

# THE NEEDS OF CLINICAL DOMAIN LIBRARY FOR ELICITING ACCURATE CLINICAL REQUIREMENTS

Nadiah Daud<sup>1</sup>, Massila Kamalrudin<sup>2</sup>, Safiah Sidek<sup>2</sup>, Rosmiza Wahida Abdullah<sup>2</sup>

<sup>1</sup>Universiti Teknikal Malaysia Melaka, Hang Tuah Jaya, 76100 Durian Tunggal, Melaka, Malaysia.

<sup>2</sup>Innovative Software System and Services Group, Universiti Teknikal Malaysia Melaka, Hang Tuah Jaya, 76100 Durian Tunggal, Melaka, Malaysia.

Email: <sup>1</sup>nadahdaud@yahoo.com, <sup>2</sup>massila@utem.edu.my, <sup>2</sup>safiahsidek@utem.edu.my, <sup>2</sup>rosmiza@utem.edu.my

**ABSTRACT:** *Issues in misinterpretation of terms and miscommunication with stakeholders still persist although there are various approaches and tools available to elicit and capture accurate requirements. Specifically in healthcare domain, these issues need serious attention considering that there are myriad complex medical terminologies, unfamiliar to most requirements engineers. Further, accurate terms and words need to be captured as misinterpretations in eliciting requirements may lead to harmful consequences to human's lives and well-being. This paper presents two preliminary studies that compare the difficulties in eliciting clinical and business requirements. Based on a survey conducted with 20 respondents, it was found that eliciting clinical functional requirements is more difficult than the business requirements. Similar findings were also drawn from interviews conducted with 5 experienced requirements engineers. They also claimed that a clinical domain library could help them to elicit accurate functional requirements. The domain library should also have several functions that can be used to facilitate the elicitation of accurate functional requirements.*

**KEYWORDS:** requirements elicitation, functional requirements, clinical requirements, domain library, accurate requirements.

## 1.0 INTRODUCTION

Healthcare software is distinctive from other system as they have their own structures and properties, and its distinctiveness needs to be addressed when developing healthcare software [1]. Further, it has been reported that the failures of many healthcare projects are not due to flawed technology, but the lack of systematic and human consideration issues throughout systems requirements and specifications processes [2]. Considering that eliciting and capturing requirements are heavily influenced by human factor, there is a need to find ways to ensure systematic ways of eliciting and capturing requirements.

Requirements are statements of a system service and they are captured at the beginning of software development [3]. Recognizing that they shape the structure of the software system, it is important for requirements engineers to capture and elicit accurate requirements to develop good quality software that is consistent with the expectations and needs of the stakeholders. Further, requirements are usually developed based on communication between the stakeholders and the requirements engineers using a formal language, which is a natural language. Hence, ambiguity and misinterpretations are among the common issues faced by requirements engineers when eliciting and capturing requirements. However, issues in misinterpretation of terms and miscommunication with stakeholders still persist although there are various approaches and tools available to elicit and capture accurate requirements. Clinical software is one of the many healthcare software which requirements are derived from technical terminologies, expressions and concepts used in clinical statements [4]. Clinical requirements are information given by stakeholders to requirements engineer or developer to develop clinical system before development starts. Normally, the patterns of clinical requirements are more complex as compared to other requirements such as business requirements. Business

requirements are original requirements derived from the industry and they provide a standard that needs to be delivered. Unlike business requirements, capturing and eliciting clinical requirements is a challenging task as requirements engineers have to work with the complex and high-level technical terms and terminologies which they are not familiar [1,5]. The use of these expressions in the requirements has direct implications on human safety and lives and it gives significant impact on individual patient care [6]. In this respect, it is very important for them to avoid misrepresentations and misunderstanding of the technical terms as a poor quality of any software adopted in healthcare domain may lead to harmful consequences to human life and well being. Hence, requirements engineers have to ensure consistent requirements to minimise medical errors and increase the quality of health services [7].

This paper presents two studies that lead to the motivation to embark on a project to develop a clinical domain library that can facilitate accurate elicitation of clinical requirements. A review of literature and two preliminary studies have been conducted to justify the difficulties in eliciting clinical requirements as compared to business requirements. In this regard, this paper is organised into four sections. Besides the Introduction, the second section presents the motivation of this project, while the third section describes the two preliminary studies and their findings. Finally, the fourth section presents the conclusion and future work.

## 2.0 LITERATURE SURVEY

There are different types of techniques, approaches, methods and tools useful for understanding the complexity of the requirements elicitation process. For example, Proynova et al. [8] developed an elicitation technique that can be merged with the existing requirements elicitation techniques. Their work focuses on personal values and their relationship in

software requirements. User can discover useful information when using this approach parallel to the existing requirements elicitation techniques. Nevertheless, how the personal values the impact of software requirements in healthcare domain is still questionable.

McGee-Lennon [9] designed a flexible methodology and documented the method to ease the elicitation process of complex and dynamic multi-stakeholders' requirements. The method allows stakeholders to identify how their current work practices fit into the home care plans. Yet, this research only aims at reducing the complexity and uniqueness of the home care domain and not to overcome the problems in the clinical domain. Another cited work is from Martin *et al.* [10] who emphasised the importance of focusing on the whole process of elicitation. They suggested that a user-centered design approach should begin at the early stage and continue until the end of the process. They conducted open-ended semi-structured interviews to examine the clinical needs of the device and its potential benefits to patients and clinical users. However, this approach does not consider conducting interview with the specialists during the elicitation phases.

There are also some tools developed to ease the difficulties of the elicitation process, for example Kushwaha *et al.* [11] described an automated novel software intelligent agent model that can automatically sense and gather requirements from users. The performance of HMS (Hospital Management System) can be increased from the report generated from the intelligent model for HMS, and it can then send directly to the developers. Even though the software intelligent agent reduces the major issue of software invention, it does not specifically develop for healthcare domain, particularly the clinical domain. Furthermore, there are some works to develop a library for understanding the terminology found in the requirements. For example, Knauss *et al.* [12] proposed SmartWiki tool that can check the consistency and integrate constructive and analytical quality assurance. Focusing on requirements engineering, a good quality requirements can be written by using this wikis. SmartWiki also provides support in the forms of glossary to assist users to use consistent technical terminologies. However, this approach does not focus on functional requirements in the clinical domain.

Lee *et al.* [13] evaluated the content coverage and data quality of Clinical Data Dictionary (CiDD), which has a total of 12,994 terms collected from 98 clinical forms of a tertiary cancer center hospital. With the addition of textual or context-sensitive definitions, use cases of term, value sets, or hierarchies, it is a reliable tool as different users can use it as reference to avoid the possibility of different interpretation of the concepts or terms. However, this data dictionary is drawn from patient records and it does not focus on functional requirements in clinical software. Babre [14] presented a process for coding medical terms in clinical data using the Medical Dictionary for Regulatory Activities (MedDra) and World Health Organisation Drug Dictionary Enhanced (WHO-DDE), the most common medical data dictionaries used in data management. Although these dictionaries are helpful for understanding the process of

medical coding, their usefulness for eliciting and capturing functional requirements is restricted.

As a conclusion, there are many works to facilitate the process of eliciting requirements in healthcare. Yet, its usefulness for capturing and eliciting functional requirements is very limited. There are also works on developing a library or data dictionary in clinical domain, but they provide general terms not specific to functional requirements. Finally, there is none so far work on developing a domain library for clinical to ease the process of eliciting clinical functional requirements.

### **3.0 PRELIMINARY STUDIES: A SURVEY AND AN INTERVIEW**

This section presents the two preliminary studies to address the need to develop a clinical domain library to assist the elicitation of clinical functional requirements. The two studies, a survey and interview were conducted to justify that clinical is more difficult than the business requirements.

#### **3.1 THE SURVEY**

The survey was conducted with 20 respondents comprising of three different backgrounds: i) the experts from healthcare background and postgraduate students of software engineering ii) with healthcare background, and iii) without healthcare background. The conduct of the survey was to justify the problems in eliciting the healthcare requirements specifically the clinical requirements. The survey consists two sets of requirements: Set A contains tasks related to business requirements and Set B contains tasks related to clinical requirements. Both sets of requirements were taken from published requirements: The clinical requirements were from the Health Information Management Systems Society [15], and from Lappeenranta University of Technology. The business requirements were from the Library Management System. For each set, ten statements consisting of functional and non-functional requirements were given and respondents were expected to identify the functional requirements only. To measure the level of difficulties, time taken by respondents to identify the functional requirements was also recorded.

The results of the survey are shown in Table 1 below. Based on Table 1, the percentage of identifying correct business functional requirements is 75%, while the incorrect answers for business functional requirements is 25%. The percentage of identifying correct clinical functional requirements is 61%, while the incorrect answer for clinical functional requirements is 39%. Hence, this result shows that relatively the clinical functional requirement is more complex than the business functional requirements. Despite the different percentage of identifying correct functional requirements for business and clinical, the difference between the two is 14% only.

We also measured the time taken to complete the two tasks. Respondents took 5 minutes to identify the functional clinical requirements, whilst they took only 3 minutes for the functional business requirements. Therefore, we can conclude that the functional clinical requirements are more complex than the business requirements as respondents took longer time to identify the functional clinical requirements.

These results provide justification to conduct a study to develop a domain library to help requirements engineers to elicit the functional clinical requirements

**Table 1:** Result of Survey

	Correct requirements	Wrong requirements	Time Taken (min)
Business requirements	75%	25%	3
Clinical requirements	61%	39%	5

.interview

The second study, the interview was conducted with 5 experienced requirements engineers who have backgrounds in healthcare software. The purpose of the interview was to investigate the problems they face in developing software for clinical usage. Four open-ended questions seeking their experience and opinions relating to eliciting functional clinical requirements were asked. Based on the interview, the respondents said that some of the problems faced while eliciting the functional requirements are the difficulties in understanding the information, terminology and the data collection in the healthcare industry. Most of the respondents said that the more direct, straightforward and clearly stated expressions in the functional business requirements made it easier for them to identify the functional requirements. Furthermore, they emphasised that business requirements do not have many complex and technical terminologies. Some respondents who did not have the background in eliciting clinical requirements stated that the clinical requirements have many uncommon terminologies, which are difficult to understand. The majority of the respondents highlighted the need for a tool that provides brief understanding for beginner requirements engineers who do not have any healthcare background.

When asked about the features that they would like to have in a tool for the clinical domain library, they requested for a tool that could provide options to choose the category of requirements and the glossary of the terminology. One of interviewees asked for a tool with a modelling feature, which can give a framework model after inserting the requirements and provide a suggestion and synonyms of the terminologies. By having the synonyms it can help them to capture the meanings easily. They also would like to have a tool with a light-searching feature with dynamic feedback. One of the interviewees also requested a compilation of functional requirements from the existing healthcare projects to be in the library in for helping them to easily understand a new project to be developed.

Based on the two studies, we conclude that requirements engineers have difficulties to identify the functional requirements for clinical requirements in comparison to business requirements. From the interview, the respondents admitted that they have problems in eliciting accurate

functional requirements in clinical and there is a need for a tool support to help them in eliciting accurate requirements.

#### 4.0 RESEARCH IMPLICATION

This paper presents a literature search, survey and interview to justify that there is a need to develop a domain library for clinical domain. Based on the literature survey, domain library specifically for eliciting clinical requirements is still non-existence. Further, the two studies proved that eliciting functional requirements for clinical requirements is more difficult than the business requirements and there is a need to provide a domain library that can help to ensure the accuracy in eliciting clinical requirements by requirements engineers.

#### ACKNOWLEDGEMENTS

This research is funded by Universiti Teknikal Malaysia Melaka and MOE with Grant PJP: PJP/2013/FTMK(12D)/S01176 and FRGS: FRGS/2/2013/ICT01/FTMK/02/2/F00185.

#### REFERENCES

- [1] L. M Cysneiros, "Requirements engineering in the health care domain," in *Requirements Engineering. Proceedings. IEEE Joint International Conference on* (pp. 350-356), 2002.
- [2] S. Rinkus, M. Walji, K. A. Johnson-Throop, J. T. Malin, J. P. Turley, J. W. Smith and J. Zhang, "Human-centered design of a distributed knowledge management system," *Journal of Biomedical Informatics*, 38(1), 4-17, 2005.
- [3] G. Kotonya and I.Sommerville, *Requirement Engineering Process and Techniques*. West Sussex,England. John Wiley & Sons Ltd, 1998.
- [4] A. L. Rector, "Clinical terminology: why is it so hard?," *Methods of information in medicine*, 38(4/5), 239-252, 1999.
- [5] N. Daud, M. Kamalrudin, S. Sidek, and R. Wahida, "Characterisation of Healthcare Domain Library to Capture Accurate Requirements of Healthcare Software," In *e-Proceeding of Software Engineering Postgraduates Workshop (SEPoW)* (p. 17), 2013.
- [6] L. Teixeira, V. Saavedra, C. Ferreira, and B. S. Santos, "The User's Role in the Development Process of a Clinical Information System: An Example in Hemophilia Care," In *Human Centered Design* (pp. 922-931), 2009.
- [7] A. Al-Dahmash, S. El-Masri, "A New Proposed Software Engineering Methodology for Healthcare Applications Development," in *International Journal of Modern Engineering Research (IJMER)* on (pp-1566-1570), 2013.
- [8] R. Proynova, B. Paech, A. Wicht, and T. Wetter, "Use of personal values in requirements engineering—A research preview," In *Requirements Engineering—Foundation for Software Quality* (pp. 17-22), 2010.
- [9] M. R. McGee-Lennon, "Requirements engineering for home care technology," In *Proceedings of the SIGCHI*

- Conference on Human Factors in Computing Systems* (pp. 1439-1442), 2008.
- [10] J. L. Martin, D. J. Clark, S. P. Morgan, J. A. Crowe, and E. Murphy, "A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective," *Applied ergonomics*, 43(1), 184-190, 2012.
- [11] N. Kushwaha, S. Sahu, and P. Ahmed, "Gathering Requirements for Hospital Management System Using Intelligent Agents. Environment," 1(3), 2012.
- [12] E. Knauss, O. Brill, I. Kitzmann, and T. Flohr, "Smartwiki: Support for high-quality requirements engineering in a collaborative setting," In *Wikis for Software Engineering, 2009. WIKIS4SE'09. ICSE Workshop on* (pp. 25-35), 2009
- [13] M. K. Lee, H. Park, Y. H. Min, Y. Kim, H. K. Min and S. W. Ham, "Evaluation of the Clinical Data Dictionary (CiDD)," *Healthcare informatics research*, 16(2), 82-88, 2010.
- [14] D. Babre, "Medical coding in clinical trials," *Perspectives in clinical research*, 1(1), 29, 2010.
- [15] Healthcare Information and Management Systems Society, <http://www.himss.org/>, accessed from: April 2014.