International Research Journal of Engineering and Technology (IRJET) e-ISSN: 2395 -0056
Volume: 04 Issue: 06 | June -2017 www.irjet.net p-ISSN: 2395-0072

Eliciting Functional Requirements in Clinical Domain: A Review

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Abstract – *Requirements elicitation is the most crucial and complex tasks in requirement engineering as it determines the quality of requirements in software development. Further, considering that clinical requirements are more complex in comparison to other requirements, requirements engineers have to give more attention when eliciting requirements for clinical software as any errors may lead to disastrous effects in healthcare. In this case, requirement engineers need to be cognizant of the accuracy and completeness of requirements to ensure the development of a full-function software. Although various methods, approaches and tools have been developed to assist requirements engineers to elicit accurate requirements, there have been very limited work involved in the clinical domain. This paper aims to present a comparison analysis of the existing methods, approaches and tools that help requirements to elicit requirements. The analysis of tools can be used a guidance to identify the existing work related to requirements elicitation.*

Key Words: **Requirements Elicitation, Clinical Requirements, Software development, Accuracy**

1. INTRODUCTION

Requirements elicitation is a complex process as it involves many activities [1]. There are various techniques, methods, approaches, and tools to assist requirements engineers to elicit correct requirements, and among the common approaches to elicit requirements are, such as interview [2] [3], questionnaire [3] [4] [5] and observation [5].

The process of requirements elicitation involves communication with relevant stakeholders [1], which is a highly interactive process and the most important activity in requirements elicitation. To elicit quality requirements, requirements engineers need to have a strong basic knowledge of eliciting requirements and familiarity with the domain of software to be used. Further, capturing the right requirements has become a concern when developing a security software [6]. In this case, requirements engineers need to clearly understand the meaning transmitted by the stakeholders. According to [7][23], there are three levels of communication issues or barriers exist during the elicitation, which are technical, semantic and effectiveness issues. The technical issues relate to the accuracy of the symbols of communication transmitted. The semantic issues relate to the accuracy of the transmitted symbols that convey the desired meaning. The effectiveness issues focus on the effectiveness of the received meaning that affect conduct in the desired way.

In this context, the communication problem between both parties may lead to incorrect elicitation of requirements, which eventually lead to poor quality of software development.

Clinical requirements are more complex in comparison to other requirements due to its jargons and specific terms. Further, requirements engineers have to give more attention when eliciting requirements for clinical software as any errors may lead to disastrous effects in healthcare. Researchers in the field of software engineering are aware of need to have extra attention when eliciting clinical requirements to develop new clinical software. They were eager to look into the area of elicitation to overcome the misunderstanding of the requirements used among stakeholders. Although various methods, approaches and tools have been developed to assist requirements engineers to elicit accurate requirements, they tend to have different emphasis and functions. This paper aims to present a review based on a comparison analysis of the existing methods, approaches and tools that help requirements engineers to elicit accurate requirements.

This paper is organised into three main sections. After the introduction, the second section presents the methodology of the review. The third section presents the findings and discussion, and this paper ends with a conclusion presented in the fourth section.

2. METHODOLOGY

The review presented in this paper is based on a literature search and review. We designed a literature review protocol to search for the existing relevant literature. The literature review protocol is as shown in Figure 1. The purpose of adopting the literature review protocol is to ensure that all the relevant literatures are captured for the analysis.

As shown in Fig. 1, the literature search consists of two phases. In the first phase, a review protocol was formulated specific to our literature search in the field of clinical functional requirements elicitation. The empirical studies were searched using search engines, such as IEEE Xplore, ScienceDirect, Springer, Scopus, Google Scholar, Elsevier, ACM Digital Library, Empirical Software Engineering – An International Journal Requirements Engineering Journal and National Center for Biotechnology Information.

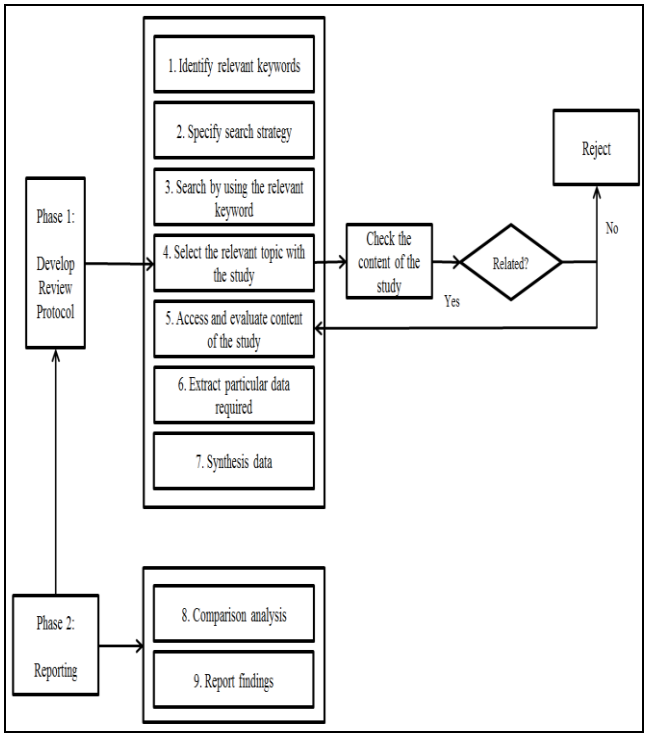

Fig -1: Literature Review Protocol

The search keywords were used for different relevant topics to ensure that all related papers are included. The search strategy needs to be specified. As such, manual search, automated search, or mixed search using the relevant keywords was identified. Then, the content of the paper were accessed and evaluated. Any irrelevant papers were rejected at this phase, while the relevant papers were scrutinized for analysis conducted in the next phase. The data that were extracted from the relevant paper are: i) the objective, ii) the methodology of the studies, iii) the result presented and iv) the limitation of the studies. The extracted data were studied in-depth to filter and distil possible overlaps.

In this literature review, almost 400 papers have been reviewed. The title of the papers was examined to remove any studies that are not clearly related to the research focus. Then their abstract, key words and conclusion were examined to eliminate any unrelated studies. After applying these steps, 200 studies were retained. We examined these 200 studies and applied the inclusion/exclusion criteria as outlined in Table 2.1 to select the related papers as primary studies for this study. Further, we applied the same selection steps to the reference lists of the selected 65 primary studies to find additional primary studies related to the research focus. Finally, only 16 papers were found to be relevant for the comparison analysis.

Table -1: Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Papers focusing on eliciting, capturing, gathering clinical, healthcare or medical requirements Papers focusing methods, approach and techniques used in eliciting requirements Papers describes EUC and EUI model used in eliciting functional requirements Papers focusing on tools used in eliciting requirements Papers about domain library used in eliciting requirements	Papers do not focus on requirements elicitation Papers do not focus on clinical, healthcare and medical functional requirements. Studies are not related to the research questions Findings are not clear and ambiguous.

The second phase involved conducting the comparison analysis and reporting the analysis of the related works. The following section presents the review of the literature based on two aspects, namely the methods and approach used in requirements elicitation and the tools used in elicitation and requirements domain library for healthcare software.

3. FINDINGS AND DISCUSSION

The list of related literature is presented in a table of comparison as shown in Table 2. As shown in Table 2, the comparison analysis of the methods, approaches and tools involves three domains, which are healthcare, clinical and non-clinical. In this respect, a total of 16 related works have been analysed, in which seven related works were identified within the domain of healthcare and another seven in the non-clinical domain. However, only two works were found in the clinical domain. This finding indicates that there is very limited work in the clinical domain.

Table-2 Methods, Approaches and Tools of Requirements Elicitation

Aspect	Healthcare	Clinical	Non-Clinical
Methods and Approaches	(Al-dahmash & El-masri 2013)	(Teixeira et al. 2007)	(Staccini et al. 2001)
			(Laporti et al. 2009)
			(Kamalrudin et al. 2010b)
	(Gausepohl et al. 2011)		(Kamalrudin & Grundy 2011)
	(Widya et al. 2009)	(Martin et al. 2012)	(Proynova et al. 2010)
	(Dilek Ozdemir & Gozlu 2008)		(Vijayan & Raju 2010)
Tools	(Proynova et al. 2011)	-	(Kamalrudin et al. 2014)
	(Kushwaha et al. 2012)		
	(Teixeira et al. 2014)		
Total	7	2	7

With respect to the comparison between the two aspects, most of the related works focus on developing methods and approaches, while very limited work were involved in developing tools. As presented in Table 2, there are three works relating to developing tools that focus on healthcare, one on non-clinical and none was found for clinical domain. It is important to note that work conducted by Teixeira et al. [8] can also be considered in the clinical domain, but the work has not been proven as an adequate and reliable tool for clinical software development by any expert from the healthcare software developer. In this case, the method and approach developed by [8] can be positioned as clinical domain, but its tool development is positioned in the healthcare domain in general. This analysis indicates that tool for eliciting requirements in clinical domain is still lacking.

The next two sections provide a synthesis of the analysis related to the methods and approaches as well as the tools used in requirements elicitation.

3.1 Methods and Approaches in Requirements Elicitation

Requirements engineers are aware of the difficult tasks in eliciting requirements and various methods and approaches have been proposed. All of the methods are found to assure the correctness of the requirements. [9]proposed a method using a process-oriented analysis to elicit and structure the user requirements, which fits with the dynamic of data input. However, this method cannot be applied successfully without understanding their roles and actors, and the hierarchical analysis. On the other hand, Al-dahmash & El-masri [10] proposed a methodology to build the healthcare application and systems with reliable and protected software. They proposed a method called Software Engineering Methodology for Healthcare Applications development (SEMHTA) in order to achieve their aim. The method proposed focused on what developers do when developing a new system rather than focusing on elicitation phase.

Another method of exploring the requirements is Storytelling, proposed by [11]. The Storytelling is an elicitation method for medical device requirements that focuses on comparing the information elicited. The elicited information was collected from nurses during requirements gathering for an infusion pump that adopted two methods: Focus groups followed by interviews (Group #1) and focus groups followed by Storytelling sessions (Group #2). The results suggested for further exploration of Storytelling considering that Group #2 contributed similar quantity and breadth of information in significantly less time. The results also indicated the potential support for the efficacy of Storytelling within the healthcare domain as Group #2 participants contributed more distinct context-of-use information with an emphasis on the social context. However, this approach is presented for the elicitation of medical device requirements rather than in clinical requirements.

Another similar work is conducted by [12] that proposed a method for enhancing requirements elicitation using the ontology domain. They added some values to the ontology value and used web mining as well as lightweight natural language processing techniques. A supporting tool called OREW was also developed to perform this method. Nevertheless, this work did not focus on the requirements in healthcare domain and did not develop any domain library to help the elicitation process. Likewise, [8] used another type of method named task analysis to manage clinical information in haemophilia care in order to improve the requirements elicitation. This method has been proven to be a practical way of involving user by allowing a better understanding of the human factors in their system. However, their research has not been proven by any experts from healthcare background that their research is the most efficient way and the domain is not in the clinical domain.

Widya et al. [13] proposed another method to elicit requirements in eHealth domain. They proposed a mix of methods and techniques known in the literature in the area of requirements engineering or medical trial design. Mix methods and techniques were applied to elicit requirements holistically to achieve in alignment with the evidence based working practice in medicine. In this study, Trial designers and ICT developers developed a scenario which reflects the treatment protocol proposed in the trial design. The requirements for the intended system is elicited based on the developed scenario. Although it supports a particular telemedicine treatment, this method does not assist the elicitation of clinical requirements.

There are works that proposed several types of approach to help in eliciting the requirements. Martin at el. [14] suggested that a user-centered design approach should begin early and continued throughout the development. They conducted an open-ended semi-structured interview to examine the clinical need for the device and the potential benefits for patients and clinical users. In their study, requirements elicitation is considered as a one-off process to collect the information required to develop a prototype device. However, it is important to highlight that it is problematic to view the elicitation process as a discrete task. As such, this approach highly depends on the interview data during the elicitation phase, without requiring a specialist in the interviewing techniques. In the same context, there is an approach proposed by [15] named Athena. Athena is a collaborative approach to elicit requirements, which is based on the group storytelling approach. In this approach, stakeholders tell stories about the current and past systems that support a given activity. It describes a solution to overcome problems including viewpoint, mental model and expectation of differences among users and analysts. Anthena is also an approach found on collective knowledge to progressively build the system requirements from a narrative of user stories to the definition of Use Cases. The stories taken are then merged in a form of single story.

Stories are then transformed into scenarios, and from the scenarios into Use Cases. The solution consists of a knowledge model based on stories about the system, a collective construction method, and a tool to support interactions. Even though this approach has been applied in requirements elicitation, this approach has yet to be applied in clinical requirements.

There are also other approaches applied to capture requirements. For example, Kamalrudin et al. [16] have developed a lightweight approach to capture consistent requirements from the client-stakeholders. Here, a library pattern that supports various application domains is developed to store the essential requirements following the EUC methodology. However, the library pattern does not focus on the usage of the healthcare requirements [16] [17]. Proynova et al. [18] gives a preview of their approach in developing elicitation techniques to develop an elicitation techniques to be merged with the existing requirements elicitation techniques. They tend to focus on personal values and their relationship into software requirements. Useful information can be discovered by using this approach parallel with the existing requirements elicitation techniques. Nevertheless, this work is still at the stage of inspection on how personal value impacts software requirements healthcare domain.

Additionally, [19] proposed a new approach to improve the current approach for requirements elicitation using paper prototype. This paper prototype is a visual representation of what the system will look like. This approach can be visualised by hand drawing or using graphics program. This approach is changeable based on user's feedback and the requirements gathered. However, once the prototypes are finalized, the requirements are stabilized. When the requirements specification is done after the stabilization process, the prototype can be discarded. Three case studies have been conducted in a postgraduate group to help them to analyse the usefulness of this technique. The results for the study indicate that this approach was suitable to be used for small and medium sized projects. Even though this approach permits easy understanding of the requirements among the stakeholder, it is not suitable to be applied in clinical domain. This is because clinical domain is a relatively large and complex domain in comparison to other domains. Additionally, the clinical domain involves human lives that require correct elicitation of requirements to avoid any misunderstanding of the terms used.

In determining the performance criteria for Health Information System (HIS), Ozdemir & Gozlu [20] intend to develop performance measurement criteria for organisation-wide in HIS and three levels of study conducted in this research; literature survey, in-depth analysis and classification of all the information gained according to operational levels. As a result, HIS performance criteria should be evaluated according to four perspectives; data, healthcare staff, and patients. Yet, this research still needs future study because it does not cover the security element in software.

3.2 Tools Used in Requirements Elicitation

Although there are various tools were developed for eliciting requirements, tools for eliciting clinical functional requirements is almost non-existence. A work from [18] developed instruments to elicit all personal values and their relationships to software requirements by interviewing nurses and physicians. Their results were used to develop two small test cases. Yet, their results show that the instruments are impossible to elicit value-related information and correlate it with the software features.

Kamalrudin et al.[21] developed a Malay-English Requirements Engineering Tool (MEReq) a tool to elicit and check the consistencies of requirement. With the same context of domain library, MEReq employs the Essential Use Case (EUC) and Essential User Interface (EUI) models derived from the interaction pattern libraries. However, MEReq only caters multi-lingual requirements for various business application domains in both Malay and English language requirements, except the clinical domain. Then, they also extended MEReq to TestMEReq[24][25] to validate the captured requirements. This tool is also able to validate the captured requirements especially in detecting inconsistency of requirements compared to essential requirements stored in the pattern library,but still not handling the validation of clinical requirements.

Another work found is from [22] that describes an automated novel software intelligent agent model that could automatically sense and gather requirements from users. Here, the performance of the Hospital Management System (HMS) can be increased from the report generated through the intelligent model as it can directly send to the requirements to developers. Even though the agent helps to reduce the major issue of software invention, it does not cater the clinical software or system.

There is another work from [8] which aims to minimize the problems associated to elicitation process by using Lumzy as the prototyping tool; they presented their perspective in the requirements engineering process in health information system (HIS). Lumzy is one of the tools that allows user to create a prototype. Lumzy is an easy tool to create mock-ups, share and send the mock-up prototype back to the stakeholders in real-time. With the experience in the development of a distributed web-application, they used Portuguese National Registry of Hemophilia and other Congenital Coagulopathies (NRH&CC) as their case study to support the development. They found that prototyping method helps the success of the development of software, especially in eliciting requirements. Even though this tool is a promising tool, it only focuses on the design rather than the requirements. Additionally, this tool focuses more in healthcare domain rather than on the clinical domain specifically.

4. CONCLUSION

An analysis of the methods and approaches as well as tools to elicit requirements has been conducted. A summary of the list of existing work related to eliciting requirements has been presented in Table 2. Based on the analysis of existing works, it can be concluded that most of methods and approaches of requirements elicitation are positioned in the non-clinical and healthcare domain. There has been very limited work in clinical domain. Further, most of the work in elicitation focus on the traditional methods and approaches although there were attempts to modify these approaches. With respect to the tool used to elicit requirements, it can be concluded that there is a scarcity in the tools for elicitation requirements. Although there are tools being developed for the business requirements and healthcare requirements, tools to elicit clinical requirements are still non-existence.

Considering the complexity of the clinical requirements and the need for accurate elicitation of requirements for quality software, there is a need to develop a tool to elicit clinical requirements.

ACKNOWLEDGEMENT

The authors would like to thank Universiti Teknikal Malaysia Melaka for the facilities provided for the research.

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