient in terms of scope and quality for the award of Master of Science in Information and Communication Technology

Signature :

Supervisor Name : Associate Professor Dr. Massila Kamalrudin

Date :

DEDICATION

This thesis is dedicated to my beloved parents; Haji Daud bin Maizan and Hajah Zurida binti Mohamad, siblings and family:

Who have always loved me unconditionally and whose good examples have taught me to work hard for the things that I aspire to achieve. Also thanks to my beloved husband, Muhammad Izuddin Jasmi who always support and give me strength throughout this journey. They have successfully made me the person I am becoming.

ABSTRACT

Eliciting correct clinical functional requirements is crucial as it determines the quality and sustainability of clinical software. However, eliciting correct functional requirements is very challenging, especially for requirements engineers who are not well versed with the business process and the vocabulary used in clinical domains. The complexity and specificity of the terms and terminologies used in the clinical domain may lead to misunderstanding and misinterpretation of terms. Motivated from this problem, this thesis proposes a Clinical Functional Requirements (CFR) Domain Library to assist requirements engineers to elicit correct functional clinical functional requirements. This domain library was specifically developed to address the challenges in eliciting clinical functional requirements and the lack of appropriate tool to assist requirements engineers to automatically elicit clinical requirements. This study adopted a three-phase research method consisting of the analysis, design and development and evaluation and testing. The first phase involved identifying the research gap and conducting two preliminary studies to determine the focus of the study. In the second phase, we developed the Clinical Functional Requirements (CFR) domain library, based on the key structural patterns. A collection of clinical functional requirements was compiled and the domain library was embedded in an automated tool called Malaysia English Requirements (MEReq) to elicit clinical requirements. We employed the EUC and EUI methodologies with GUI capability to elicit and to visualise the clinical functional requirements. The evaluation of the correctness and usability of the CFR domain library was conducted in phase three. Two evaluations were carried out in this research: 1) correctness test and 2) usability test. We found that the correct rate of eliciting clinical functional requirements based on the CFR domain library approach is better than the manual approach. Further, the usability study reported that the CFR domain library approach is able to help requirements engineer to ease the phase of eliciting clinical requirements. It can be concluded that the CFR domain library embedded in MEReq tool able to enhance the correct and the usability of the elicited clinical requirements.

ABSTRAK

Mencungkil fungsi keperluan klinikal dengan tepat adalah penting kerana ia menentukan kualiti dan kemampuan perisian klinikal. Walau bagaimanapun, mencungkil fungsi keperluan yang tepat adalah sangat mencabar, terutamanya kepada keperluan jurutera yang tidak mahir dengan proses perniagaan dan pembendaharaan kata yang digunakan dalam bidang klinikal. Kerumitan dan pengkhususan terma dan istilah yang digunakan dalam bidang klinikal boleh membawa kepada salah faham dan salah tafsir terma. Justeru itu, tesis ini mencadangkan Keperluan Fungsi Klinikal (CFR) bidang pangkalan data untuk membantu keperluan jurutera bagi mencungkil fungsi keperluan klinikal dengan tepat. Secara spesifiknya, bidang pangkalan data ini dibangunkan untuk menangani cabaran-cabaran dalam mencungkil fungsi keperluan klinikal dan kekurangan alat yang sesuai untuk membantu keperluan jurutera mencungkil keperluan klinikal secara automatik. Kajian ini mangamalkan tiga fasa kaedah penyelidikan yang terdiri daripada analisis, reka bentuk dan pembangunan dan penilaian dan ujian. Fasa pertama adalah mengenal pasti masalah penyelidikan dan menjalankan dua kajian awal untuk menentukan fokus kajian. Fasa kedua, kami membangunkan Keperluan Fungsi Klinikal (CFR) bidang pangkalan data, berdasarkan corak struktur penting. Koleksi keperluan fungsi klinikal disusun dan bidang pangkalan data digunakan dalam alat automatik yang dipanggil Keperluan Malaysia English (MEReq) untuk mencungkil keperluan klinikal. Kami menggabungkan EUC dan EUI metodologi dan GUI untuk mencungkil dan menggambarkan keperluan fungsi klinikal. Penilaian ketepatan dan kebolehgunaan CFR bidang pangkalan data dijalankan dalam tiga fasa. Dua penilaian telah dijalankan termasuk 1) ujian ketepatan dan 2) ujian kebolehgunaan. Kami mendapati bahawa kadar ketepatan pencungkilan keperluan fungsi klinikal berdasarkan CFR bidang pangkalan data lebih baik daripada pendekatan manual. Di samping itu, kajian kebolehgunaan menunjukkan pendekatan CFR bidang pangkalan data mampu membantu keperluan jurutera untuk memudahkan fasa mencungkil keperluan klinikal. Ia boleh disimpulkan bahawa CFR bidang pangkalan data digunakan dalam alat MEReq boleh meningkatkan ketepatan dan kebolehgunaan bagi mencungkil keperluan klinikal.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

RE	-	Requirements Engineer
CFR	-	Clinical Functional Requirements

LIST OF RELATED PUBLICATIONS

No.	Publications	Related Chapter
Journal		
1	Kamalrudin, M., Sidek, S., Daud, N., "A Clinical Functional Requirements Domain Library to Elicit Accurate Clinical Requirements of Clinical Software", JNIT: Journal of Next Generation Information Technology, Vol. 7, No. 1, pp. 1 ~ 13, 2016	2, 3, 4, 5
Conference Paper		
1	Daud, N., Kamalrudin, M., Sidek, S. and Abdullah, R.W., 2014. The Needs of Clinical Domain Library for Eliciting Accurate Clinical Requirements.*Science International*, *26*(4), p.l.	1
Proceedings		
1	Daud, N., Kamalrudin, M., Sidek, S. and Abdullah, R.W. "Characterisation of Healthcare Domain Library to Capture Accurate Requirements of Healthcare Software." In *e-Proceeding of Software Engineering Postgraduates Workshop (SEPoW)*, p. 17. 2013.	2

CHAPTER 1

INTRODUCTION

1.1 Introduction

Requirements elicitation is a crucial process in software development as the quality of software depends on the elicitation of correct requirements. Failure to elicit correct requirements may result in developing software that does not meet the needs of the client stakeholders. Motivated by the myriad development of software in clinical industry and the need for requirements engineers to elicit correct requirements, this research aims to develop an approach that facilitates the elicitation of correct clinical requirements.

This chapter introduces this research project by first presenting the background information of this study. The next section provides the main concepts that frame this research which are the clinical requirements and clinical domain library. Further the motivation of study is presented followed by the research questions and the research objectives. The contribution of this research is provided next and this chapter ends with the organisation of the thesis.

1.2 Research Background

This research focuses on the issues in requirements elicitation process for the development of quality software. Zowghi & Coulin (2005) defined requirements elicitation as "the process of seeking, uncovering, acquiring, and elaborating the requirements

collected from the stakeholders for any computer based systems" (Zowghi & Coulin 2005). The correctness of the requirements produced reflects how requirements engineer interpret and understand the requirements upon discussion with the stakeholders. However, requirements elicitation is considered as the most crucial and challenging part in the early stage of software development (Kotonya & Somerville 1998). There are challenges in eliciting correct requirements as ambiguity, miscommunication and misinterpretation of the terminology, conflicts of verbal statements, difficulty in understanding their needs, poor requirements quality produced and missing information (Duncan et al. 2012; Daud et al. 2014; Teixeira et al. 2012b) may occur any time during the process of developing the software. In this context, capturing correct requirements is crucial in requirements elicitation as failure to do so can lead to software failure.

Eliciting clinical requirements is more complicated and challenging than the business requirements (Cysneiros 2002; Daud et al. 2014). This is because the clinical requirements have different types of pattern structures and terms used. Researchers have reported that requirements engineer and stakeholders often face the problem of understanding the terminology used (Cysneiros 2002; Rector 1999; Teixeira et al. 2007; Daud et al. 2014; Joseph & Nanda 2012). A possible reason is that they are not familiar with the terminology used in the clinical requirements although they are expert in the field of software engineering. The misunderstanding of terminology during requirements elicitation activity due to the specific meaning, phrase and statements (Rector 1999) often result in the incorrect of the clinical requirements (Daud et al. 2013; Daud et al. 2014). The incorrectness of requirements includes ambiguity, inconsistency, incompleteness and incorrectness. Therefore, requirements document need to be well understood by both parties (requirements engineer and stakeholders) in order to avoid any misunderstanding.

In this case, requirements engineers need to have close communication with the stakeholder from time to time during the development of the clinical software.

The traditional requirements elicitation techniques used are document reading, questionnaire, interviews, JAD Section, protocol analysis, video and audio transcripts, use cases and scenarios and observation (Cysneiros 2002; Zowghi & Coulin 2005). However, a particular approach is suitable for only a specific situation; hence, it is a challenge for requirements engineer to choose the right technique for a particular situation (Cysneiros 2002). Up to now, there is no specific type of approach; method and tool are designed for clinical requirements elicitation in practice. Additionally, to ensure correct requirements, the common practice among the requirements engineer is to try to understand the requirements statement given. When any confusion occurs, requirements engineer will communicate with the stakeholders to get more feedback to elicit the requirements that match with the needs of the stakeholders. In this case, fixing the errors at the later stages of software development process tend to be costly (Chantree et al. 2005). Drawn from the challenges in eliciting correct clinical requirements and there are none existing tool for eliciting clinical requirements, this research aims to develop an approach to elicit correct clinical requirements

1.3 What is Requirements?

Requirements are statements of a system service that are captured at the beginning of software development (Kotonya & Somerville 1998). Requirements are also described as "system services and constraints that are generated during the requirements engineering process" (Sommerville 2004). Software requirements specification provide completed and accepted agreement between requirements engineer and stakeholder of what the system should do and why. Most of the requirements engineers are trained to write the

requirements in natural language (NL) (Berry & Kamsties 2005) for stakeholders. In this respect, the requirements are commonly described in the form of natural language as is it one of the important reasons that can help stakeholders to articulate and communicate with the requirements during the software development process. However, the use of natural language for these requirements lead to typical NL problem such as ambiguity (Yang, Willis, et al. 2010) which is also referred as unintentional ambiguity (Berry & Kamsties 2005). In this case, requirements may lead to conflict, error and vague that may or may not express the user's need. If there are any ambiguities found in the later stage of the software development, the cost to fix the error are very costly (Chantree et al. 2005).

Requirements are classified as functional and non-functional requirements (Sommerville 2004). Functional requirements are the statements of what the system should do whereas non-functional requirements specify how the system should work. Correct functional requirements are important to ensure the correctness of the software project being develop. For the purpose of this research, we focus on the elicitation of functional clinical requirements. In the next section, we provide a description of Clinical functional requirements.

1.3.1 What is Clinical Functional Requirements?

Clinical functional requirements are information collected by requirements engineer from stakeholders for the purpose of developing clinical software. It is found that clinical requirements are more critical and complex in comparison to normal business requirements (Rector 1999; Kamalrudin et al. 2016)This is due to the fact that clinical domain is a sensitive domain as all the activities in this domain have direct impact on people's well-being and lives. Considered as the largest domain in healthcare, capturing and eliciting clinical requirements are considered as very challenging task for the requirements

engineers. Further, they have to work with complex and high-level technical terms and terminologies which they are not familiar (Cysneiros 2002; Daud et al. 2014)Additionally, clinical domain needs to be dealt carefully because if there is any conflict between the need of requirements engineers and stakeholders (Rector 1999) it may jeopardize one's life. It is also important to note that although most of the requirement engineers are expert in their software engineering domain, they are not expert in the clinical domain. The common problem faced by requirement engineers when developing software for clinical usage is to understand the information provided by the stakeholders who are medical practitioners, doctors, medical assistant and nurse (Cysneiros 2002; Chantree et al. 2006). As mentioned earlier the complexity of the terms and terminologies in the clinical domain influence their performance to elicit correct requirements. In other words, ambiguity and misinterpretation of the terms may lead to misunderstanding towards the requirements (Tveito & Hasvold 2002; Rector 1999; Chantree et al. 2006; Yang, de Roeck, et al. 2010)

1.3.2 Clinical Domain Library

There are many interpretations of domain library; some are called as databases, ontology, glossary, corpus and taxonomy. In clinical domain, database storage which gather the information related to the clinical domain is also known as data dictionary. According to Lee et al. (2010), the clinical data dictionary can be defined as "centralised source of all clinical information about data such as names, meanings, types, formats, ranges of values, sources and relationships to their data element". In this context, the information in the data dictionary is considered as requirements to develop clinical software. However, a clinical functional requirements domain library is still non-existence.

1.4 Problem Statement

The process eliciting clinical requirements are tedious, complex and difficult (Garde & Knaup 2006; Cysneiros 2002; Daud et al. 2014) due to the impact of the new system to the patients on the quality of care is unknown and can harm to the patients. Further, it is a challenge for requirements engineers to elicit correct clinical requirements as they need to have knowledge to understand the meaning of clinical information. However, they have difficulties to capture the correct meaning of the clinical terms because the clinical domain has many different and complex terms used in the requirements. Understanding the information in clinical domain is found to be even more difficult due to the information given by the stakeholders consists of different structure and terms. In addition, the structure and terms need to be analysed and captured correctly in order to avoid any misinterpretations in eliciting clinical requirements as it can cause harmful consequences to human's lives and well-being.

Other than that, there are many projects in clinical domain found to be abandoned due to the poor quality of the product (Teixeira et al. 2012). If the project are reported to be failure, to rebuild the clinical project would be costly. It has been reported that many failed healthcare projects are not because of flawed technology but the lack of systematic and human consideration issues throughout systems requirements and specification process (Teixeira et al. 2007).

To summarize, based on all of these issues and problems, we are motivated to develop and propose a new domain library for clinical requirement's, called CFR Domain Library. This research is aimed to help requirement engineers to elicit clinical functional requirements in terms of producing correct requirements.

1.5 Research Questions

Here are the two main research questions related to our research motivation:

1. What are the problem faced by RE in eliciting clinical requirements?"

This research question guides the motivation of the study and identifies research gaps. The preliminary studies and the literature review are conducted to answer the research question. The answers for this research question are reported in Chapter 2, Literature Review.

2. "How does CFR domain library help the elicitation of correct clinical requirements?"

This question addresses the main objective of this research, the design and development of the approach to elicit correct clinical requirements. It focuses on the process involved in developing clinical functional requirements domain library. This domain library helps requirements engineers to elicit correct functional requirements at the early stage of software development. In this respect, the process developing CFR domain library is explained in detail to give a complete description of the development of the clinical functional requirements domain library. The description is provided in Chapter 4, Our Approach.

3. "Does the CFR domain library able to help the elicitation of correct clinical functional requirements?"

This question focuses on our evaluation to evaluate the correctness and usability of the CFR domain library. In this respect, two (2) evaluations were conducted 1) correctness test and 2) usability test. The results of the evaluations are explained in Chapter 5, Result and Discussion.

1.6 Research Objectives

The main objective of this research is to develop domain library that supports the elicitation of correct clinical requirements at the early stage of requirement elicitation. In particular, the research aims to provide the following.

1. To identify the gaps and problems faced by REs in elicitng correct clinical requirements.
2. To develop a domain library for clinical functional requirements (CFR) using key structural patterns.
3. To evaluate the correct and usability of the CFR domain library.

1.7 Research Contributions

The contributions of this research are as follow:

1. This research provides a significant finding on the challenges and difficulties faced by requirements engineer when eliciting clinical requirements. We conducted preliminary studies with 105 novice software engineering (SE) students (final years) and 5 software engineering (SE) expert who are familiar with clinical requirements. In addition, we clarify further on the common techniques, approaches and methods adopted in eliciting clinical requirements in Chapter 2. This contribution is published in (Daud et al. 2014).
2. This research provides the findings of the existing adoption of domain library in clinical requirements elicitation. We found that there is almost none of the existing works adopt the domain library using key structural pattern for clinical requirements elicitation.