# Requirements Engineering in Healthcare: Lessons Learned from Practice

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Abstract—Healthcare systems are facing grand challenges in improving current processes and meeting the high demand on resources while maximizing the quality of delivered services. Although technology is a key enabler of improvement, it still fails, in healthcare, due to several reasons, such as poor acceptance by users/physicians, disturbance to existing practices, and lack of comprehensive analysis prior to the implementation of solutions. Hence, we found an opportunity to investigate the effectiveness of some Requirement Engineering (RE) methods, such as goal-oriented and process modeling, in capturing the context of a process under improvement, collecting requirements, and analyzing multiple views and conflicting opinions to support decision-making in healthcare. In this paper, I'm reporting on the challenges and opportunities that were learned while observing and applying some RE modeling and analysis methods in five real-world projects, over five years, in healthcare. In addition, some future research directions are discussed.

Index Terms—Requirements Engineering; Healthcare; URN; Goal-oriented modeling; Process modeling; Industry.

# I. INTRODUCTION

These days, most healthcare systems are going through different types of transformations such as changing the purchasing system, from service-based to value-based, and digital health transformation [1] [2]. The transformation aims to deliver a high quality of services, provide patient-centered solutions, and enable technology to improve and digitalize current processes while controlling the budget [2] [3]. As a result, many core changes may be introduced to the structure of healthcare institutions, the role of physicians, healthcare processes and workflow, and the definition of measures and performance targets. Some changes in healthcare, which are related to technological solutions, are still perceived as timeconsuming while preventing physicians from doing their jobs, and are difficult to use, with risk exposure and security threats [2] [4] [5]. Thus, physicians, patients, and all stakeholders who belong to the context under change have to be fully engaged in the decision-making process where their goals and concerns are addressed and analyzed adequately.

Requirements Engineering (RE) and its methods regroup proven practices for the elicitation, modeling, analysis, and validation of requirements. It gives a holistic view of the context, including stakeholders, their goals and practices, and enablers and threats. It also supports the evaluation of the potential impact of solution alternatives on those goals and practices in order to select the appropriate solution [6]. The absence of sufficient RE effort can lead to systems that result in unsatisfied users, time/effort lost, low performance, or ignorance about impactful changes [7]. Hence, we were motivated to investigate the use of RE modeling and analysis methods in healthcare-related projects and assess its usefulness in introducing changes and emerging technology effectively [8].

In this study, we report on lessons learned while practicing RE, over five years, in five healthcare projects. we started by exploring RE practices in real-world cases (in one project), then applying advanced RE-based methods to integrate technology effectively into current processes (in three projects) [7] [8]. User Requirements Notation (URN) and its sub-languages Goal-oriented Requirements Language (GRL) and Use Case Maps (UCM) were used for modeling and analysis of stakeholder intentions, values, and processes [6] [9]. In addition, jUCMNav was used for illustration and analysis [10]. One of the major findings in this study is the promising potential for RE methods to be used effectively in healthcare; however, domain-specific solutions and appropriate tool support are needed.

The rest of the paper is organized as follows. Section II provides background about the study motivation and the RE methods used. Section III presents the lessons learned in each project including challenges and opportunities. Lastly, Section IV discusses some of future research opportunities and Section V draws conclusions.

#### II. BACKGROUND

This section describes the projects and RE methods used.

#### A. Study Plan

Briand et al. argued that in a practical field such as Software Engineering, which relies intensively on customers and industry, studies shall be driven by industry needs tailored to a certain context [11]. Context-driven research makes clear assumptions and a well-defined context in addition to achievable objectives and attainable results [11]. As we share the same beliefs, we had planned to study RE practices in healthcare over five years in multiple projects that belong to Canadian and Saudi hospitals. In all projects, managers and their teams were not familiar with most RE practices. In addition, their RE practices did not go beyond requirements gathering, which are technical, security and functional requirements. Microsoft Excel and Word were used to document the requirements. As illustrated in Figure 1, the study plan consists of three main phases that are observation, design, and implementation. The first project (2015) was meant to investigate RE practices in a real case and observe how the decision on technology selection is made in practice (see Section III-A), which is the observation phase. The investigation resulted in discovering some technology selection and integration problems. Hence, we designed an RE-based framework, which is described in Section II-C, that integrates technology into healthcare practices effectively. Lastly, the framework was implemented successfully in four projects (2016 -2019) that are related to technology integration and context modeling (see Sections III-B and III-C). The next section presents the RE modeling language (URN) that was used to implement the proposed RE-based framework, and to capture and analyze requirements in the projects.



Fig. 1. The study plan of investigating and practicing RE in healthcare

#### B. User Requirements Notation

URN is the first standardized modeling language that supports requirements engineering activities in a graphical representation way [6]. URN provides two complementary sub-languages that are Goal-oriented Requirement Language (GRL) and Use Case Maps (UCM) [6]. GRL has the capabilities of capturing and modeling stakeholders and intentional elements which include operation goals, softgoals, and tasks. It has three types of relationships between the intentional elements (decomposition, contribution, and correlation) that show how intentional elements are linked to each other and contribute to the satisfaction of stakeholders' goals. GRL also provides a trade-off analysis of design alternatives. The analysis is enabled by the propagation mechanism that propagates the initial evaluation values of goals and the weighted contributions to the root goals to compute their satisfaction values, and the satisfaction of stakeholders [10].

UCM is a causal graphical representation of functional requirements and system behavior. A UCM model consists of start and end points, responsibilities (activities), directions and conditions to guard the transition from one responsibility to another. GRL and UCM can be linked together through URN links to provide a holistic view of the system quality and stakeholder goals, and the system functionalities and behavior. URN has a tool-support (jUCMNav) that enables requirements analysts to model GRL and UCM effectively, and apply appropriate analysis [12]. URN was used to implement the AbPI framework that is presented in the next section.

# C. Activity-based Process Integration (AbPI) Framework

The AbPI is a RE-based analysis framework that provides technology integration alternatives into current processes. It also provides a holistic and comprehensive analysis of the impact those alternatives have on stakeholder needs and practices, long-term values, and healthcare urgent needs. The AbPI takes the goal models and the process models of the context under improvement and the new technology to be integrated as inputs. Then, it applies to the main methods: the integration and the evaluation.

In the integration method, the activities of the technologyrelated process are integrated sequentially into current processes where the relationship between the new activity, to be integrated, and existing ones is captured. For example, a new activity may eliminate, replace, or add to existing activities. Having multiple relationships between new activities of the technology-related process and existing activities of the current process results in several integration alternatives. Hence, the evaluation method analyzes the integration alternatives and assesses the impact of each alternative on predefined criteria. The output of the AbPI framework is the best integration alternative that increases the satisfaction of stakeholders, achieves performance targets, and satisfies selection criteria. The AbPI profiled URN to model and analyze the integration context, GRL was used to capture goal models and UCM to model business and technology-related processes [1] [7] [8].

The AbPI is meant to overcome challenges identified in practice (project 1), and to fill the gap, found in literature, of comprehensively analyzing technology integration in the context of process improvement [7]. There were few RE-based studies that were conducted specifically for the healthcare domain. Most of those studies focus either on requirements elicitation and system design [13]–[16] or process analysis with regard to business objectives [17] [18].

#### III. LESSONS LEARNED

This section reports on observations, opportunities, and challenges faced during the practice of RE in healthcare projects.

# A. Project 1: Technology Selection

The project was about selecting the most appropriate technology for physicians to communicate through. It was led by the IT department. The tasks of the projects were to meet physicians, identify the communication issues, gather their requirements and needs, and map them to a set of offthe-shelf technologies. According to the mapping results and the analysis of the requirements/goals, we reported on the technologies that could be used in this context. The following are observations collected during our work.

1) Requirement analysis: collecting and analyzing requirements started after the business case was prepared. The functional requirements were collected from some physicians; meanwhile, technical and security requirements were identified later by the IT team and the Security and Privacy Office during multiple meetings with service providers. It was observed that little work was done to gather and analyze requirements, especially user requirements, of all involved stakeholders/users in different units, which led to a reluctance to change and an unsatisfied group of users. In addition, there was a paucity in considering non-functional requirements, such as usability, safety, and regulatory compliance.

2) Premature solutions: the main issue was the premature discussions of solutions before identifying current problems and user needs. Also, the lack of an achievable vision, long-term values, and convincing reasons for new changes did not help to negotiate the changes successfully with some groups. Resistance to change was a big obstacle due to the different computer literacy levels, urgent needs, and current goals of each unit. It was clear that the IT and the Security and Privacy teams were in agreement on requirements and the possible solutions; however, physicians were not. Some physicians refused to collaborate at all as they did not see the changes as reasonable; on the other hand, some were very involved and welcoming to those changes.

3) Flexible integration: in a critical environment, such as healthcare, where lives are saved, it is not feasible to impose changes on physicians and obligate them to use certain technology as it may cause delay or deterioration of the quality of provided services. Hence, flexible integration of new changes into current processes is needed, where the current situation, processes, and goals/needs of different stakeholders of different units are captured and analyzed, resulting in integration alternatives. Each alternative, and the status quo, would be evaluated against goals, long-term values, and performance objectives to get a shared understanding of the best way to achieve desired outcomes. This was absent and not thought through in the project.

At the end of the project, the opportunity of using REbased methods to tackle some of the above-mentioned issues was discussed with the IT manager and team, and caregivers at the hospital. Both groups encouraged applying RE methods as they would be able to have a holistic view of the situation, including the interests and concerns of other units and stakeholders. Also, they emphasized the need for considering long-term values, urgent needs, and sustainability of solutions before implementing them. As a result, we developed the AbPI framework (presented in Section II-C) that was used in the next projects.

# B. Projects 2, 3 & 4: Technology Integration

The AbPI framework, discussed in Section II, was applied in three projects: two in Canadian hospitals and one in a Saudi hospital (2016-2018). The three projects were about emerging technologies to automate existing processes: patient information documentation, real-time tracking of lab samples, and real-time waiting estimation systems. Two projects were led by the Security and Privacy Office, and one by the Quality and Patient Safety Department [8]. The tasks were to model goals and processes of different stakeholders, design integration alternatives, and recommend the best integration alternative. Below are lessons drawn on using the AbPI and the tool, where the effectiveness of the framework was proven in practice and some important technical issues arose.

1) Effectiveness: the AbPI framework guided the integration process in the three projects effectively; in addition, the results of the AbPI supported the project managers' decisions. In one project, the project manager decided to suspend the project temporarily, based on the recommendation of the AbPI framework, until a better solution was found. While in the other two, managers chose to implement current solutions partially to satisfy some urgent needs, even though the cost was high, and some stakeholders were unsatisfied. In the projects, one of the major challenges faced was the definition of measures. The AbPI supported the definition of measures and linked them to goals and activities of the processes for analysis.

2) Tool support: it is challenging to use current RE tools in industry. In the context of AbPI, there are many types of relations within activities of processes, and between activities and goals. In jUCMNav for example, the relations could only be captured through URN links between UCM and GRL models, which require many interactions and are not entirely visible on diagrams. For analysis, tasks were used in the goal model to represent the impact of activities on goal satisfaction. Hence, there is a need for usable context-specific tools, as in the integration, that provide appropriate support. The tool shall automate the creation of models, especially alternatives, and provide semantic correctness and consistency checking. Also, the impact of activities of processes on goals shall be illustrated automatically when appropriate data is available, such as the time or cost of an activity.

3) Context-specific goals: urgent needs and long-term values are examples of special types of goals that are used in healthcare [8]. Assessing potential solutions against urgent needs was fairly straight forward. However, capturing and analyzing long-term values by GRL intentional elements was challenging. On one hand, healthcare always strives for maximizing values in delivered services. For example, would the satisfaction level of a goal of long-term value type exceed 100 be considered positive or a desired outcome? What does 100 mean in long-term values evaluation? On the other hand, most solutions evolve over time until long-term values are achieved. Accordingly, some solutions may not fully satisfy long-term values at a certain time; however, they build the basis for more advanced solutions to be developed. Hence, there should be a way to distinguish between low satisfaction values resulting from poor solutions and low satisfaction values which were produced due to the evolution of solutions and current capabilities of hospitals; the former is negative, while the latter is positive.

4) Conflicting opinions of stakeholders: in healthcare, physicians are a special type of stakeholder. They are the owners and users of most of the processes and e-systems. Hence, capturing all their requirements and opinions is essential as it will influence greatly the selection of solutions. The challenge faced was modeling the conflicting opinions of stakeholders who belong to one group. For example, a

group of physicians may see system X as a facilitator, while another group sees it as an obstacle on their way to save lives. GRL does not give the flexibility to model the conflicting opinions of the same stakeholder (actor) in one model, which happens always in healthcare. However, this could be solved partially, in jUCMNav, using a contribution override option in the strategy evaluation or having another actor of the same stakeholder type but with a different name.

5) Scalability and effort: one process may cut across multiple units of an organization, or even across different organizations (e.g., hospitals and clinics). Each unit has its own processes, roles, goals, and quality criteria. Although large URN models were created and analyzed in the past, URN models may not scale well at modeling, analyzing, and maintaining multiple large processes across the organization or across organizations. Also, we modeled the context manually; hence, automation will be required for a large set of processes and wider contexts. A considerable amount of time was spent to collect data and build the models as we had to build our own domain expertise along the way; processes were not documented anywhere.

6) Usability: the usability of AbPI was assessed by real users in healthcare participating in a usability study [8]. The participants were given a task of applying AbPI to design integration alternatives and choose the best integration alternative. Even though the unit under analysis was the AbPI, direct comments about GRL and UCM were received. Participants perceived UCM as easy to understand and implement. They described GRL to be a powerful analysis method as it includes stakeholders, goals, and measures. However, GRL also was considered complicated and difficult to use, especially the contribution and propagation mechanism. GRL and UCM seemed to give a holistic vision and evaluation of the context as participants reported. A comment was received to customize GRL and UCM to the healthcare domain, or potentially develop a domain-specific language for healthcare, and consider the use of healthcare wording rather than using RE vocabulary.

7) Change Management: combining change management methods, such as Lean management, and the AbPI led to better analysis. The strongest points of Lean is defining measures and assigning performance targets. However, Lean focuses only on customer (patient) value, while ignoring other stakeholders. Hence, the AbPI was leveraged by the data collected in the Lean approach; at the same time, AbPI was used to capture other stakeholder goals and needs, and analyze solutions designed by the Lean. Combining them both brought another benefit that is reducing the number of the integration alternatives as the design of alternatives is guard, in the Lean, by a condition such as add-value or non-added value activities. Hence, this minimized the effort associated with designing and evaluating all integration alternatives [19].

# C. Project 5: Context Modeling and System Design

In a Canadian hospital, a department that was responsible for managing research projects was facing issues of 1) monitoring the projects after the funding was granted, 2) unifying the process for receiving and approving those projects, and 3) dealing with a high workload for staff. In addition, staff did not use the system that was designed specifically to solve some of those issues. Hence, in this project, we applied the AbPI framework partially as there was no technology to be integrated. First, we attempted to analyze the problem and identify the opportunities and issues through several meetings with stakeholders. Then, I prepared the input of the AbPI that are the goal and the process models. Following that, a design thinking session was conducted, which resulted in an initial design of the system to be used to facilitate monitoring and tracking the projects and the workload for staff. The initial design of the system was the base point for several modifications, features and additions that appeared in following meetings and brainstorming sessions. The evaluation method of the AbPI, later, was used to select the best system design alternative based on stakeholders' requirements and goals, and other criteria defined by the hospital.

The project manager found three major benefits of the AbPI framework that are:

1) Visualization: the UCM model helped in visualizing the main obstacles in the process that prevented them from achieving their goals. It was to the base point to agree and disagree on the processes' definitions and roles. In addition, the UCM model became the first source in which the process was defined completely and formally.

2) Goal model evaluation: the team, around seven stakeholders, was interested in the capabilities of GRL and the evaluation model. They all agreed that it reflected how far they were from achieving their goals and how likely the new solution may satisfy the goals. Moreover, it helped them to focus on points of improvement rather than guessing what to be improved and why.

*3) Tool support:* some comments were left also on jUCM-Nav; they found it effective and very useful throughout the project; however, it required technical expertise, and it was not user friendly. It is worth mentioning that the designed solution was implemented, later, in the hospital.

# IV. DISCUSSION

As seen in the previous sections, RE methods were used effectively in practice in the context of technology selection and integration, and system design. The AbPI influenced the decisions made on technology selection in the projects and provided rationals. Also, it is obvious that stakeholders of the projects agreed on the usefulness of the tool support (jUCMNav) and its visualization capabilities, but also agreed that it is unusable in practice and required special technical skills. In addition, it was suggested, in the three projects, that RE practices have to be customized and tailored to the specific needs of healthcare, especially as stakeholders have, almost, equal power of influencing decisions and have conflicting opinions. Another reason is that, now, the domain is going through major transformations, such as shifting from service-based to value-based payment systems and digital health transformation. The transformations expand the circle of stakeholders and decision-makers to include patient and direct community, leverage data-driven techniques, change the model of care, and change the role of caregivers. In the following sections, we discuss those grand changes and highlight some future research opportunities.

1) Value-based Healthcare System (VBHC): aims to provide high-quality healthcare services for individuals and the population while optimizing the distribution and allocation of resources [20] [21]. It puts healthcare under pressure as running processes, technologies, and stakeholder practices always have to be questioned and reassessed for optimization and improvements. Also, value-based healthcare system is different from the traditional system as it brings a new model of care along with new concepts and implementation, such as segmentation of population based on healthcare needs, moving from corrective to preventive model, better patient, and provider experience, etc. [20] [22].

One of VBHC strategies is the Integrated Care Model (ICM) which refers to having a multidisciplinary team, of diverse views, (physicians of different specialties, policymakers, social workers, managers, etc.) to provide the best services to patients while putting patients in control of their health decisions. It is one the most agreed on, globally, care models in VBHC [23]. There is a big opportunity for RE to contribute greatly to this matter in different ways. For example, having different perspectives on patient health, while providing a high quality of service and optimizing resources is a very interesting case to investigate for an informative and evidence-based decision-making process. Also, it is interesting to investigate the opportunity of providing domain-specific modeling and analysis methods that speak healthcare language, and model healthcare environment (processes, roles, units, strategies, etc.) and characteristics of its entities. That is to identify, quantify, and analyze value in delivered care services.

Adequate and usable tool support is needed that provides automated analysis for the continued evaluation of current solutions, identification of improvements opportunities, and synthesis of models. In addition, there are important aspects to investigate and questions to answer, empirically, in this context such as What is value in healthcare?, How do we model and analyze value in healthcare?, How do we quantify value in delivered care services?, Are current RE methods sufficient to capture and analyze value in healthcare?. An interesting challenge in VBHC is defining and using the right measures. While the value definition is still not unified or agreed on globally, there are too many measures of VBHC that have been published by healthcare organizations. That emphasizes the need to define value formally, as mentioned before, support practitioners to identify appropriate goals and measure, and align measures to those goals systematically. Goal-measure alignment is important not only to quantify and assess goals, but also to avoid wasting resources on using too many irrelevant measures. In addition, pathway-measure alignment is essential too because VBHC strategies, such as the integrated care model, change the traditional pathways; hence, it is important to ensure that measures' definitions are aligned with pathways' definitions and correct observations/measurements will be collected from those pathways.

2) Digital Health Transformation: is another essential change that most healthcare will be going through intensively in the coming decades. It is meant to emerge advanced technologies, such as AI and data-driven solutions, to minimize the load on healthcare providers, and to ensure that services are delivered to patients [24]. It aims, in the long term, to shift the nature of healthcare services from being corrective, where treatments are provided to patients, to preventive, where users are treated and diagnosed before they become patients [24]. As a result, dramatic changes will be brought to the structure of hospitals, workflows, service delivery, and physician-patient relationships. This creates a situation where culture change. physician resistance, risks, ethics, privacy and security issues become obvious [2]. Hence, RE could play a pivotal role in many directions starting from assessing the healthcare system readiness for such change, to the user acceptance of such a model for delivering care. Moreover, it could be used effectively to analyze associated risks, user acceptance, concerns, and compliance. Also, RE-based methods could be used to elicit domain knowledge, anticipate events, guide decisions in the presence of uncertainty, and provide customized care delivery processes that are specific to the needs of each patient [25]. Another interesting research dimension is personalized care where RE can support in identifying opportunities for personalization, trade-off analysis of conflicting interests and preferences of patients, and optimizing the patient experience.

The pandemic of Covid-19 fostered the implementation of healthcare digital transformation in some countries and in many directions [26]. For example, in Saudi Arabia, the Ministry of Health launched many healthcare applications to minimize the number of cases in which patients need to go to hospitals. One of the applications is Sehaty (My Health) which provides virtual clinics where patients can see and talk to caregivers online [27]. However, there is no available literature or technical reports that assess the usability of those applications and how users felt when they interacted with the application (User Experience), especially, for elderly and special needs users. The healthcare digital transformation embraces patient-centric strategies. It leverages technology to increase accessibility to healthcare services. Hence, some technologies are meant to be used directly by patients, such as selftriage apps [28], virtual clinics [29], etc. In this context, we believe more focus should be given to usability requirements and user emotions because they affect patients' perception of the effectiveness of provided services directly [28]. Usability requirements and user emotions should be treated as first-class citizen requirements and appropriate support to model and analyze them (frameworks, modeling languages, and analysis tools) is needed. Also, human values, privacy, and information security should be given more attention and addressed formally to avoid any harm for end-users and to preserve their rights.

3) Industry-Academia Collaboration: we want to emphasize the need for more collaborations with the healthcare sector. RE research is growing rapidly with many new methods and algorithms; at the same time, the healthcare context is changing quickly and facing grand challenges, which could be resolved by RE support. we believe that RE research should not be kept in the laboratory or, mainly, for academic illustrations; it should be driven by real-world needs and its solutions should be practical and used by end-users.

# V. CONCLUSION

In this paper, it was shown that RE methods were used effectively in five healthcare-related projects and brought real and tangible positive results. The discussed lessons learned also showed that it is essential for both researchers and practitioners to continue investigating the applicability of requirements engineering practices in healthcare, the gap between current practices and desired outcomes, and the needed tools for the RE to be an effective part of healthcare practices. In addition, URN-GRL is perceived as powerful at analysis while URN-UCM is easy to understand and follow. However, they need to be customized to healthcare needs and to use healthcare vocabulary.

Moreover, some grand challenges that healthcare is facing these days are discussed too. The value-based healthcare system brings many research opportunities and areas of improvement, such as defining and analyzing value in delivered care services, where RE-based methods can contribute greatly. Also, the health digital transformation puts end-user (patients) face to face with new technologies that they might not be familiar with or not be confident dealing with it; hence, user needs, emotions, values, and rights shall be addressed adequately in RE research.

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