IEEE Access
Multidisciplinary | Rapid Review | Open Access Journal

Received July 22, 2020, accepted August 5, 2020, date of publication August 7, 2020, date of current version August 19, 2020.

Digital Object Identifier 10.1109/ACCESS.2020.3015144

Using Dissemination and Implementation Strategies to Evaluate Requirement Elicitation Guidelines: A Case Study in a Bed Management System

GASTÓN MÁRQUEZ AND CARLA TARAMASCO
Escuela de Ingeniería Civil Informática, Universidad de Valparaíso, Valparaíso 2390302, Chile
Centro Nacional en Sistemas de Información en Salud, Santiago 8380000, Chile

Corresponding authors: Gastón Márquez (gaston.marquez@uv.cl) and Carla Taramasco (carla.taramasco@uv.cl)

This work was supported in part by the FONDEF-Ideas through the Project Sistema inteligente para la gestión y análisis de la dotación de camas en la red asistencial del sector público under Grant ID16I10449, and in part by the Centro Nacional en Sistemas de Información en Salud (CENS).

ABSTRACT Clinical software is a fundamental tool for supporting healthcare systems because it improves the quality of patient care and automatizes the most frequently performed clinical tasks. Nevertheless, since health systems include various components, such as supplies, transportation, laboratories, and interoperability, eliciting the most critical requirements for understanding the problem that the clinical software must solve is quite a complex task. Indeed, the requirement elicitation process may directly determine the success or failure of the clinical software. In this article, we present the D&I framework, a methodology that uses dissemination and implementation strategies to recommend guidelines for the elicitation of clinical software requirements. The objective of this framework is to support software developers in the identification of key requirements with the goal of more holistically understanding the problem to be solved by the clinical software. We evaluated the D&I framework with a real case study related to a bed management system. We employed a usability instrument with 50 clinicians to evaluate tasks in software modules that represent clinical priorities defined by stakeholders. The results indicate that the perception of usability by end users is acceptable, suggesting that the evaluated tasks satisfy the established clinical priorities. The D&I framework provides a starting point for research and discussion about the contribution of dissemination and implementation strategies to the body of knowledge about requirement engineering.

INDEX TERMS Requirements elicitation, implementation strategies, dissemination strategies, software development, stakeholders.

I. INTRODUCTION

The introduction of clinical software to digital health has produced significant advantages from the perspective of clinical management, since such software focuses on improving, assisting and supporting the daily activities performed by clinicians and automating various administrative processes [1]. Additionally, such software facilitates communication between clinicians and patients, ensuring data privacy and reliability.

Health systems are often composed of several components of different natures [2]. Some of these components correspond to management, interoperability, human resources, clinical departments, and laboratories, among others. Therefore, developing and deploying clinical software can ultimately involve the interaction of one or more components of a health system, making the requirement elicitation process a fundamental and complex activity. Requirement elicitation describes the collaborative process between users and stakeholders that reveals the needs, functionalities and properties that the software must address [3]. Consequently, if this process is improperly conducted, the problem that the clinical software must solve cannot be entirely addressed.

The consequences of incorrect requirement elicitation can be extrapolated from clinicians' rejection to poor software development management. On the one hand, several studies

The associate editor coordinating the review of this manuscript and approving it for publication was M. Anwar Hossain.

(such as [4]–[6]) have established that incorrect requirement elicitation causes the clinical software to fail to satisfy clinician and stakeholder expectations, thus leading to rejection of new technologies in clinical processes. On the other hand, other studies (such as [7]–[11]) mention that if clinical software developers do not have the correct tools for eliciting requirements in health systems, some issues may arise that compromise project success. Some of these issues are (i) unclear project goals, (ii) lack of stakeholder support and involvement with the end user and (iii) poor planning and unrealistic scheduling or resource requirements.

In this article, we present the D&I framework, a methodology that uses implementation and dissemination strategies [12] to recommend requirement elicitation guidelines [13] that support clinical software developers in the identification of requirements in health systems. The novelty of this framework is related to the use of dissemination and implementation strategies that define methods that translate clinical research into practice. The framework uses clinical priorities defined by stakeholders as inputs to be translated into implementation strategies. Through a multidimensional catalogue, these implementation strategies enable the recommendation of requirement elicitation guidelines to identify and characterize the problem that the clinical software must solve. To evaluate the D&I framework, we conducted a case study in which we analysed a bed management system that was developed using the D&I framework.

The main contributions of our research are as follows:

- The generation of a framework that recommends requirement elicitation guidelines based on clinical priorities
- The use of dissemination and implementation strategies as mechanisms for requirement elicitation
- A model and a multidimensional catalogue that translates implementation strategies into requirement elicitation guidelines

This article is organized as follows: Section II describes the background; Section III describes the related work; Section IV describes the D&I framework; Section V details the case study; Section VI discusses the threats to validity; and Section VII concludes the article and describes future work.

II. BACKGROUND

This section describes the main research concepts, which are elicitation requirement and dissemination and implementation sciences.

A. REQUIREMENTS ELICITATION

Requirement engineering refers to the process of developing and deploying software [14]. Requirement engineering uses principles, methods, techniques, and tools that allow the requirements of systems to be discovered, documented, and maintained in a systematic and repeatable manner.

Requirement engineering is organized into activities whose objective is to understand, structure and document the needs that users wish to satisfy in software. One of these activities corresponds to requirement elicitation; requirement elicitation consists of various techniques to identify the stakeholders' needs, which are generally described in natural language and thus with ambiguities [3]. Eliciting requirements means inquiring, investigating, and understanding a problem that needs to be solved, a need to be addressed, or a functionality that must be created.

The objectives of requirement elicitation are the definition of (i) the tasks to be performed, (ii) the products to be obtained, and (iii) the techniques to be employed during the software development [13].

B. DISSEMINATION AND IMPLEMENTATION SCIENCES

Dissemination and implementation sciences (D&I) is a discipline that investigates the factors that influence the effective and comprehensive use of scientific and technological innovations in practice, aiming to maximize the beneficial effects of health interventions [12]. D&I is formally defined as the study of methods that promote the systematic incorporation of research findings into clinical routines, with the aim of improving the quality and effectiveness of health services, thus contributing to maximizing the favourable effects of health interventions [15].

Implementation science is concerned with studying the adoption of clinical interventions supported by scientific evidence by providers and health systems, aiming to bring evidence-based medicine into evidence-based practice. Implementation, in turn, encompasses the deployment and implementation of a wide range of interventions, such as policies, programmes, practices, strategies and services aimed at improving people's health [16].

On the other hand, dissemination sciences refer to the dissemination of information about the results of the evaluation of a clinical intervention, clinical practice guidelines or the impact assessment of a strategy or policy. Pedagogical designs may assist dissemination, along with information and communication technologies. While implementation includes the dissemination of information, it is part of a more significant effort to create effective strategies that must be adequately communicated to stakeholders [17].

III. RELATED WORK

This section introduces the existing work that addresses techniques and methods for eliciting requirements in the healthcare domain and studies that use D&I strategies to identify and/or elicit requirements.

Proynova *et al.* [18] discuss the importance of stakeholders in the development of health information systems. Fundamentally, the authors mention that the requirements described by stakeholders cannot be based merely on objectives. Therefore, the authors propose considering stakeholders' personal values, obtained through psychological techniques, in the elicitation of requirements. For this purpose, this study describes a technique to detect personal values and their relationships to describe and define software requirements.

This study highlights the importance of defining stakeholder profiles for identifying and eliciting requirements. However, the authors do not use D&I strategies to identify stakeholders' personal values.

Salini and Kanmani [19] mention the importance of information accuracy in health information systems. More precisely, the authors analyse the complexity of health security. With the aim of strengthening security requirements in health information systems, the authors propose the MOSRE (Model-Oriented Security Requirement Engineering) framework. This model is used to detect and elicit requirements related to threats and vulnerabilities in E-Health systems. Although the proposal addresses the complexity of eliciting requirements in the health context, the authors use a framework based on security requirements modelling rather than using D&I strategies.

Cysneiros [20] discusses the different approaches that can be used to describe requirements in the healthcare domain. The author emphasizes that health is a complex domain, and several problems may emerge in the elicitation of requirements in health information systems. In this regard, the author's proposal is based on describing his experiences with software requirement elicitation during his practical experience in hospitals and laboratories. The experiences described in this study are relevant for a better understanding of how to elicit requirements for developing clinical software. Nevertheless, these experiences make little reference to D&I strategies.

Teixeira *et al.* [21] address the problem of requirement elicitation in the health domain through the use of mock-ups and prototypes. According to the results described by the authors, these strategies improve the effectiveness of system requirement elicitation in the health context. Although using mock-ups and prototypes proves to be an excellent way to elicit requirements, the authors' proposal focuses more on eliciting requirements through software representations rather than using D&I strategies.

Glasgow *et al.* [22] use implementation and dissemination sciences in a framework called RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) to plan and evaluate projects of different natures. The authors use this framework to identify project requirements and guide planning in five projects related to improving health services for the Veterans Health Administration (VA). The study results indicate that the use of implementation strategies helps various types of projects achieve rapid and feasible adaptations by stakeholders. The main focus of the authors is to use implementation strategies to evaluate projects. Although the authors mention that the results obtained suggest that implementation strategies can be used in different types of projects, this study does not address the use of D&I strategies in technology projects.

Sisk *et al.* [23] proposed a framework that translates ethical norms into practice using implementation science. The authors argue that once a normative claim is developed, it is imperative to make changes based on this standard. However, the authors mentioned that promulgation of standards is a process that requires multidisciplinary collaboration of individuals with extensive expertise that goes beyond normative ethics. Thus, the authors use implementation science to employ explicit implementation strategies that help to drive changes in ethical standards. This study shows how the use of implementation strategies is successful in translating requirements that represent ethical standards for healthcare into practice. Nevertheless, the authors do not address how these ethical standards can be used in technology projects.

We realize that several proposals exist to help identify, elicit, and describe software requirements for clinical software. On the one hand, some studies [18]–[21] describe the challenges involved in eliciting requirements to understand the problem to be solved by clinical software. On the other hand, other studies [22], [23] show that the use of D&I strategies produces favourable results for eliciting and characterizing requirements in different types of projects. Despite this interest, to the best of our knowledge, few researchers have studied the use and impact of D&I strategies as a mechanism for requirement elicitation to support the development and deployment of clinical software. Therefore, our research attempts to complement the existing body of knowledge about requirement elicitation in the context of healthcare by introducing D&I strategies to enhance the adoption and implementation of clinical software.

IV. THE D&I FRAMEWORK

The framework (see Figure 1) considers two entities:

- *IT professionals*: This entity corresponds to all types of IT professionals (e.g., developers, analysts, and architects) who participate in the development and deployment of the system.
- *Clinicians*: This entity represents every clinical professional who is related to or involved in the system. This entity is very knowledgeable about its domain and the clinical processes concerning the system to be developed.

The conceptual idea of the D&I framework is based on the science of dissemination. Dissemination sciences drive the adaptation of clinical interventions for deployment in practice through the use of dissemination agents who work hand-in-hand with practice-based agents to choose, adapt and implement evidence-based programmes [12]. Dissemination sciences have been used and evaluated in several case studies, ranging from the development and deployment of clinical alert systems [24] to the study of public health system effectiveness [25]. Therefore, since clinical software must generally translate diverse and complex clinical interventions, we believe that the dissemination sciences can be beneficial to facilitating this translation.

The D&I framework is inspired by the dissemination approach proposed in [26], which aims to expand evidence-based methods to clinical practice using design teams and dissemination field agents. The approach considers the following entities:

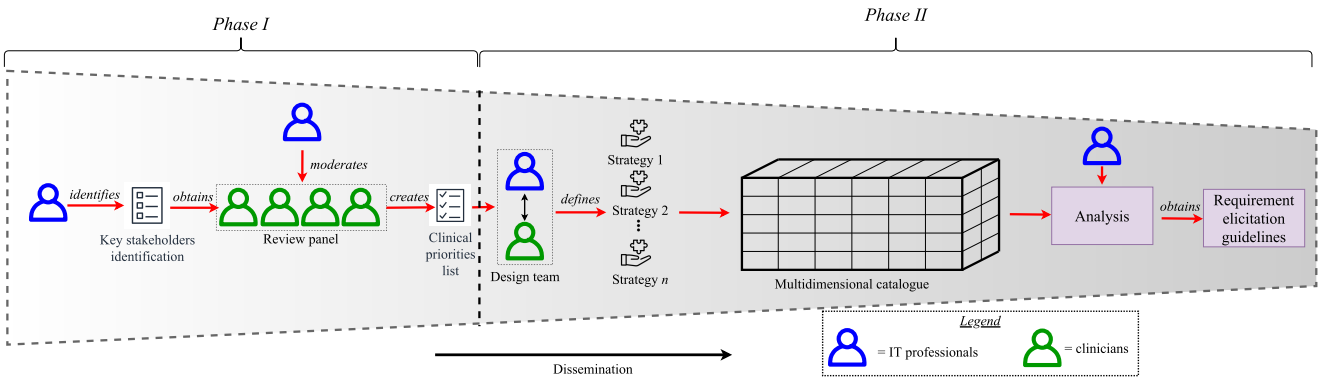

FIGURE 1. The framework D&I overview.

- *User review panels* to identify interventions for which there is genuine demand;
- *Design and marketing teams* to convert in-demand interventions into practice-ready programmes; and
- *Dissemination field agents* to generate awareness, provide training, and support the use of evidence-based, practice-ready programmes by adopters.

Similarly, the D&I framework defines a review panel composed of IT professionals and clinicians who identify the clinical priorities (interventions) that clinical software should address. In turn, the D&I framework also uses a design team (our proposal does not address marketing procedures) that converts clinical priorities into implementation strategies (practice-already programs). Finally, the D&I framework does not use dissemination agents but rather requirement elicitation guidelines to promote the use of explicit implementation strategies in the requirement elicitation process.

The D&I framework considers two phases, which are described in the following sections.

A. PHASE I: STAKEHOLDERS AND CLINICAL PRIORITIES

The first phase of the framework corresponds to stakeholder and clinical priority identification. The objective of this phase is to bring together a group of people who belong to the clinical software domain to obtain a holistic view of the main perspectives that must be addressed. We were inspired by the proposal of Anwar and Razali [27] to define a stakeholder selection process. Below, we describe the steps we execute to select the stakeholders:

- *Description of the clinical software context*: This first step corresponds to the description of the context in which the clinical software will be developed. The objective of this step is to identify the needs and the problem that the clinical software must solve.
- *Identification of stakeholders*: Once the context has been described, the next step is to identify all the stakeholders that engage with the clinical services in which the clinical software will be used. The objective of this step is to identify the mandatory and optional stakeholders. The classification of mandatory or optional depends on the importance of the stakeholders in using the clinical software.
- *Stakeholder selection*: In this step, we proceed to interview each stakeholder to select the mandatory stakeholders who should use the D&I framework. We sometimes also interview the optional stakeholders. The inclusion of optional stakeholders depends on the context and complexity of the clinical software.

Each selected stakeholder is identified using the following fields:

- *Name*: Describes the name of the stakeholder.
- *Role*: Describes the role of the stakeholder in the clinical service in which the software will be used (e.g., ''floor nurse'')
- *Activity in the clinical service*: Details the main clinical activities that the stakeholder performs in the clinical service (e.g., ''performing healing and palliative care activities on patients'').
- *Interest in the system*: Identifies the stakeholder's expectation of the clinical software (e.g., ''the stakeholder wants to manage patient demographics and visualize them through a dashboard'').
- *Role in the system*: Identifies the profile of stakeholders in the system (e.g., ''end-user'')

These fields allow the characterization of the importance of the stakeholders in the project. Regarding the stakeholder's role, this field helps IT professionals understand the degree of influence of a certain stakeholder in the project. Regarding the fields (i) activity in the clinical service, (ii) interest in the system and (iii) role in the system, these fields allow IT professionals to analyse and identify possible groups of stakeholders with similar characteristics. In addition, these fields also allow IT professionals to identify individual characteristics and interests, determine what motivates them, and determine whether there are conflicts between them [28].

Subsequently, the next step suggested by the D&I framework is to establish a review panel. This review panel, made up of the already identified stakeholders, should define the clinical priorities that the software should address.

Clinical priorities are systematically defined statements that support IT professionals in making decisions about practices and procedures for specific clinical circumstances. These priorities, expressed in natural language, describe which treatments, concerns or clinical professional services should be prioritized in clinical software. The analysis of clinical priorities helps IT professionals classify stakeholders, select or exclude stakeholder concerns, support technology decisions, and more. The D&I framework determines clinical priorities through an event (e.g., meeting or workshop) that allows stakeholders to make decisions by consensus. This step follows others inspired by practical experiences (such as [29]–[31]) to discuss, vote on and select decisions. Therefore, the steps that the D&I framework establishes for selecting clinical priorities are as follows:

1) Each stakeholder describes and argues for the clinical priority or priorities that, according to their judgement, should be addressed in the clinical software.
2) A moderator (IT professional) records the rationales given by the stakeholders.
3) If one or more clinical priorities are selected by all stakeholders, it is added to the list of clinical priorities.
4) If there is no consensus on a clinical priority, stakeholders can argue their rationale and try to make a new common choice. If the stakeholders still do not reach an agreement, the clinical priority is rejected.
5) Repeat steps 1), 2), 3) and 4) until no clinical priority remains to be analysed.

Since the scope of the review panel can be extensive, it is prudent for the moderator to impose some restrictions regarding the identification of clinical priorities. These restrictions state that clinical priorities (i) must be focused on clinical activities and services and (ii) must describe what inputs, clinical processes and/or data surround them. Finally, the primary artefact obtained from this phase is a list that describes the main clinical priorities that the software must address.

B. PHASE II: IMPLEMENTATION STRATEGIES AND REQUIREMENT ELICITATION GUIDELINES

In this phase, a multifunctional team consisting of IT professionals and clinicians (design team in Figure 1) is created. This team's purpose is to select implementation strategies that will make it possible to address clinical priorities. The D&I framework uses a knowledge source to generate the recommendation of requirement elicitation guidelines once the strategies are selected. This source of knowledge is composed of a model and a multidimensional catalogue that describes the relationship between implementation strategies and requirement elicitation guidelines.

1) A MODEL OF IMPLEMENTATION STRATEGIES AND REQUIREMENT ELICITATION GUIDELINES

Aiming at translating implementation strategies into requirement elicitation guidelines, we propose a model that represents in general how evidence-based intervention (EBI) relates to requirement engineering (see Figure 4).

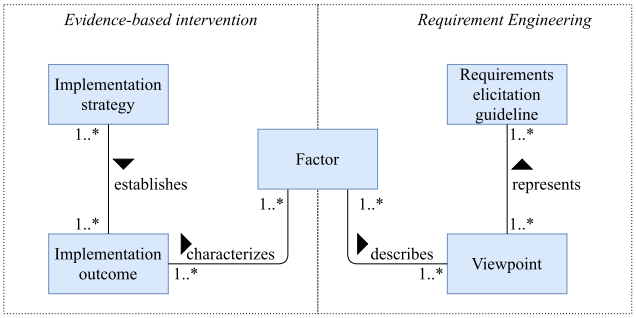

FIGURE 2. Implementation strategies and requirement elicitation guidelines model.

EBI is a discipline of D&I that represents practices or programmes that have documented and peer-reviewed, empirical evidence [32]. EBI uses a set of integrated policies, strategies, activities, and services whose effectiveness has been proven or reported by the scientific community, and in turn, it is described by implementation strategies, which establish a set of implementation outcomes [33]. These outcomes are immediate effects represented by systems services, behaviour changes, and guidelines, among others, whose objective is to improve broader population health. Since the implementation outcomes are oriented towards different areas of the population [33], they can be organized through factors. These factors encompass a set of concrete strategies influenced by various viewpoints representing clinical processes, organizational aspects, government policies, and others. Some of these viewpoints, such as project and organizational characteristics, can be used to represent requirement elicitation guidelines [34].

2) A MULTIDIMENSIONAL CATALOGUE OF IMPLEMENTATION STRATEGIES, REQUIREMENT ELICITATION GUIDELINES AND FACTORS

With a goal of using the model to recommend requirement elicitation guidelines, we conducted the following activities:

a: IMPLEMENTATION STRATEGIES

We started by identifying the implementation strategies that can be translated into requirement elicitation guidelines. For this purpose, we used the implementation strategies identified by Powell *et al.* [35]. The authors provide a list of 73 discrete strategies that can serve as ''building blocks'' for constructing multifaceted, multilevel implementation strategies for implementation efforts or comparative effectiveness research. Subsequently, two researchers on our team, along with three clinicians from the National Center on Health Information Systems (Chile)[1], analysed the implementation strategies and identified those associated with technology-related implementations. For this reason, we used the guidelines described by Kirchner *et al.* [36] to analyse and describe each implementation strategy. These guidelines suggest categorizing

[1] https://cens.cl

TABLE 1. Implementation strategies description.

Id	Strategy	Description
S1	*Assess for readiness and identify barriers and facilitators*	Assess various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort.
S2	*Build a coalition*	Recruit and cultivate relationships with partners in the implementation effort.
S3	*Capture and share local knowledge*	Capture local knowledge from implementation sites on how implementers and clinicians made something work in their setting and then share it with other sites.
S4	*Conduct educational meetings*	Hold meetings targeted toward different stakeholder groups (e.g., providers, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to teach them about the clinical innovation.
S5	*Conduct local consensus discussions*	Include local providers and other stakeholders in discussions that address whether the chosen problem is important and whether the clinical innovation to address it is appropriate.
S6	*Conduct local needs assessment*	Collect and analyse data related to the need for the innovation.
S7	*Develop and implement tools for quality monitoring*	Develop, test, and introduce the right input into quality-monitoring systems, the appropriate language, protocols, algorithms, standards, and measures (of processes, patient/consumer outcomes, and implementation outcomes) that are often specific to the innovation being implemented.
S8	*Develop and organize quality monitoring systems*	Develop and organize systems and procedures that monitor clinical processes and/or outcomes for the purpose of quality assurance and improvement.
S9	*Involve executive boards*	Involve existing governing structures (e.g., boards of directors, medical staff boards of governance) in the implementation effort, including the review of data on implementation processes.
S10	*Involve patients/consumers and family members*	Engage or include patients/consumers and families in the implementation effort.
S11	*Obtain and use patients/consumers and family feedback*	Develop strategies to increase patient/consumer and family feedback on the implementation effort.
S12	*Promote network weaving*	Identify and build on existing high-quality working relationships and networks within and outside the organization, organizational units, teams, etc. to promote information sharing, collaborative problem-solving, and a shared vision/goal related to implementing the innovation.
S13	*Use data warehousing techniques*	Integrate clinical records across facilities and organizations to facilitate implementation across systems.
S14	*Use mass media*	Use media to reach large numbers of people to spread the word about the clinical innovation.

each implementation strategy by identifying the granularity of the strategy, the action that describes the strategy, the conceptual target the strategy attempts to impact, and the implementation outcome. To avoid bias in the selection of implementation strategies, we conducted a workshop where each researcher and clinician selected implementation strategies based on their judgement. Later, in a group activity, we selected the strategies that were unanimously selected, i.e., the strategies chosen if all the members of the workshop chose it.

The implementation strategies we considered were mainly related to developing stakeholder interrelationships, supporting clinicians and adapting and tailoring contexts. Those we omitted were related to financial issues and organizational infrastructure. These types of strategies described actions linked to managing financial and administrative resources; therefore, they did not belong in our research focus. In conclusion, Table 1 summarizes the identified strategies.

b: FACTORS

Subsequently, we identified the factors that allowed us to characterize implementation strategies and represent requirement elicitation guidelines. For this purpose, we used Kheirkhah *et al.*'s proposal [34], which describes the necessary abilities to select requirement engineering techniques, which are additionally organized under three points of view: technique attributes, project characteristics, and organizational characteristics.

Since the proposal describes factors for different tasks in the requirement elicitation process (such as modelling, analysis, validation, verification, and management), we used factors that characterize only requirement elicitation tasks. These factors were as follows:

- Techniques attributes
  - Ability to facilitate communication
  - Ability to help understand social issues
  - Ability to help obtain domain knowledge
  - Ability to help obtain implicit knowledge
  - Ability to help identify non-functional requirements
  - Ability to help identify viewpoints
- Project characteristics
  - Ability to elicit complex requirements
  - Ability to identify requirements based on project size
  - Ability to precisely elicit requirements to reduce volatility
- Organizational characteristics

- Ability to support customer/client involvement
- Ability to elicit requirements based on organizational changes

c: REQUIREMENT ELICITATION GUIDELINES

We then explored primary studies reported in systematic literature reviews regarding requirement elicitation, such as [37]–[39], to identify potential techniques to perform implementation strategies. This review aims to develop a comprehensive set of proposals to be evaluated and subsequently included in the D&I framework as guidelines. We classified each primary study using the following categories:

- *Study title*
- *Authors*
- *Context*: In this category, we summarize the context of the primary study.
- *Problem*: This category concisely describes the main problem addressed by the primary study.
- *Proposal*: This category details the proposed method or technique of the primary study related to requirement elicitation.
- *Validation*: This category describes how the primary study validated the proposal (case study, experiment, survey, interview, other).
- *Results*: This category summarizes the main findings of the primary study.

d: MAPPING

In this final activity, we proceeded to map implementation strategies to factors and factors to requirement elicitation guidelines. For each implementation strategy, we manually organized the factors that allow the implementation strategy to be executed. For example, Table 2 shows the factors that characterize the implementation strategies S1, S2 and S14.

TABLE 2. A portion of the mapping regarding the characterization of implementation strategies and factors.

Id	Strategy	Factors
S1	*Assess for readiness and identify barriers and facilitators*	Ability to facilitate communication
		Ability to support customer/client involvement
		Ability to help obtain domain knowledge
S2	*Build a coalition*	Ability to help identify viewpoints
		Ability to facilitate communication
S14	*Use mass media*	Ability to help understand social issues

Once the factors for each strategy were established, we defined criteria to determine which requirement elicitation guidelines represent these factors. For each primary study, we applied the following criteria:

- *Does the primary study clearly describe the research objectives?*
- *Does the primary study include research, proposals, practices, or recommendations regarding software requirement elicitation?*
- *Does the primary study describe how it addresses the factor under revision?*
- *Does the primary study describe how the proposal is validated?*

Each criterion is evaluated using the following values: *Yes* (value = 1), *Partial* (value = 0.5) and *No* (value = 0). Furthermore, we established that a primary study is accepted if the final criteria score is 0.75. Thus, out of a total of 85 primary studies reviewed, 27 (32%) were accepted, and 58 (68%) were omitted. Therefore, we used this set of accepted primary studies as a source to identify and describe the corresponding guidelines to elicit requirements. For this purpose, we grouped the primary studies based on the proposal they define. Consequently, Table 3 describes the guidelines, the description of these and the corresponding primary studies that support each guideline. Additionally, Figure 3 represents the multidimensional catalogue that describes the relationship between requirement elicitation guidelines, implementation strategies, and factors.

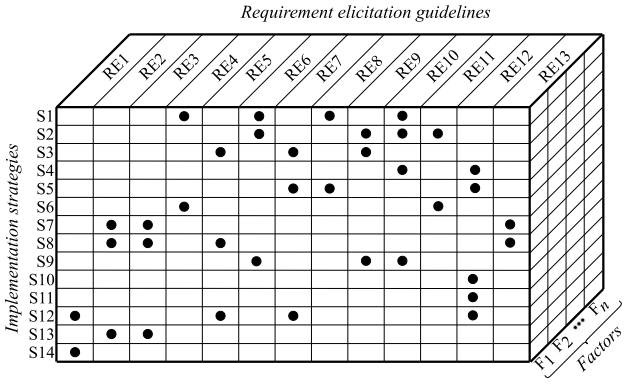

FIGURE 3. Implementation strategies, requirement elicitation guidelines and factors catalog.

Finally, the combinations described in the catalogue generate a set of guidelines for the elicitation of requirements that the IT professional should evaluate. The selection of guidelines depends on the project's context and resources and the judgement of the IT professional. It is important to mention that the evaluation and selection of guidelines may consider more than one IT professional. This decision depends on the complexity of the clinical software.

C. ILLUSTRATIVE EXAMPLE

Let us assume that part of the clinical priorities for a certain clinical software project are the following: "we need to create clinical examination requests for the paediatric service," and "we need to monitor the results of paediatric examinations already validated or pending" (see Figure 4).

TABLE 3. Requirement elicitation guidelines.

ID	Guidelines	Description	Studies
RE1	*Social networks as a mechanism for requirements elicitation*	Social networks provide an essential source for eliciting requirements. Potential end-users often describe their needs on social networks, which can be used to identify more specific requirements.	[40] [41]
RE2	*Supervised learning to extract information from requirements*	Supervised learning algorithms are useful for detecting potential requirements through text analysis if there is no opportunity to use stakeholders or end-users to elicit requirements. Additionally, they help identify both functional and non-functional requirements. [42].	[43] [44] [45]
RE3	*Model the domain to elicit requirements*	Model the domain enables the identification of potential requirements through analysis of entities, attributes and relationships between entities. In turn, if the problem to be solved by clinical software involves several domains, modelling these domains allows to identify which entities and relationships they have similarities and, thus, further increase the identification of new requirements.	[46] [47] [48]
RE4	*Model the requirements through its features*	Feature modelling helps to identify dependencies between requirements. This, in turn, can generate new requirements to be analysed.	[49] [50]
RE5	*Semantic and ontologies to verify requirements elicitation*	Semantics and ontologies are methods for understanding domain properties and entities. In case the problem to be solved by clinical software is quite complex, these methods help to understand and elicit requirements more holistically.	[51] [52] [53]
RE6	*Obtain the requirements through business modelling*	Model the activities of clinical services allows for requirements to be elicited. In addition to fully understanding how a clinical service works, model the business also permits to identify the inputs, processes and outputs of clinical services.	[54] [55]
RE7	*Elicit the requirements by consensus*	Discussion among stakeholders or end-users is an inexhaustible source of requirements. Each person who will use the clinical software has a viewpoint that may be a potential requirement. In case the profiles of the stakeholders or end-users are very heterogeneous, the elicitation of requirements by consensus allows the convergence of transversal needs.	[56] [57]
RE8	*Elicit the requirements by identifying conflicts between stakeholders and end-users*	The conflict between stakeholders and end-users also emerges new requirements. These requirements can, in turn, directly influence the performance of the clinical software.	[58]
RE9	*Identify the requirements outside the organization (e.g., suppliers)*	Some clinical services depend on entities outside the health domain. For this reason, if clinical software should be interoperated with these entities, it is necessary to identify requirements in these domains in order to address the problem completely.	[59]
RE10	*Analyse the relationship between stakeholders and end-users to obtain requirements*	The relationship between stakeholders and end-users of a particular clinical service provides potential requirements. This relationship may reveal previously established communication mechanisms between stakeholders and end-users that the clinical software must eventually implement.	[60]
RE11	*Identify the requirements through the organization's goals*	If the clinical service has clearly defined its objectives, these may reveal potential requirements that the clinical software must implement. Some objectives, e.g., "reducing patient care time", are possible non-functional requirements.	[61] [62]
RE12	*Identify the requirements through brainstorming sessions and education*	If stakeholders and/or end-users do not have a particular idea about what kind of clinical software they need, brainstorming sessions not only enable identifying main software requirements but also provide an instance to explain to them how software can innovate in the clinical service.	[63] [64]
RE13	*Explore the business processes to identify requirements*	If the clinical service has already established the process that defines the sequence of activities that are performed daily, the analysis of this process allows the identification of potential new requirements.	[65] [66] [67]

Furthermore, these priorities involve two clinical services: paediatrics and ward.

The design team discusses and analyses the priorities and selects the following implementation strategies: S1, S3, S5, S6 and S7. The rationale behind these decisions is summarized in the following points:

- The design team selected S1 because they know that the paediatric and ward services do not know each other very well. This situation may lead to communication problems between end users of both services.
- The main reason S3 was selected is that both services (paediatrics and ward) have different management processes.
- Similar to S3, the team selected S5 as a strategy because it may produce new procedures from this clinical priority.
- S6 was selected because it is necessary to understand the needs of both services to satisfy the clinical priorities.
- According to stakeholders, it is necessary to develop tools to monitor paediatric examinations (S7).

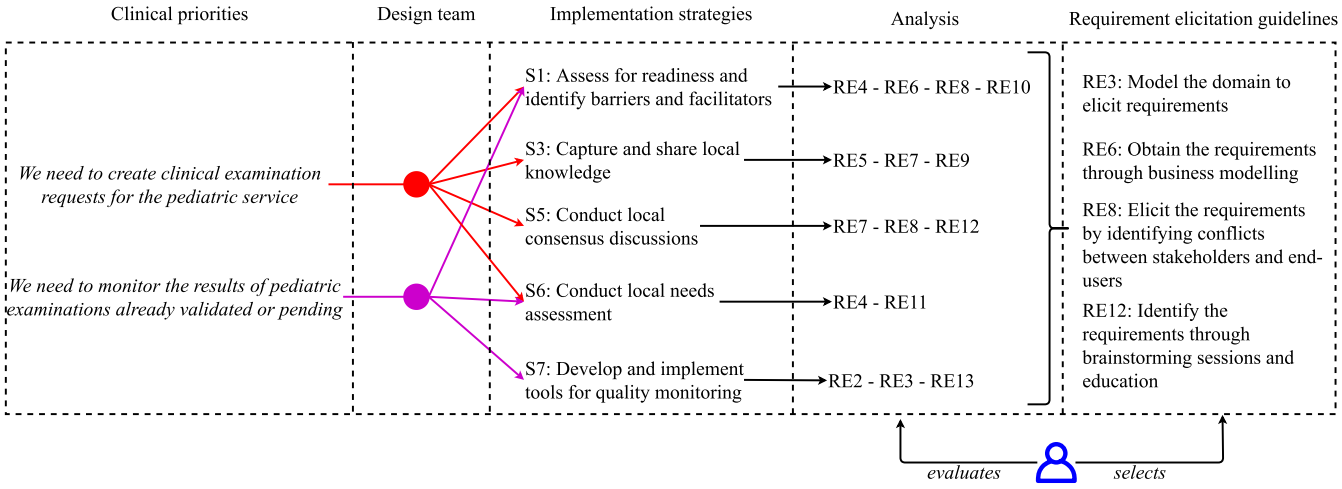

FIGURE 4. Illustrative example.

The multidimensional catalogue (see Figure 3) generates the corresponding recommendations of requirement elicitation guidelines. Finally, the IT professional analyses each guideline and selects those that best help her/him elicit requirements. In this example, the IT professional performs the following steps:

- Apply domain modelling techniques to determine which entities are similar or different and the relationships between entities and clinical services (RE3).
- Apply business modelling techniques to understand the inputs and outputs of each service to integrate both processes (RE6).
- Since both services are composed of clinicians with different profiles, it is necessary to identify if there are conflicts between clinicians that may compromise functionalities of the clinical software. For this purpose, brainstorming sessions are adequate to elicit requirements (RE8 and RE12).

V. CASE STUDY

In this section, we describe a case study in which we evaluate the impact of using the D&I framework in real clinical software.

A. CONTEXT

During the last few years in Chile, the increase in the demand for healthcare has become a significant problem due to the continued growth of the adult population (15-59 years), which is estimated to reach 60% of the population by 2020. In this regard, the Chilean Ministry of Health developed the Centralized Bed Management Unit (CBMU), which coordinates, monitors, and supports all institutional bed demands and the clinicians involved in the bed management process. Although CBMU has had favourable results, the complexity of bed management requires more resources. According to CBMU, the primary need is to develop models and tools that help to reduce wait lists for hospital beds.

Hence, we have created SIGICAM[2] [68], a system that uses statistical models, simulations, and optimization for the management of beds in hospitals and clinical institutions. Additionally, this system allows CBMU to communicate with other hospital departments using interoperability technologies to execute optimization algorithms to improve the allocation, bed reconversion, and patient management processes. The system is currently deployed at the Copiapó Hospital, Chile[3], and is currently being implemented in two more hospitals.

The reason why we selected SIGICAM as a case study is based on the fact that this system was developed using the D&I framework as a support for eliciting requirements. In this regard, the implementation strategies that were selected by the design team were as follows:

- Conduct local consensus discussions (S5).
- Conduct local needs assessments (S6).
- Develop, implement and organize tools for system quality assurance and data monitoring (S7 and S8).
- Assess for readiness and identify barriers and facilitators (S1).

Similarly, the selected eliciting requirement guidelines were as follows:

- Elicit the requirements by consensus (RE7).
- Model the domain to elicit requirements (RE3).
- Obtain the requirements through business modelling (RE6).
- Explore the business processes to identify requirements (RE13).
- Elicit the requirements by identifying conflicts between stakeholders and end-users (RE8).

[2]A more detailed description of SIGICAM, its objectives, scope, and impact on patients at Copiapó Hospital can be found at the following link (in Spanish): http://sigicam.cl

[3]https://www.hospitalcopiapo.cl/index.php

The other elicitation guidelines generated by the D&I framework (RE4, RE5, RE10 and RE11) were not considered by the IT professionals because, given the magnitude of the SIGICAM domain, the RE3, RE6, RE7, RE8 and RE13 techniques were considered to be sufficient.

B. CASE STUDY PLANNING

1) RESEARCH OBJECTIVE

Since SIGICAM was released in 2018, we have been monitoring the adoption of the system by clinicians and its usefulness in improving hospital bed management. Overall, SIGICAM has become an effective solution for hospital bed management; it has reduced wait times in beds by 40%, thus achieving better patient care.

Nevertheless, two years after the deployment of SIGICAM in the hospital, our scientific curiosity has extended beyond the current satisfactory situation. Although we know that SIGICAM, in general, has achieved good results in the hospital, we intend to evaluate whether the decisions made using the D&I framework were the right decisions from the perspective of the main stakeholders of the system. More precisely, we evaluated whether the clinical priorities defined by the stakeholders are satisfied in SIGICAM, i.e., we analysed whether the implementation strategies and the requirement elicitation guidelines selected to develop SIGICAM were sufficient to satisfy system expectations.

The discipline of D&I states that dissemination and implementation strategies are evaluated based on outcomes [33]. These outcomes are organized by a taxonomy, which establishes the following categories: Reach, Acceptability, Appropriateness, Feasibility, Adoption, Fidelity, Cost, Penetration and Sustainability. Each of these categories, in turn, suggests different procedures for evaluating the outcomes of dissemination and implementation strategies. In this case study, we focused on evaluating system acceptability; more precisely, we evaluated the characteristics that influence the usage of SIGICAM by clinicians. Therefore, we decided to employ usability as a measurement instrument.

Usability has acquired high relevance in the healthcare domain, especially since the increased adoption of new technologies to perform clinical procedures [69], [70]. Moreover, usability is considered to be an essential factor that determines success (or failure) in the implementation of information systems in the healthcare domain [71]. That said, given that the D&I framework translates the clinical priorities defined by stakeholders into requirement elicitation guidelines that eventually enable the implementation of SIGICAM, the research objective of this case study is *to evaluate stakeholders' perceptions regarding the explicit implementation of clinical priorities in SIGICAM*.

2) RESEARCH QUESTION

The research question of this case study is as follows: *What is the result of usability evaluation regarding the tasks that characterize clinical priorities defined by the stakeholders?*

As the D&I discipline suggests [33], we used a survey to answer this research question. Thus, we used the Health-ITUES (Health Information Technology Usability Evaluation Scale) as an assessment instrument [72]. Health-ITUES is a customizable questionnaire with a four-factor structure: impact, perceived usefulness, perceived ease of use and user control. The Health-ITUES explicitly considers a task by addressing various levels of expectation of support for the task by the healthcare information system. Additionally, this questionnaire considers ''tasks'' as a variable because it has been demonstrated that tasks are essential for the usability evaluation of healthcare information systems [73].

C. PREPARATION

To conduct the evaluation, we identified the leading roles that use SIGICAM, which are emergency nurses, floor nurses, bed managers, and facility directors. Subsequently, the SIGICAM tasks to be evaluated correspond to the following clinical priorities:

- *Request for beds*: This priority is related to the hospital's need for a procedure that can automate the process of requesting patient beds. Additionally, this process should also determine if there are any patients on wait lists.
- *Categorization of patients*: This priority is related to the classification, established by the hospital, used to assign patients to a clinical bed. The classification of patients is mainly established by two groups: ''patients with dependent care'' and ''patients with specific nursing care''.
- *Observe the evolution of the patient's diagnosis*: Each bed has a patient who has a particular diagnosis. It is a priority for the hospital to visualize the evolution of the patients' diagnoses to make decisions.
- *Patients in transit*: It is a priority to monitor those patients who have already been assigned a bed but are not physically using it yet.
- *Evaluate ICD-10 diagnostics*: Stakeholders need to add the evolution of patients using clinical beds following the codes provided in the ICD-10 classification[4].

Additionally, Table 4 details which clinical priorities were selected by each stakeholders.

Since SIGICAM has several software modules, we conducted the Health-ITUES evaluation on the tasks of those modules that are directly related to the clinical priorities. Therefore, the evaluation is conducted in two days. On the first day, we addressed the day shift to conduct the evaluations. Similarly, on the second day, we addressed the evening shift. In this way, we included all the clinicians with the aim of evaluating SIGICAM as extensively as possible.

We rated Health-ITUES using a Likert scale, from strongly agree (value = 5) to strongly disagree (value = 1). Furthermore, the interpretation of each Health-ITUES question was explained to the clinical professionals so that they could answer the survey as objectively as possible.

[4]https://www.who.int/classifications/icd/icdonlineversions/en/

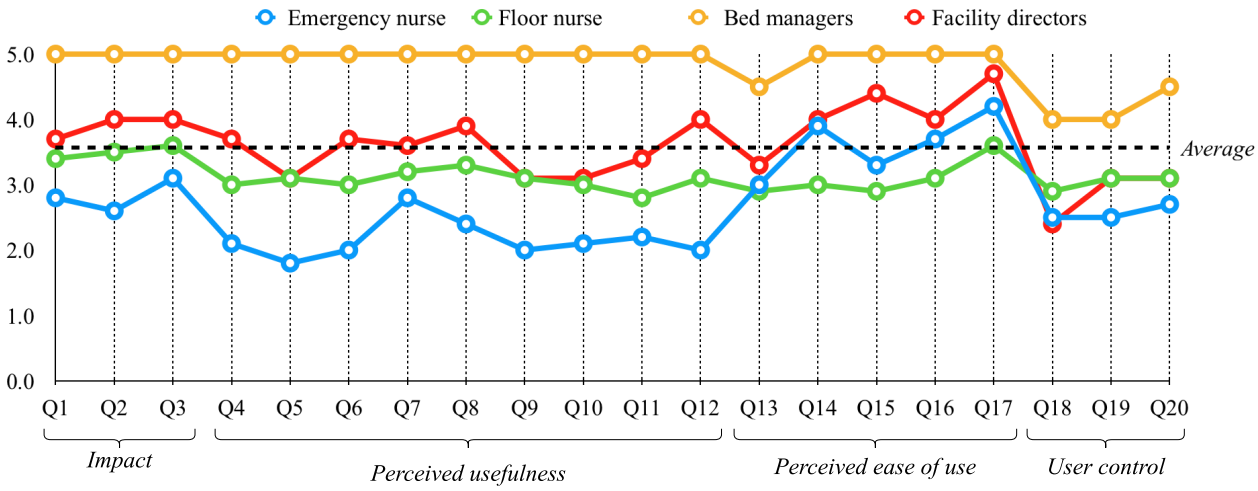

FIGURE 5. Trend chart of the Health-ITUES scores.

TABLE 4. Priorities and stakeholders.

	Emergency Nurse	Floor Nurse	Bed Managers	Facility Directors
Request for beds	●			
Categorization of patients		●		
Manage the evolution of the patient's diagnosis	●	●	●	●
Patients in transit		●	●	●
Evaluate ICD-10 diagnostics		●		

D. COLLECTION OF DATA

We identified 50 clinical professionals to answer the survey. The respondents included 10 emergency nurses, 25 floor nurses, 8 bed managers, and 7 facility directors. For the convenience of the respondents, we used the Survey Anyplace platform[5] to conduct the corresponding surveys. Additionally, we used tablets to facilitate the survey completion experience. At the end of the survey, we provided a space where each respondent could write feedback regarding SIGICAM tasks.

E. RESULTS

The results of the survey are described in Table 5.

According to the results, the overall average is 3.6, which indicates an acceptable level of usability (based on the Health-ITUES scale), with approximately 72% approval (see Figure 5).

The roles that scored below average were emergency nurses and floor nurses. On the other hand, the roles that scored equal to or above average were bed managers and facility directors. More precisely, the highest score corresponds to bed managers with an average of 4.9, followed by facility directors with a score of 3.6, floor nurses with 3.1 and emergency nurses with 2.7, where the maximum possible score is 5.0.

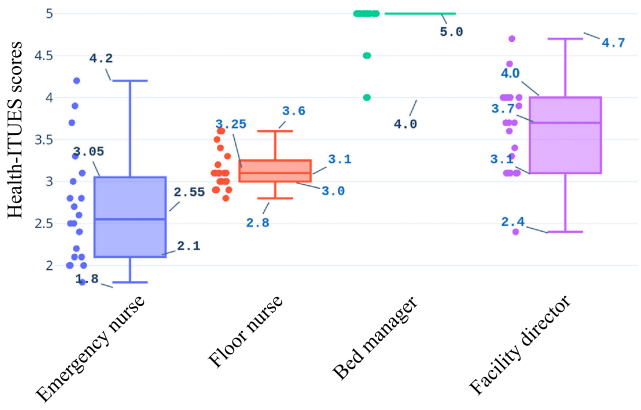

FIGURE 6. Boxplot of Health-ITUES results.

On the other hand, Figure 6 shows that 75% of the results concerning the emergency nurses indicate a low level of usability, where the maximum of this sample corresponds to a score of 3.05 and a mean of 2.55. Additionally, it is possible to observe a greater dispersion of the responses given by this group. Concerning the floor nurses, the results indicate that 75% of the group's responses are in an acceptable range of usability (close to the general average), where the maximum value is 3.6 and the minimum value is 2.8 without outliers. Subsequently, the group that best evaluated SIGICAM was the bed managers. Most of the values are at the maximum score level with two outliers. Finally, regarding the facility directors, the values obtained by this group describe a greater dispersion of responses, where the minimum and maximum usability scores are 2.4 and 4.7, respectively.

[5]https://surveyanyplace.com

TABLE 5. Results of the Health-ITUES survey. "EN" corresponds to Emergency Nurses, "FN" to Floor Nurses, "BM" to Bed Managers, and "DF" to Facility Directors.

Domain		Questions	EN	FN	BM	FD
Impact	Q1	*I think SIGICAM has been a positive contribution to nursing work*	2.8	3.4	5	3.7
	Q2	*I think SIGICAM has been a positive contribution to the hospital*	2.6	3.5	5	4
	Q3	*The technology delivered by SIGICAM is an essential part of the bed management and analysis process*	3.1	3.6	5	4
Perceived usefulness	Q4	*Using SIGICAM makes it easy to request available beds*	2.1	3.0	5	3.7
	Q5	*SIGICAM makes it possible to manage beds more quickly*	1.8	3.1	5	3.1
	Q6	*SIGICAM increases the probability of assigning or reassigning a bed to a patient*	2	3	5	3.7
	Q7	*SIGICAM is useful for requesting beds and managing patients on wait lists*	2.8	3.2	5	3.6
	Q8	*I think SIGICAM presents a more equitable process for bed management*	2.4	3.3	5	3.9
	Q9	*I am satisfied with SIGICAM for managing and analyzing the provision of beds in the healthcare network*	2	3.1	5	3.1
	Q10	*I can perform bed management tasks promptly due to the use of SIGICAM*	2.1	3	5	3.1
	Q11	*SIGICAM increases effectiveness in hospital waiting times*	2.2	2.8	5	3.4
	Q12	*I am able to fulfill all my assigned tasks using SIGICAM*	2	3.1	5	4
Perceived ease of use	Q13	*I'm comfortable with my ability to use SIGICAM*	3	2.9	4.5	3.3
	Q14	*Learning to use SIGICAM is easy for me*	3.9	3	5	4
	Q15	*It's easy for me to be proficient in the use of SIGICAM*	3.3	2.9	5	4.4
	Q16	*SIGICAM is easy for me to use*	3.7	3.1	5	4
	Q17	*I can always remember how to start and use SIGICAM*	4.2	3.6	5	4.7
User control	Q18	*SIGICAM shows error messages that tell me clearly how to solve problems*	2.5	2.9	4	2.4
	Q19	*If I make mistakes in SIGICAM, I can solve it easily and quickly*	2.5	3.1	4	3.1
	Q20	*The information (such as online help, on-screen messages and others) provided with SIGICAM is clear*	2.7	3.1	4.5	3.1
		Mean ($\overline{x}$)	2.7	3.1	4.9	3.6
		Median	2.6	3.1	5	3.7
		Standard deviation (s)	0.7	0.2	0.3	0.5
		Standard error ($\sigma_{\overline{x}}$)	0.2	0.1	0.1	0.1

F. ANALYSIS

We identified a gap between operational tasks and management tasks in SIGICAM. On the operational side, these tasks are mainly performed by emergency and floor nurses. Although these roles are fundamental in the management of hospital beds, the results described in Table 5 illustrate that emergency nurses and floor nurses, in general, are not satisfied with the usability of SIGICAM.

Emergency nurses perform tasks corresponding to two clinical priorities: request beds and manage patient evolution. According to the judgement of the design team, to develop the software modules corresponding to these two priorities, it is essential to identify (i) the local needs of the emergency nurses (S6) and (ii) the barriers and facilitators (S1). Thus, modelling the emergency department and bed management domain (RE3) and exploring the preestablished clinical processes of the emergency department (RE13) were the guidelines selected to elicit requirements. However, despite this, the emergency nurses' perception of usability was negative. To explore this observation further, we investigated the feedback manifested by emergency nurses. Feedback reveals that the emergency nurses are satisfied with the ease of use of the tasks; it is for this reason that in Figure 5, the curve increases between Q13 and Q17. Nevertheless, the questions related to impact (Q1-Q3), perceived usefulness (Q4-Q12) and user control (Q18-Q20) have low scores because the steps involving the tasks are not optimal, i.e., they are easy to use but do not reduce the time to manage the request for beds or manage the patient's evolution in a high-pressure work environment.

Extending the analysis to the floor nurses, the situation is not very different. Feedback from the floor nurses suggested the same situation described by the emergency nurses: the steps to execute tasks related to categorizing patients, managing patient progress, managing patients in transit, and evaluating patients are easy to use, but expectations regarding time optimization are low.

With respect to the management tasks, the results regarding the usability of SIGICAM are favourable. Both bed managers and facility directors positively evaluated the tasks of managing the evolution of the patients' diagnosis and the patients in transit. The implementation strategies that were selected to satisfy the priorities of bed managers and facility directors were the same as those for emergency and floor nurses,

including the development, implementation, and organization of data quality assurance and monitoring tools (S7 and S8), conduct of local consensus discussions (S5) and conduct of local needs assessments (S6). These strategies, similarly, allowed for the selection of the following requirement elicitation guidelines: RE3, RE6, RE7, RE8 and RE13. This set of guidelines was sufficient to understand the problem that bed managers and facility directors presented with respect to bed management. In turn, this set of guidelines allowed us to identify new potential requirements that were not initially identified. For example, business modelling (RE6) allowed the identification of clinical activities that were not adequately established. Anecdotally, these clinical activities were essential for the follow-up of patients in critical beds and were frequently used by bed managers.

G. LESSONS LEARNED

There is no doubt that developing clinical software requires considerable effort. The knowledge provided by implementation and dissemination strategies helps to explain the processes and variables involved in using scientific evidence to design and implement policies, programmes, and interventions in healthcare services and other contexts.

Since the development and deployment of software depend on more activities (such as software design, software testing, and maintenance, among others), we are aware that we cannot establish that a set of guidelines to elicit requirements can ensure the success of clinical software. Nevertheless, the results obtained in the case study indicate that broadening the spectrum of requirement elicitation guidelines allows software developers to collect more requirements to more deeply understand the problem that clinical software must solve. This becomes relevant in the context of healthcare, since the problems that clinical software solves are complex.

Additionally, our experience in using the D&I framework in the development of SIGICAM shows that concrete implementation and dissemination strategies help reduce communication problems between clinicians and software developers. More precisely, the D&I framework acts as a ''bridge'' that defines a common vocabulary between clinicians and IT professionals, achieving traceability that ranges from the clinical priorities established by the project stakeholders to the specification of requirements that are eventually developed and implemented. SIGICAM usability results encourage us to continue improving and using the D&I framework to further involve clinicians in the development of software projects.

H. STUDY LIMITATIONS

We conducted a case study on the main software components of SIGICAM that are related to clinical priorities. However, these components represent 85% of SIGICAM components but do not represent other components related to finance and interoperability. Regarding the latter, assessing the impact of the use of the D&I framework on interoperability components requires an additional effort beyond the objectives of this research. However, the promising results obtained in this case study lead us to realize that the D&I framework is an effective tool to support IT professionals to better understand the problems that clinical software must solve.

VI. THREATS TO VALIDITY

In this section, we proceed to describe the threats to the validity of our study. For this purpose, we used the description of validity threats by Wohlin *et al.* [74].

A. CONCLUSION VALIDITY

The threats to the conclusion validity are concerned with issues that affect the ability to draw the correct conclusion about the relationships between the treatment and the outcome of a study. The main threats detected are as follows:

- *Subjectivity in the creation of the implementation strategies and requirement elicitation guidelines catalogue*: This threat is related to the possible subjectivity regarding the creation of the multidimensional catalogue depicted in Figure 3. To mitigate this threat, we established rigorous criteria to determine which implementation strategies can be translated into requirement elicitation guidelines. On the other hand, we conducted working sessions with different researchers, IT professionals and clinicians to establish the corresponding relationships between implementation strategies and requirement elicitation guidelines in order not to produce bias in the decisions. We were especially careful to ensure that each strategy/guideline relationship was fully explained.
- *Reliability of measures*: This threat is related to the confidence of the measurement applied in the study. To mitigate this threat, we use Health-ITUES, a quality instrument specifically created for the health context that has the capacity to adapt to the system being evaluated. Health-ITUES has been employed in several health-based system usability studies, which suggests that the results we obtained with this instrument allow us to represent objective conclusions.

B. INTERNAL VALIDITY

The threats to internal validity are influences that can affect the conclusion about a possible causal relationship between treatment and outcome. The main threats detected and their mitigation are as follows:

- *Instrumentation*: This threat refers to the impact of using incorrect artefacts to execute the case study. To mitigate this threat, we used the Survey Anyplace tool to deploy the Health-ITUES instrument. In addition, we used tablets to conduct the survey for the convenience of clinicians.
- *Selection*: This threat is the effect of natural variation in human performance. Depending on how the subjects are selected from a larger group, the selection effects can vary. Furthermore, the effect of letting volunteers

participate in an experiment may influence the results. To mitigate this threat, before conducting the case study, we determined how many clinicians could participate in the survey to obtain a representative sample of respondents. In turn, we informed the clinicians that their participation in the survey contributed to the improvement of SIGICAM. Thus, we clarify that the survey was not voluntary.

- *Diffusion or imitation of treatments*: This effect occurs when a control group learns about the treatment from the experiment group in the study or when the control group tries to imitate the experiment group's behaviour in the study. To mitigate this threat, we kindly informed clinicians that survey responses were personal.

C. CONSTRUCT VALIDITY

Construct validity concerns generalizing the result of the experiment to the concept or theory behind the study. The main threat detected is evaluation apprehension. To mitigate this threat, we informed participants at the beginning of the survey that the results will be used for academic purposes. In this way, we prevented respondents from responding to the survey with any concern about being misjudged.

D. EXTERNAL VALIDITY

Threats to external validity are conditions that limit the ability to generalize the results of our experiment to industrial practice. The main threat we detected is related to the interaction of setting and treatment. This threat is the effect of not having the experimental setting or material representative of, for example, an industrial practice. To mitigate this threat, we previously studied what other studies have used Health-ITUES to evaluate usability in clinical systems. Our review results indicate that this instrument has been widely used to validate the information systems used in the healthcare context. Consequently, the results obtained by Health-ITUES can be replicated and extended to other systems to perform comparative studies.

VII. CONCLUSION

In this article, we have presented the D&I framework, a methodology that uses dissemination and implementation strategies to select requirement elicitation guidelines to develop and deploy clinical software. The main objective of the D&I framework is to support the specification of requirements through a dissemination process that allows for (i) the identification of stakeholders, (ii) the definition and characterization of clinical priorities and (iii) the selection of implementation strategies. The D&I framework is composed of two phases. In the first phase, clinicians describe clinical priorities that the system should address. Correspondingly, in the second phase, a team of IT professionals and clinicians select the implementation strategies to address clinical priorities. The D&I framework subsequently uses a model that employs implementation strategies to obtain a set of elicitation requirement guidelines to extend the spectrum of the specification and characterization of requirements for developing and deploying clinical software.

Aiming at evaluating the D&I framework, we analysed a bed management system called SIGICAM that was developed using the D&I framework to identify, define, and characterize requirements. Given the complexity of the system, we used the Health-ITUES instrument to conduct a survey in the most critical software modules where the D&I framework was the key to specifying requirements. The results indicate that, in general, the main stakeholders approve of the tasks implemented in SIGICAM. The requirements obtained and specified through the requirement elicitation guidelines recommended by the D&I framework were sufficient for SIGICAM to gain acceptance by clinicians.

To further our research, we plan to extend the D&I framework to the evaluation and design of software architectures. We are working to include the D&I framework in software architecture design and evaluation methods, such as the Attribute-Driven Design (ADD) [75] and the Architecture Tradeoff Analysis Method (ATAM) [76]. In addition, we are working on an automatic process for recommending guidelines about requirement elicitation to produce better results for IT professionals.

ACKNOWLEDGMENT

The authors would like to thank Francisco Vera, René Noël, and Gabriela Montenegro for their support in this study. They would also like to thank the National Center for Health Information Systems [Centro Nacional en Sistemas de Información en Salud (CENS)], Chile, for supporting this study.

REFERENCES

[1] A. Sharma, R. A. Harrington, M. B. McClellan, M. P. Turakhia, Z. J. Eapen, S. Steinhubl, J. R. Mault, M. D. Majmudar, L. Roessig, K. J. Chandross, E. M. Green, B. Patel, A. Hamer, J. Olgin, J. S. Rumsfeld, M. T. Roe, and E. D. Peterson, "Using digital health technology to better generate evidence and deliver evidence-based care," *J. Amer. College Cardiol.*, vol. 71, no. 23, pp. 2680–2690, Jun. 2018, doi: 10.1016/j.jacc.2018.03.523.

[2] *The World Health Report 2000: Health Systems: Improving Performance*, World Health Org., Geneva, Switzerland, 2000.

[3] P. Bourque and R. E. Fairley, *Guide to the Software Engineering Body of Knowledge (SWEBOK (R)): Version 3.0*, 3rd ed. Washington, DC, USA: IEEE Computer Society Press, 2014.

[4] R. N. Charette, "Why software fails [software failure]," *IEEE Spectr.*, vol. 42, no. 9, pp. 42–49, Sep. 2005, doi: 10.1109/MSPEC.2005.1502528.

[5] H. Doloi, "Cost overruns and failure in project management: Understanding the roles of key stakeholders in construction projects," *J. Construct. Eng. Manage.*, vol. 139, no. 3, pp. 267–279, 2013, doi: 10.1061/(ASCE)CO.1943-7862.0000621.

[6] M. D. Cabana, C. S. Rand, N. R. Powe, A. W. Wu, M. H. Wilson, P. A. C. Abboud, and H. R. Rubin, "Why don't physicians follow clinical practice guidelines?: A framework for improvement," *Jama*, vol. 282, no. 15, pp. 1458–1465, 1999, doi: 10.1001/jama.282.15.1458.

[7] C. W. Johnson, "Identifying common problems in the acquisition and deployment of large-scale, safety–critical, software projects in the US and UK healthcare systems," *Saf. Sci.*, vol. 49, no. 5, pp. 735–745, Jun. 2011, doi: 10.1016/j.ssci.2010.12.003.

[8] C. W. Johnson, "Why did that happen? Exploring the proliferation of barely usable software in healthcare systems," *Qual. Health Care*, vol. 15, no. 1, pp. i76–i81, Dec. 2006, doi: 10.1136/qshc.2005.016105.

[9] B. Kaplan and K. D. Harris-Salamone, "Health IT success and failure: Recommendations from literature and an AMIA workshop," *J. Amer. Med. Inform. Assoc.*, vol. 16, no. 3, pp. 291–299, May 2009, doi: 10.1197/jamia.M2997.

[10] R. Heeks, "Health information systems: Failure, success and improvisation," *Int. J. Med. Informat.*, vol. 75, no. 2, pp. 125–137, Feb. 2006, doi: 10.1016/j.ijmedinf.2005.07.024.

[11] R. Chowdhury, R. E. Butler, and S. Clarke, "Healthcare IT project failure: A systems perspective," *J. Cases Inf. Technol.*, vol. 9, no. 4, pp. 1–15, Oct. 2007, doi: 10.4018/jcit.2007100101.

[12] R. C. Brownson, G. A. Colditz, and E. K. Proctor, *Dissemination and Implementation Research in Health: Translating Science to Practice*. London, U.K.: Oxford Univ. Press, 2017.

[13] S. Tiwari, S. S. Rathore, and A. Gupta, "Selecting requirement elicitation techniques for software projects," in *Proc. CSI 6th Int. Conf. Softw. Eng. (CONSEG)*, Sep. 2012, pp. 1–10, doi: 10.1109/CONSEG.2012.6349486.

[14] B. Nuseibeh and S. Easterbrook, "Requirements engineering: A roadmap," in *Proc. Conf. Future Softw. Eng. (ICSE)*, 2000, pp. 35–46, doi: 10.1145/336512.336523.

[15] R. G. Tabak, E. C. Khoong, D. A. Chambers, and R. C. Brownson, "Bridging research and practice," *Amer. J. Preventive Med.*, vol. 43, no. 3, pp. 337–350, Sep. 2012, doi: 10.1016/j.amepre.2012.05.024.

[16] E. S. Lang, P. C. Wyer, and R. B. Haynes, "Knowledge translation: Closing the evidence-to-practice gap," *Ann. Emergency Med.*, vol. 49, no. 3, pp. 355–363, Mar. 2007, doi: 10.1016/j.annemergmed.2006.08.022.

[17] M. W. Kreuter and M. L. Wang, "From evidence to impact: Recommendations for a dissemination support system," *New Directions Child Adolescent Develop.*, vol. 2015, no. 149, pp. 11–23, Sep. 2015, doi: 10.1002/cad.20110.

[18] R. Proynova, B. Paech, S. H. Koch, A. Wicht, and T. Wetter, "Investigating the influence of personal values on requirements for health care information systems," in *Proc. 3rd Workshop Softw. Eng. Health Care (SEHC)*, 2011, pp. 48–55, doi: 10.1145/1987993.1988004.

[19] P. Salini and S. Kanmani, "Elicitation of security requirements for E-health system by applying model oriented security requirements engineering (MOSRE) framework," in *Proc. 2nd Int. Conf. Comput. Sci., Eng. Inf. Technol. (CCSEIT)*, 2012, pp. 126–131, doi: 10.1145/2393216.2393238.

[20] L. M. Cysneiros, "Requirements engineering in the health care domain," in *Proc. IEEE Joint Int. Conf. Requirements Eng.*, Sep. 2002, pp. 350–356, doi: 10.1109/ICRE.2002.1048548.

[21] L. Teixeira, V. Saavedra, C. Ferreira, J. Simões, and B. S. Santos, "Requirements engineering using mockups and prototyping tools: Developing a healthcare Web-application," in *Proc. Int. Conf. Hum. Interface Manage. Inf.*, 2014, pp. 652–663, doi: 10.1007/978-3-319-07731-4_64.

[22] R. E. Glasgow, C. Battaglia, M. McCreight, R. A. Ayele, and B. A. Rabin, "Making implementation science more rapid: Use of the RE-AIM framework for mid-course adaptations across five health services research projects in the veterans health administration," *Frontiers Public Health*, vol. 8, p. 194, May 2020, doi: 10.3389/fpubh.2020.00194.

[23] B. A. Sisk, J. Mozersky, A. L. Antes, and J. M. DuBois, "The 'ought-is' problem: An implementation science framework for translating ethical norms into practice," *Amer. J. Bioethics*, vol. 20, no. 4, pp. 62–70, 2020, doi: 10.1080/15265161.2020.1730483.

[24] M. W. Kreuter, E. Vehige, and A. G. McGuire, "Using computer-tailored calendars to promote childhood immunization," *Public Health Rep.*, vol. 111, no. 2, p. 176, 1996.

[25] M. W. Kreuter, C. A. Caburnay, J. J. Chen, and M. J. Donlin, "Effectiveness of individually tailored calendars in promoting childhood immunization in urban public health centers," *Amer. J. Public Health*, vol. 94, no. 1, pp. 122–127, Jan. 2004, doi: 10.2105/AJPH.94.1.122.

[26] J. T. Steensma, M. W. Kreuter, C. M. Casey, and J. Bernhardt, "Enhancing dissemination though marketing and distribution systems: A vision for public health," in *Dissemination and Implementation Research in Health: Translating Science to Practice*. London, U.K.: Oxford Univ. Press, 2017, ch. 12, pp. 191–200.

[27] F. Anwar and R. Razali, "A practical guideline of selecting stakeholders for requirements elicitation-an empirical study," *Int. J. Softw. Eng. Appl*, vol. 9, no. 2, pp. 95–106, 2015, doi: 10.14257/ijseia.2015.9.2.09.

[28] S. Missonier and S. Loufrani-Fedida, "Stakeholder analysis and engagement in projects: From stakeholder relational perspective to stakeholder relational ontology," *Int. J. Project Manage.*, vol. 32, no. 7, pp. 1108–1122, Oct. 2014, doi: 10.1016/j.ijproman.2014.02.010.

[29] R. A. McGee, U. Eklund, and M. Lundin, "Stakeholder identification and quality attribute prioritization for a global vehicle control system," in *Proc. 4th Eur. Conf. Softw. Archit. Companion Volume (ECSA)*, 2010, pp. 43–48, doi: 10.1145/1842752.1842765.

[30] M. Svahnberg, "An industrial study on building consensus around software architectures and quality attributes," *Inf. Softw. Technol.*, vol. 46, no. 12, pp. 805–818, Sep. 2004, doi: 10.1016/j.infsof.2004.02.001.

[31] F. Osses, G. Márquez, M. M. Villegas, C. Orellana, M. Visconti, and H. Astudillo, "Security tactics selection poker (TaSPeR) a card game to select security tactics to satisfy security requirements," in *Proc. 12th Eur. Conf. Softw. Archit., Companion*, 2018, p. 54, doi: 10.1145/3241403.3241459.

[32] A. M. Kilbourne, M. S. Neumann, H. A. Pincus, M. S. Bauer, and R. Stall, "Implementing evidence-based interventions in health care: Application of the replicating effective programs framework," *Implement. Sci.*, vol. 2, no. 1, p. 42, Dec. 2007, doi: 10.1186/1748-5908-2-42.

[33] C. C. Lewis, E. Proctor, and R. C. Brownson, "Measurement issues in dissemination and implementation research," in *Dissemination and Implementation Research in Health: Translating Science to Practice*. London, U.K.: Oxford Univ. Press, 2017, ch. 14, pp. 229–242.

[34] E. Kheirkhah and A. Deraman, "Important factors in selecting requirements engineering techniques," in *Proc. Int. Symp. Inf. Technol.*, vol. 4, 2008, pp. 1–5, doi: 10.1109/ITSIM.2008.4631895.

[35] B. J. Powell, T. J. Waltz, M. J. Chinman, L. J. Damschroder, J. L. Smith, M. M. Matthieu, E. K. Proctor, and J. E. Kirchner, "A refined compilation of implementation strategies: Results from the expert recommendations for implementing change (ERIC) project," *Implement. Sci.*, vol. 10, no. 1, p. 21, Dec. 2015, doi: 10.1186/s13012-015-0209-1.

[36] J. E. Kirchner, T. J. Waltz, B. J. Powell, J. L. Smith, and E. K. Proctor, "Implementation strategies," in *Dissemination and Implementation Research in Health: Translating Science to Practice*, vol. 2. New York, NY, USA: Oxford Univ. Press, 2017, pp. 245–266.

[37] C. Pacheco and I. Garcia, "A systematic literature review of stakeholder identification methods in requirements elicitation," *J. Syst. Softw.*, vol. 85, no. 9, pp. 2171–2181, Sep. 2012, doi: 10.1016/j.jss.2012.04.075.

[38] I. Inayat, S. S. Salim, S. Marczak, M. Daneva, and S. Shamshirband, "A systematic literature review on agile requirements engineering practices and challenges," *Comput. Hum. Behav.*, vol. 51, pp. 915–929, Oct. 2015, doi: 10.1016/j.chb.2014.10.046.

[39] C. Pacheco, I. García, and M. Reyes, "Requirements elicitation techniques: A systematic literature review based on the maturity of the techniques," *IET Softw.*, vol. 12, no. 4, pp. 365–378, Aug. 2018, doi: 10.1049/iet-sen.2017.0144.

[40] N. Ali and J. E. Hong, "Value-oriented requirements: Eliciting domain requirements from social network services to evolve software product lines," *Appl. Sci.*, vol. 9, no. 19, p. 3944, Sep. 2019, doi: 10.3390/app9193944.

[41] N. Seyff, I. Todoran, K. Caluser, L. Singer, and M. Glinz, "Using popular social network sites to support requirements elicitation, prioritization and negotiation," *J. Internet Services Appl.*, vol. 6, no. 1, p. 7. Dec. 2015, doi: 10.1186/s13174-015-0021-9.

[42] L. Chung, B. A. Nixon, E. Yu, and J. Mylopoulos, *Non-Functional Requirements in Software Engineering*, vol. 5. New York, NY, USA: Springer, 2000.

[43] Z. S. H. Abad, V. Gervasi, D. Zowghi, and B. H. Far, "Supporting analysts by dynamic extraction and classification of requirements-related knowledge," in *Proc. IEEE/ACM 41st Int. Conf. Softw. Eng. (ICSE)*, May 2019, pp. 442–453, doi: 10.1109/ICSE.2019.00057.

[44] C. Duan, P. Laurent, J. Cleland-Huang, and C. Kwiatkowski, "Towards automated requirements prioritization and triage," *Requirements Eng.*, vol. 14, no. 2, pp. 73–89, Jun. 2009, doi: 10.1007/s00766-009-0079-7.

[45] A. Casamayor, D. Godoy, and M. Campo, "Identification of non-functional requirements in textual specifications: A semi-supervised learning approach," *Inf. Softw. Technol.*, vol. 52, no. 4, pp. 436–445, Apr. 2010, doi: 10.1016/j.infsof.2009.10.010.

[46] M. I. Sanchez-Segura, F. Medina-Dominguez, D. M. Vásquez-Bravo, G. Illescas, and C. G. de Jesús, "Selecting a software elicitation technique according to layers of knowledge and preciseness: A case study," *J. Universal Comput. Sci.*, vol. 23, no. 4, pp. 385–403, 2017.

[47] S. Sukumaran and K. Chandran, "The unspoken requirements-eliciting tacit knowledge as building blocks for knowledge management systems," in *Proc. Int. Conf. Knowl. Manage. Org.*, 2015, pp. 26–40, doi: 10.1007/978-3-319-21009-4_3.

[48] W. Liu, K.-Q. He, K. Zhang, and J. Wang, "Combining domain-driven approach with requirement assets for networked software requirements elicitation," in *Proc. IEEE Int. Conf. Semantic Comput.*, Aug. 2008, pp. 354–361, doi: 10.1109/ICSC.2008.14.

[49] O. De Troyer and E. Janssens, "A feature modeling approach for domain-specific requirement elicitation," in *Proc. IEEE 4th Int. Workshop Requirements Patterns (RePa)*, Aug. 2014, pp. 17–24, doi: 10.1109/RePa.2014.6894839.
[50] W. Zhang, H. Mei, and H. Zhao, "A feature-oriented approach to modeling requirements dependencies," in *Proc. 13th IEEE Int. Conf. Requirements Eng. (RE)*, Aug./Sep. 2005, pp. 273–282, doi: 10.1109/RE.2005.6.
[51] H. Hu, L. Zhang, and C. Ye, "Semantic-based requirements analysis and verification," in *Proc. Int. Conf. Electron. Inf. Eng.*, vol. 1, Aug. 2010, p. V1-241, doi: 10.1109/ICEIE.2010.5559882.
[52] H. Kaiya, Y. Shimizu, H. Yasui, K. Kaijiri, and M. Saeki, "Enhancing domain knowledge for requirements elicitation with Web mining," in *Proc. Asia Pacific Softw. Eng. Conf.*, Nov. 2010, pp. 3–12, doi: 10.1109/APSEC.2010.11.
[53] D. V. Dzung and A. Ohnishi, "Ontology-based reasoning in requirements elicitation," in *Proc. 7th IEEE Int. Conf. Softw. Eng. Formal Methods*, Nov. 2009, pp. 263–272, doi: 10.1109/SEFM.2009.31.
[54] A. Krishna and H. Lu, "Requirements elicitation using goal-based organizational model," in *Proc. 19th Austral. Conf. Softw. Eng. (aswec)*, Mar. 2008, pp. 543–551, doi: 10.1109/ASWEC.2008.4483244.
[55] V. T. Heikkilä, M. Paasivaara, K. Rautiainen, C. Lassenius, T. Toivola, and J. Järvinen, "Operational release planning in large-scale scrum with multiple stakeholders—A longitudinal case study at F-secure corporation," *Inf. Softw. Technol.*, vol. 57, pp. 116–140, Jan. 2015, doi: 10.1016/j.infsof.2014.09.005.
[56] N. Nurmuliani, D. Zowghi, and S. P. Williams, "Using card sorting technique to classify requirements change," in *Proc. IEEE Int. Requirements Eng. Conf.*, Sep. 2004, pp. 240–248, doi: 10.1109/ICRE.2004.1335681.
[57] F. Dalpiaz, R. Snijders, S. Brinkkemper, M. Hosseini, A. Shahri, and R. Ali, "Engaging the crowd of stakeholders in requirements engineering via gamification," in *Gamification*. 2017, pp. 123–135, doi: 10.1007/978-3-319-45557-0_9.
[58] M. Suhaib, "Conflicts identification among stakeholders in goal oriented requirements engineering process," *Int. J. Innov. Technol. Exploring Eng.*, vol. 8, no. 12, pp. 4925–4930, 2019, doi: 10.35940/ijitee.L3557.1081219.
[59] M. Z. Kolpondinos and M. Glinz, "GARUSO: A gamification approach for involving stakeholders outside organizational reach in requirements engineering," *Requirements Eng.*, vol. 25, pp. 185–212, Jun. 2019, doi: 10.1007/s00766-019-00314-z.
[60] T. Bhowmik, "Stakeholders' social interaction in requirements engineering of open source software," in *Proc. IEEE 22nd Int. Requirements Eng. Conf. (RE)*, Aug. 2014, pp. 467–472, doi: 10.1109/RE.2014.6912300.
[61] M. Sadiq and S. K. Jain, "Stakeholder identification method in goal oriented requirements elicitation process," in *Proc. IEEE 5th Int. Workshop Requirements Prioritization Commun. (RePriCo)*, Aug. 2014, pp. 25–33, doi: 10.1109/RePriCo.2014.6895219.
[62] M. Arif and S. Sarwar, "Identification of requirements using goal oriented requirements elicitation process," *Int. J. Comput. Appl.*, vol. 120, no. 15, pp. 17–21, Jun. 2015, doi: 10.5120/21303-4070.
[63] V. Kulkarni, "A conceptual model for capturing stakeholders' wish list," in *Proc. Int. Conf. Comput. Sci. Softw. Eng.*, vol. 2, 2008, pp. 275–278.
[64] N. Boulila, A. Hoffmann, and A. Herrmann, "Using storytelling to record requirements: Elements for an effective requirements elicitation approach," in *Proc. 4th Int. Workshop Multimedia Enjoyable Requirements Eng. (MERE)*, Aug. 2011, pp. 9–16, doi: 10.1109/MERE.2011.6043945.
[65] B. Aysolmaz, H. Leopold, H. A. Reijers, and O. Demirörs, "A semi-automated approach for generating natural language requirements documents based on business process models," *Inf. Softw. Technol.*, vol. 93, pp. 14–29, Jan. 2018, doi: 10.1016/j.infsof.2017.08.009.
[66] H. Ordóñez, A. F. E. Villada, D. L. V. Vanegas, C. Cobos, A. Ordóñez, and R. Segovia, "An impact study of business process models for requirements elicitation in XP," in *Proc. Int. Conf. Comput. Sci. Appl.*, 2015, pp. 298–312, doi: 10.1007/978-3-319-21404-7_22.
[67] E. A. Carvalho, T. Escovedo, and R. N. Melo, "Using business processes in system requirements definition," in *Proc. 33rd Annu. IEEE Softw. Eng. Workshop*, Oct. 2009, pp. 125–130, doi: 10.1109/SEW.2009.8.
[68] C. Taramasco, R. Olivares, R. Munoz, R. Soto, M. Villar, and V. H. C. de Albuquerque, "The patient bed assignment problem solved by autonomous bat algorithm," *Appl. Soft Comput.*, vol. 81, Aug. 2019, Art. no. 105484, doi: 10.1016/j.asoc.2019.105484.
[69] M. C. Beuscart-Zephir, J. Brender, R. Beuscart, and I. Menager-Depriester, "Cognitive evaluation: How to assess the usability of information technology in healthcare," *Comput. Methods Programs Biomed.*, vol. 54, nos. 1–2, pp. 19–28, 1997, doi: 10.1016/S0169-2607(97)00030-8.
[70] A. W. Kushniruk and V. L. Patel, "Cognitive and usability engineering methods for the evaluation of clinical information systems," *J. Biomed. Informat.*, vol. 37, no. 1, pp. 56–76, Feb. 2004, doi: 10.1016/j.jbi.2004.01.003.
[71] J. Kjeldskov, M. B. Skov, and J. Stage, "A longitudinal study of usability in health care: Does time heal?" *Int. J. Med. Informat.*, vol. 79, no. 6, pp. e135–e143, Jun. 2010, doi: 10.1016/j.ijmedinf.2008.07.008.
[72] P. Y. Yen, D. Wantland, and S. Bakken, "Development of a customizable health it usability evaluation scale," in *Proc. AMIA Annu. Symp.*, 2010, pp. 917–921.
[73] E. Ammenwerth, C. Iller, and C. Mahler, "IT-adoption and the interaction of task, technology and individuals: A fit framework and a case study," *BMC Med. Informat. Decis. Making*, vol. 6, no. 1, Dec. 2006, Art. no. 3, doi: 10.1186/1472-6947-6-3.
[74] C. Wohlin, P. Runeson, M. Höst, M. C. Ohlsson, B. Regnell, and A. Wesslén, *Experimentation in Software Engineering*. Berlin, Germany: Springer-Verlag, 2012.
[75] R. Wojcik, F. Bachmann, L. Bass, P. Clements, P. Merson, R. Nord, and B. Wood, "Attribute-driven design (ADD), version 2.0," Softw. Eng. Inst., Carnegie-Mellon Univ. Pittsburgh, Pittsburgh, PA, USA, Tech. Rep. CMU/SEI-2006-TR-023, 2006.
[76] R. Kazman, M. Klein, and P. Clements, "ATAM: Method for architecture evaluation," Softw. Eng. Inst., Carnegie-Mellon Univ. Pittsburgh, Pittsburgh, PA, USA, Tech. Rep. CMU/SEI-2000-TR-004, 2000.

GASTÓN MÁRQUEZ is currently pursuing the Ph.D. degree in informatics engineering with Federico Santa María Technical University, Chile. He is also Researcher with the University of Valparaiso. He is working in the research fields of architectural tactics, patterns, microservice architectures, technical debt, and security in telehealth systems. He has published in several international conferences and has participated in international software architecture schools. He participated as a Research Visitor at the Rochester Institute of Technology (RIT), Rochester, NY, USA, and the Université de Technologie de Compiègne (UTC), Compiègne, France. Before becoming a Ph.D. student, he worked in financial companies for five years.

CARLA TARAMASCO received the B.Eng. degree in computer engineering from the Universidad de Valparaíso, Chile, in 2001, the M.Sc. degree in cognitive science from the École Normale Supèrieure, in 2006, and the Ph.D. degree *(summa cum laude)* from Ècole Polytechnique, France, in 2011. She was a Postdoctoral Fellow at CNRS, from 2011 to 2013. She is currently a Researcher and a Professor with the Computer Science Department, Universidad de Valparaíso. She has scientific publications in books, journals, and conference proceedings. She has organized over ten international workshops/sessions and has acted as a coordinator for over 20 national and international projects. She was involved in the development of networks for scientific collaboration between Africa, South America, and Europe. She was a Coordinator of the Latino America Committee of the Complex Systems Society, for five years. She has been involved in the investigation and development of technological solutions for health-monitoring software and hardware. Her main research interests include health, which includes mHealth, ambient assisted living for elderly persons, e-health, telemedicine and telerehabilitation, and supervision of chronic diseases, and complex social systems, including dynamic networks, socio-semantic networks, and among others.