Analysis of Software Requirements Elicitation Techniques for Medical Information Systems: A Systematic Literature Review

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Abstract. Medical Information Systems (MIS) have evolved in response to the need to manage medical and clinical information efficiently. The constant updating of these systems has become essential to comply with regulations such as the Health Insurance Portability and Accountability Act (HIPAA), ensuring the protection of patient health information. This research aims to analyze MIS requirements elicitation techniques through a Systematic Literature Review to identify the most commonly used techniques, explore the regulations that affect elicitation, and understand the challenges associated with this practice. The results revealed that, among the elicitation techniques identified and applied in the development of MIS, interviews and the observation technique are the most prevalent. In addition, techniques such as emotional target modeling, which allows the identification of the client's emotions and desires to understand their expectations, were detected.

Keywords: Medical Information Systems, Requirements Elicitation, Information Regulation, Software Development, Data Protection.

1 Introduction

Medical Information Systems (MIS) have emerged as a response to the increasing complexity of hospital medical and clinical data management. These systems, designed to organize critical information such as diagnoses, treatments, and medical procedures, have evolved significantly from the era of physical paper records to more efficient and advanced digital solutions.

The impetus behind the development of MIS is the need to overcome the limitations inherent in using physical records in hospital environments. The increase in the size of hospitals and the accumulation of medical information made the management of paper records inefficient and costly, demanding considerable human resources [1]. The transition to digital systems has not only optimized information management but has also revolutionized how medical care is provided, facilitating access to crucial clinical data to support clinical decision-making [2].

The problem lies in the need to identify particular requirements for these systems, such as those linked to quality and safety, compliance with specific regulations, and ensuring patient safety in an ever-changing environment [3]. The diversity of MIS, as well as their ability to integrate with other healthcare systems, has underscored the urgent need to develop a new system that can seamlessly integrate with other healthcare systems, ensuring a comprehensive and efficient healthcare management system [3].

This paper presents a Systematic Literature Review inspired by the method proposed by Kitchenham et al. [4], an SLR protocol was performed, covering publications from 2018 to 2023. Twenty-two primary studies that answered the research questions were identified and analyzed, applying the data mining and synthesis guidelines to provide an overview of MIS.

The results obtained can support software developers and requirements elicitation teams in MIS. Additionally, they can serve as a basis for future research and contribute to the understanding of how to perform higher-quality requirements elicitation in Medical Information Systems.

The paper is organized as follows: Section 2 describes the research method, including research questions and the conduction of the revision; Section 3 presents results; and Section 4 presents Conclusions.

1.1 Background

A Medical Information System (MIS) is a system designed to manage and organize medical information such as diagnoses, treatments, medical procedures, and any other information relevant to the patient's health; it also allows the organization of clinical information such as medical appointments, medical notes, laboratory results, surgical procedure reports, and more.

These systems were created to overcome the limitations of using physical files, consisting of medical data card collections. As hospitals grew in size and more medical information accumulated, paper records management became inefficient and costly. In addition, it demanded many human resources, which raised hospitals' operating costs [1].

Today, MIS, with their advanced capabilities, have transformed patient care by facilitating access to clinical and medical information. This revolution has increased the need for specific requirements elicitation techniques to ensure that these systems meet user needs and comply with relevant regulations, such as the DO-178B and IEC 61508 standards.

Ensuring compliance with institutions such as the Health Insurance Portability and Accountability Act (HIPAA) is a crucial aspect of MIS. These systems are designed to adhere to these regulations, ensuring patient data security and privacy.

2 Research Method

The method selected for the development of the SLR was proposed by Kitchenham et al. [4] due to its rigorous and structured approach that provides a clear framework for Planning, Conducting, and Documenting a systematic review. The method is divided into three stages (see Fig. 1). The first stage is Planning, where a protocol for the Systematic Review was developed to adhere to in order to allow reproducibility of other studies. In the second stage, Conducting, the Systematic Review activities were developed, where the primary studies were obtained and extracted. In the third and last stage, the corresponding documentation was prepared. The following subsections will detail the activities marked in bold in Fig 1.

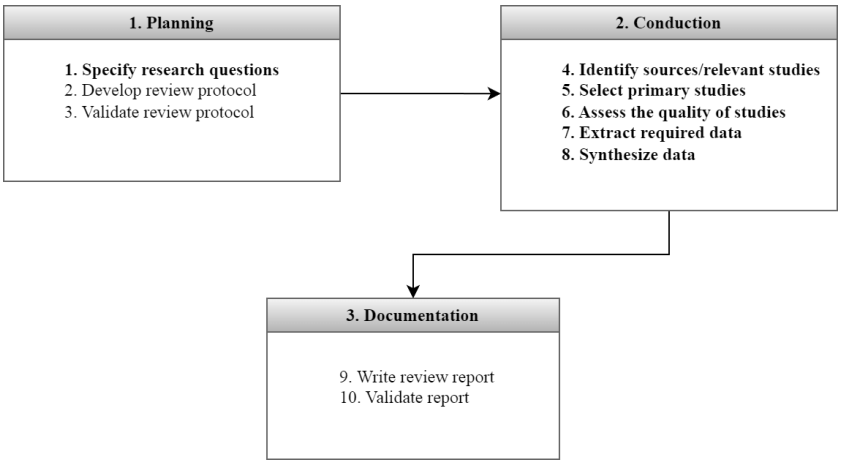

Fig. 1 SRL method proposed by Kitchenham, et al. [4]

2.1 Research Questions

Four research questions were formulated to steer the systematic literature review process. Each question delves into a crucial aspect of requirements elicitation in Medical Information Systems. The questions are as follows:

RQ 1. What requirements elicitation techniques are used in developing Medical Information Systems?

Motivation: To identify the requirements elicitation techniques used in this type of systems to determine which are the most reported and effective.

RQ 2. What are the regulations that influence requirements elicitation for Medical Information Systems?

Motivation: It is crucial to comprehend the regulations that govern requirements elicitation in Medical Information Systems. This understanding is key to ensuring their compliance and effectiveness.

RQ 3. What advantages describe the elicitation techniques in developing a Medical Information System?

Motivation: To identify the advantages of requirements elicitation techniques used in Medical Information Systems, to provide valuable insight for future developers of these systems, and to help them select the most effective techniques.

RQ 4. What are the challenges faced by elicitation techniques in Medical Information Systems?

Motivation: Understanding the challenges faced by requirements elicitation techniques in Medical Information Systems is essential. This knowledge can help devise strategies to overcome these challenges.

2.2 Identify sources and relevant studies

The search procedure was initiated with a exploration of online databases, which led to the discovery of three platforms: IEEE Xplore, Science Direct, and SpringerLink. This discovery facilitated the acquisition of secondary studies, which in turn allowed us to carefully determine the most appropriate search terms, as outlined in Table 1. These meticulously chosen terms were then used to construct the search string, ensuring the accuracy and relevance of our search.

Table 2 presents the various strings created from the terms in Table 1, which were rigorously tested in the IEEE Xplore digital library. Based on the observed results, the search string SS7 was selected for its significant yield of studies coinciding with Requirements Elicitation and MIS. This choice, unlike SS5 and SS6, which primarily focused on Health Sciences, underscores the importance of a well-crafted search string in yielding relevant research findings.

Table 1. Search terms.

Terms
"Medical information System", "Health Care Information System", "Health Information System".
Requirement, Need.
Elicitation.
Method, Strategy, Plan.
Rules, Standards, Guidelines.

Table 2. Search strings.

ID	Search string	Total studies
SS1	(("Medical System" OR "Health Care System" OR "Health System") OR (Medical OR Health) AND ("information system" OR information)) AND (requirement OR need) AND (elicitation OR identification) AND (techniques OR Method OR Strategy OR Plan) AND (Regulations OR Rules OR Standards OR Guidelines)	113
SS2	("Medical System" AND ("information system" OR	40

	information)) AND (requirement OR need) AND (elicitation OR identification) AND (techniques OR Method OR Strategy OR Plan) AND (Regulations OR Rules OR Standards OR Guidelines)	
SS3	(“Health System” AND (“information system” OR information)) AND (requirement OR need) AND (elicitation OR identification) AND (techniques OR Method OR Strategy OR Plan) AND (Regulations OR Rules OR Standards OR Guidelines)	22
SS4	(“Health Care System” AND (“information system” OR information)) AND (requirement OR need) AND (elicitation OR identification) AND (techniques OR Method OR Strategy OR Plan) AND (Regulations OR Rules OR Standards OR Guidelines)	15
SS5	((“Medical System” OR “Health Care System” OR “Health System”) OR (Medical OR Health) AND (“information system” OR information)) AND (requirement OR need) AND (elicitation OR identification)	2,569
SS6	(“Medical System” AND (“information system” OR information)) AND (requirement OR need) AND (elicitation OR identification)	728
SS7	**((“Medical System” OR “Health Care System” OR “Health System”) AND (“information system” OR information)) AND (requirement OR need) AND (elicitation OR identification)**	**1,041**

It is necessary to mention that in the SpringerLink digital library, the use of flat quotes makes a notable difference compared to curved quotes (see SS7), this because the platform is sensitive to the use of these, so the search string used for the SpringerLink platform was modified as follows:

(("Medical System" OR "Health Care System" OR "Health System") AND ("information system" OR information)) AND (requirement OR need) AND (elicitation OR identification)

For the final selection of the sources, access to the databases, their importance for Software Engineering and their relevance in Medical Information Systems were considered, resulting in the same ones that were used for the secondary studies:

- IEEE Xplore.
- Science Direct.
- SpringerLink.

For the selection process of primary studies, the inclusion and exclusion criteria shown in Tables 3 and 4 were applied, forming four stages shown in Fig. 2.

Table 3. Inclusion criteria.

Criterion
IC-1. Studies published between 2018 and 2023.
IC-2. The study must be in English language.
IC-3. In multidisciplinary sources, select the discipline "Computer Science."
IC-4. Studies containing search terms in the title.
IC-5. The abstract answers at least one research question.

Table 4. Exclusion criteria.

Criterion
EC-1. Full access to the document is not available.
EC-2. The study is not a research article.
EC-3. Repeated or duplicate studies.

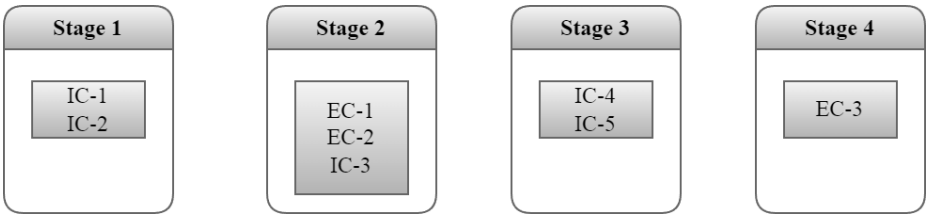

Fig. 2 Application stages of inclusion and exclusion criteria.

2.3 Select primary studies

As was mentioned, after executing the search string in the selected sources, the inclusion and exclusion criteria were applied according to the four stages presented in Fig. 2, resulting in 22 studies (see number of studies in Table 5).

Table 5. Number of studies selected per selection stage.

Source	Search	Stage 1	Stage 2	Stage 3	Stage 4
IEEE Xplore	1041	539	519	12	12
Science Direct	76,400	33,438	725	4	4
Springer Link	77,975	42,435	376	6	6
	155,416	76,412	1,620	22	**22**

See selected studies in Table 6.

Table 6. Selected primary studies.

ID	Title	Reference
PS-01	Using Work System Design, User Stories and Emotional Goal Modeling for a mHealth System.	[6]
PS-02	Representing Human Barriers in Requirements Engineering: The Case of Electronic Health Records.	[7]
PS-03	Requirement elicitation for smart flow modeling in hospital case studies.	[8]
PS-04	Using Dissemination and Implementation Strategies to Evaluate Requirement Elicitation Guidelines: A Case Study in	[9]

	a Bed Management System.	
PS-05	A User-Centered Design for Redesigning E-Government Website in Public Health Sector.	[10]
PS-06	Integrating the Voice of Healthcare Workers in Requirements Elicitation: A Balance Between Rigor and Relevance.	[11]
PS-07	Development of Mental Model in Understanding Users' Thought Processes for the Evaluation and Functional Enhancement of Clinical Decision Support Systems.	[12]
PS-08	Security requirements elicitation: A smart health case.	[13]
PS-09	Indirect Risk Related Failures of Medical Information Systems.	[14]
PS-10	Non-Functional Requirements In Health Information Systems.	[15]
PS-11	Toward Emotion-Oriented Requirements Engineering: A Case Study of a Virtual Clinics Application.	[16]
PS-12	Enhancing Requirements Elicitation through App Stores Mining: Health Monitoring App Case Study.	[17]
PS-13	Obstacles and features of health information systems: A systematic literature review.	[18]
PS-14	Proposal for a health information management model based on Lean thinking.	[19]
PS-15	Barriers and challenges to Primary Health Care Information System (PHCIS) adoption from health management perspective: A qualitative study.	[20]
PS-16	The Information System/Information Technology (IS/IT) practices in the Indonesia health referral system.	[21]
PS-17	Design and development of a disease-specific clinical database system to increase the availability of hospital data in China.	[22]
PS-18	Extracting and structuring information from the electronic medical text: state of the art and trendy directions.	[23]
PS-19	Hidden complexities in information flow between primary and specialty care clinics.	[24]
PS-20	Translational health technology and system schemes: enhancing the dynamics of health informatics.	[25]
PS-21	Continuous design control for machine learning in certified medical systems.	[26]
PS-22	Big healthcare data: preserving security and privacy.	[27]

2.4 Assess the quality of studies

The limitation to only three databases implies the probability of overlooking relevant studies published in other databases or literature sources, besides the risk of incorrectly applying the selection criteria. As mitigations, weekly meetings were held with the work team to discuss and review the selected studies. These meetings allowed for more in-depth analysis and the opportunity to identify any relevant studies that may have been overlooked. Rigorous organization and constant

verification by the review leaders were also maintained to ensure the quality of the review.

2.5 Extract required data

The extraction phase was performed using a template containing the following data per selected study:

Id – Title – DOI – Authors – Year – Source – Type – Keywords- Abstract – RQ 01 Answer – RQ 02 Answer – RQ 03 Answer – RQ 04 Answer - Notes

This template provided a clear structure for collecting, organizing, and analyzing the relevant data for each study.

2.6 Synthesize data

For data synthesis, we chose to use narrative following the guidelines proposed in [5], four non-linear elements were identified to manage and manipulate data from multiple studies and present results. It is essential to mention that, in this case, the first step, "Develop a theory," was not carried out, and only steps 2, 3, and 4 were performed:

- Develop a preliminary synthesis of the results of the included studies: This consists of synthesizing the findings and propositions found by each study to make an initial description of each study's results.
- Explore the relationships between the synthesized data of the studies: At this point in the synthesis, attention will be paid to the relationships between the individual characteristics of the articles and the relationships between the results of different studies.
- Assess the robustness of the synthesis: This step focuses on assessing the available evidence supporting the results. Aspects such as the quality and quantity of the evidence, as well as the methods used in the synthesis, were considered. In addition, steps were taken to highlight or minimize the researchers' judgment of the studies. The objective was to ensure the necessary information was available to evaluate the studies correctly.

3 Results

Fig. 3 shows the distribution of the articles by year. From 2021 to 2023, 9 articles were obtained, 3 for each year. In 2019 and 2020, there were 8, 4 for each year. 2018 had more primary studies, with five papers.

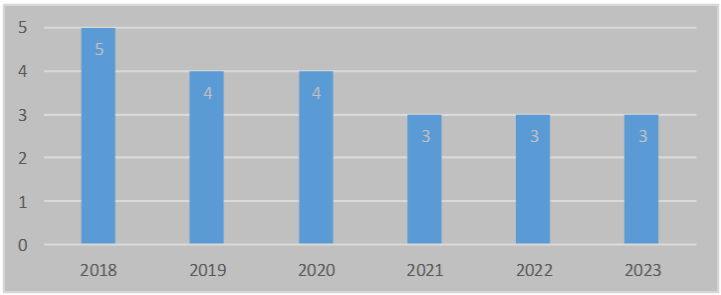

Fig. 3 Distribution of articles found by year.

Fig. 4 shows the distribution of articles among the three databases. IEEE Xplore has the most significant number of documents found, 12. SpringerLink follows with 6 documents, and finally, Science Direct has 4.

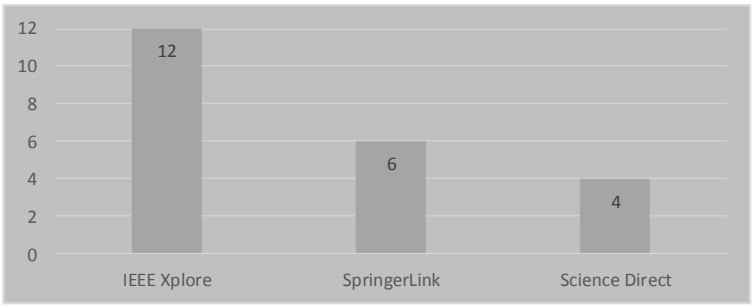

Fig. 4 Distribution of articles found by database.

As shown in Fig. 5, of the 22 studies analyzed, 52% belonged to conferences, while the remaining 48% belonged to journals.

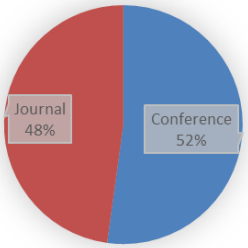

Fig. 5 Distribution of primary studies by type of publication.

3.1 Answers to the research questions

The 22 primary studies in Table 6 were used to condense the studies on the MIS study area and answer the research questions stated in Section 2.1.

RQ 1. What requirements elicitation techniques are used in developing Medical Information Systems?

Table 7 shows the most reported elicitation techniques by study. Although it is expected that the most frequent users of the MIS are health personnel, such as physicians and nurses, among others, the results show that it is mostly administrative personnel who respond to these elicitation techniques. The administrative personnel

can be social work personnel, reception personnel, warehouse personnel, product management personnel, and intrahospital services personnel.

Table 7. Elicitation techniques by study.

Technique	ID
Interview	PS-02, PS-03, PS-04, PS-05, PS-06, PS-07, PS-08, PS-10, PS-11, PS-13, PS-15, PS-16, PS-19, PS-20.
Observation	PS-03, PS-04, PS-07, PS-13, PS-15, PS-16.
Survey/questionnaire	PS-02, PS-03, PS-05, PS-07, PS-08, PS-10, PS-13.
Task Analysis	PS-05, PS-07, PS-13, PS-15.
Prototyping	PS-04, PS-05, PS-06, PS-13.
Document analysis	PS-04, PS-08, PS-13, PS-16.

Table 8 mentions techniques that may seem unusual by name. However, most are a combination of other elicitation techniques. For example, Emotional Target Modeling is an interview conducted to gather Non-Functional Requirements. This technique is based on the feelings that the customer has had or has when using the MIS. In addition, the Customer's expectations regarding the system, expressed through their feelings, are collected.

Table 8. Elicitation techniques infrequent.

Technique	ID
Causal Loop Diagram (CLD)	PS-02.
Emotional Objectives Modeling.	PS-01.
Scenario-based risk analysis.	PS-09.
Heuristic Analysis.	PS-05.
Business Process Modeling.	PS-09
Person.	PS-01.
Thinking Aloud Protocol.	PS-11.
Requirements Recommender.	PS-12.
Scenario Analysis	PS-22.

RQ 2. What are the regulations that influence requirements elicitation for Medical Information Systems?

All the regulations that are included when developing a MIS are paramount, especially standards such as ISO 14971:2019 and ISO/IEC 27001, since they manage the security of the patient information that will be handled in the MIS. These standards are accompanied by HIPAA, which is a law that manages rules on how patient information is consulted. We also find standards such as HL7 and DICOM, which regulate the interoperability of MIS with other intra-hospital systems. MIS present a complexity identified in their constant evolution to the point of being obligatorily in constant work together with other medical systems. Regulations by primary study:

- **PS-08**: ISO 21827, ISO 27000 y 27001.
- **PS-09, PS-21**: ISO 14971:20192, IEC 62304:20061, IEC 62304:20063, IEC 80001-1:20104.
- **PS-13**: HIPAA (Health Insurance Portability and Accountability Act), GDPR (General Data Protection Regulation), ISO/IEC 25010, HL7 (Health Level Seven), DICOM (Digital Imaging and Communications in Medicine), SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms), LOINC (Logical Observation Identifiers Names and Codes), ICD (International Classification of Diseases).
- **PS-21**: ISO 13485:20161, FDA 21 CFR Part 8201.

RQ 3. What advantages describe the elicitation techniques in developing a Medical Information System?

Healthcare involves intense emotional responses, and consideration of these aspects through techniques such as Emotional Objectives Modeling contributes to the system's acceptance and effectiveness. Requirements verification is essential, and combining quantitative and qualitative techniques, such as interviews and task analysis, ensures the accuracy and relevance of identified requirements. Table 9 shows the advantages identified by techniques.

Table 9. Advantages identified by technique.

Technique	Advantage	ID
User histories	Capturing Needs	PS-03, PS-04, PS-06, PS-07, PS-08, PS-12, PS-13, PS-15, PS-16.
	Effective Communication	PS-01, PS-03, PS-05, PS-13, PS-14.
Modeling Emotional Objectives	Influence of Emotions on Requirements	PS-01, PS-13.
	Emotional Impact on System	
Interview	More Detailed Requirements	PS-05, PS-07, PS-08, PS-13, PS-15, PS-16.
	Better Communication	PS-03, PS-05, PS-13, PS-14.
	Increased requirements verification	PS-04, PS-08, PS-10, PS-13.
Observation	Real understanding of the workflow	PS-06, PS-07, PS-19.
	Complementing information	PS-08, PS-13, PS-16,
	Identify areas for improvement	PS-03.
Questionnaire	Requirements Validation	PS-05, PS-08, PS-10, PS-13, PS-21.
Prototypes	Feedback	PS-04, PS-05, PS-13.
	Iterative Improvement	PS-06.

RQ 4. What are the challenges faced by elicitation techniques in Medical Information Systems?

The sensitivity of users' data and emotions intensifies the difficulty of obtaining, handling, and validating information, requiring caution and care throughout the elicitation process.

Regarding patient information and data, identifying human barriers that affect their use proves to be a complex challenge, requiring a holistic approach involving psychological, social, cultural, and ethical aspects that affect users' interaction with the MIS. A collaborative multidisciplinary approach is also required from healthcare professionals, user experience experts, psychologists, and other specialists who can provide valuable insights into how users interact with the technology and the associated barriers. The visual representation of these barriers and their implications for requirements adds another layer of difficulty, as existing visualization techniques may prove insufficient. Table 10 categorizes the challenges encountered in the reported elicitation techniques.

Table 10. Challenges reported in elicitation techniques.

	Challenge	ID
Identification of human barriers.	Complexity and dynamism of cognitive, emotional, and social barriers.	PS-02, PS-08.
	Need for effective visualization and analysis methods.	
Visual representation of human barriers.	Lack of specific techniques to visualize barriers.	
	Need for approaches that capture complexity and dynamics.	
Derivation of requirements to overcome barriers.	Definition of requirements that address emotional and ethical aspects.	
	Difficulties in specification, prioritization, and validation of requirements.	

4 Conclusions

The diversity of techniques used in software development for the healthcare sector reflects the need to adapt to the particularities of the users and their environment. Although interviews stand out as the most commonly used technique, studies reveal that they are predominantly used among administrative staff rather than healthcare staff, suggesting a gap in understanding the needs of end users. The influence of regulations and standards, such as ISO 14971:2019 and ISO/IEC 27001, highlights the importance of addressing the security and privacy of patient information. Challenges, such as lack of expertise in specific methodologies and the sensitivity of user data and emotions, underscore the need for careful and collaborative approaches.

The research underscores the importance of carefully adapting elicitation techniques to the context of Medical Information Systems development and of close

collaboration between various stakeholders, including developers, healthcare professionals, and end-user experts.

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