Experiences in Developing Requirements for a Clinical Laboratory Information System in Brazil

Jean Carlo R. Hauck[1,2], Maiara Heil Cancian[1], Christiane Gresse von Wangenheim[1, 2], Marcello Thiry[2], Aldo von Wangenheim[1], Richard H. de Souza[1]
[1]Federal University of Santa Catarina (UFSC)
Florianópolis/SC – Brazil
[2]Universidade do Vale do Itajaí (UNIVALI) – Computer Science
São José/SC – Brazil
jeanhauck@egc.ufsc.br, maiara@telemedicina.ufsc.br, gresse@gmail.com, marcello.thiry@gmail.com, awangenh@inf.ufsc.br, richardhenrique@gmail.com

Abstract

The development of health care information systems has been shown to be complex and costly. A primary concern is the thorough analysis of stakeholders' information, knowledge and their needs. Traditional processes have to be adapted in order maximize their efficiency and effectiveness. In this paper, we describe a requirements development process in alignment with CMMI-DEV and ISO/IEC 15504, which has been defined and applied for the development of new clinical laboratory information system for the Central Laboratory of the Santa Catarina State Public Health Department (LACEN)/Brazil. The system is currently being applied state-wide for more than 75 types of clinical analyses involving 7 facilities. We present our experiences in applying the requirement development process and lessons learned.

Keywords

Requirements Analysis, Health Care, Clinical Laboratory Information System, Telemedicine

1 Introduction

Brazil is the largest economy in South America and its healthcare sector is considered to be worth approximately $56 billion per year [1]. IT in the healthcare sector has significantly advanced in the last years, as a consequence of both private and public investments in the sector. Web-based systems, for decentralized healthcare access, telemedicine and continuous education of health care personnel play a central role in this context.

But, still, only a minority of Brazilian hospitals and clinical analysis laboratories has some kind of integrated system solutions [2], and even fewer exist that are web-based or telemedicine capable. Therefore, there exists, among others, a critical need for efficient clinical laboratory information systems (CLIS) designed to store, manipulate, and retrieve information for planning, organizing, directing, and controlling administrative and activities associated with the provision and utilization of clinical laboratory services. And, to allow the prompt integration of external exam results into the hospital routine and to make them also accessible to clinicians and patients, it is extremely desirable to design a CLIS as part of a distributed e-health network.

Yet, the development of information system in the health care domain has shown to be complex and costly [3]. They have to be highly collaborative, involving a large number of different stakeholders, including, doctors, nurses, clerks, etc. Eliciting their needs is difficult. Often they do not even have

sufficient time to participate in the requirement development due to their typical working conditions, nor the expertise to discover errors or missing requirements [4]. On the other side, requirement development in the health care domain, requires a thorough understanding of the domain specific concepts and terminology [5]. There exist also a large number of unconscious requirements, which may simply be overlooked [4]. Typically, health care information processes are also characterized by a large number of exceptions [6], difficult to elicit, as well as non-functional requirements, which are numerous and important, especially regarding safety and security [5]. The workflows in place may not be optimal, requiring innovation as part of the deployment of an information system [7]. Generally, health care information systems also must interface with instruments or other information systems. Therefore, a primary concern is to organize the development of health care information systems in such a way to maximize their efficiency and probability of success [6]. Of critical importance is the thorough analysis of stakeholders' information, knowledge and their requirements [7]. In this context, traditional requirements development processes have to be adapted to be effective and efficient [5].

In this scenario, the CYCLOPS Group [8] at the Federal University of Santa Catarina/Brazil aims at the development and transfer of innovative methods, techniques and tools in the health care domain, including telemedicine, medical image analysis, 3D imaging in cooperation with several hospitals and medical clinics. Recognizing the need to improve its software process, the CYCLOPS Group started an improvement program in 2006. Its software process has been organized and modeled in accordance to CMMI-DEV [9], ISO/IEC 15504 [10] and MPS.BR [11] with a special focus on the development and management of requirements (Figure 1).

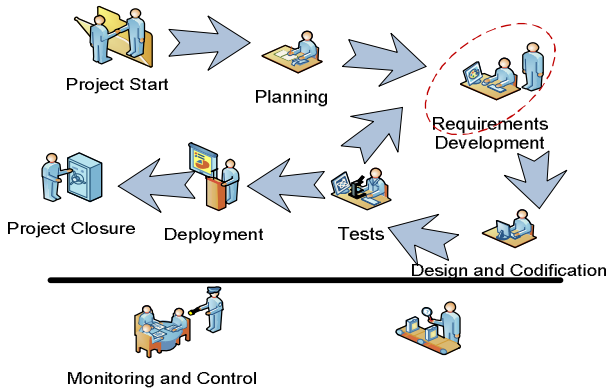

Figure 1. Overview of the CYCLOPS software process

In this paper, we describe our experiences regarding the development of software requirements for a CLIS at the Central Laboratory of the Santa Catarina State Public Health Department (LACEN). LACEN is a public institution that provides services for the state`s public healthcare network, which is part of the SUS – *Sistema Unico de Saúde*, the Brazilian public single payer health system. It has a central facility located at the capital of the Santa Catarina State and 6 facilities distributed across the state. Today, LACEN executes about 20.000 clinical analyses per month, which it receives from various institutions, such as public and private hospitals, primary healthcare facilities, etc.

Figure 2. Receiving a blood sample at LACEN

The objective of the project is to develop a web-based clinical laboratory information system supporting patient order entry, specimen processing, result(s) entry, entry tracking, web-based results inquiry, preliminary, final and public health reporting and patient demographics. The system also provides HL7-compliant interfaces to reference labs and Electronic Health Records (EHRs). The system will be applied for more than 75 types of laboratorial analyses in 25 areas, such as, hematology, immunology, etc. One important requirement was that the system was to be designed to be integrated into the Santa Catarina State Telemedicine Network (RCTM) [12], enabling it to feed the statewide public EHR system being developed in this context. The project started in July 2006, and, currently, the system is being deployed.

2 Requirements Development

One of the critical challenges in the project was the development of the requirements to assure the development of a software system that actually meets the user needs. Here, we use the term "requirements development" to refer to the process to elicit, gather, model, specify, analyze, validate, document and communicate data, information and requirements that are needed to support the respective business process. As part of the software process improvement program at the CYCLOPS Group, the current requirements development process in place was described and improved in alignment with the principal reference models, including CMMI-DEV, ISO/IEC 15504 and MPS.BR. Figure 3 illustrates the basic steps of the requirements development process.

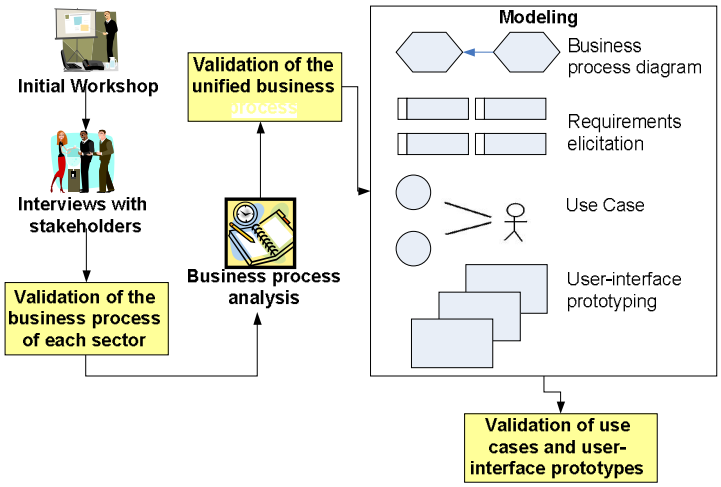

Figure 3. Overview of the requirements development process

In the LACEN project, we applied the defined process as follows:

Initial Workshop. First, we organized a 3-hours workshop involving all stakeholders in order to establish a common understanding on the scope of the project and to obtain their commitment. During the workshop, the project manager presented the CYCLOPS group and the objective and scope of the project. The director of the LACEN presented an overview on the institution, its objective and organizational structure. Then, one representative of each sector of the LACEN described the sector and presented a high-level workflow overview. These presentations had been prepared in advance together with software analysts of the CYCLOPS Group. The presentations helped to understand the context of the system to be developed and to identify relevant stakeholders. At the end of the workshop, the sponsors emphasized once more the importance of the project and their support, motivating the involvement of the stakeholders in the project. The whole workshop was filmed and the information obtained was documented by the software analysts.

Interviews with stakeholders. Based on the information obtained in the workshop, we decided to perform a group interview with relevant stakeholders per sector. A schedule for the interviews was developed and revised with LACENs' management verifying the availability of respective stakeholders.

Then, collaborative interviews were conducted using an adaptation of JAD sessions [13]. The objective of these interviews was to elicit the workflow executed by each of the sectors. In addition, we analyzed artefacts being consumed or produced as well as the inter-relationship of the sectors' process with other processes of the organization. Each interview has been analyzed by describing the respective business process in a textual form as well as a graphical model. For this visualization, we used simple stereotypes related to the health care domain, in order to facilitate the understanding of the process by the stakeholders (Figure 4).

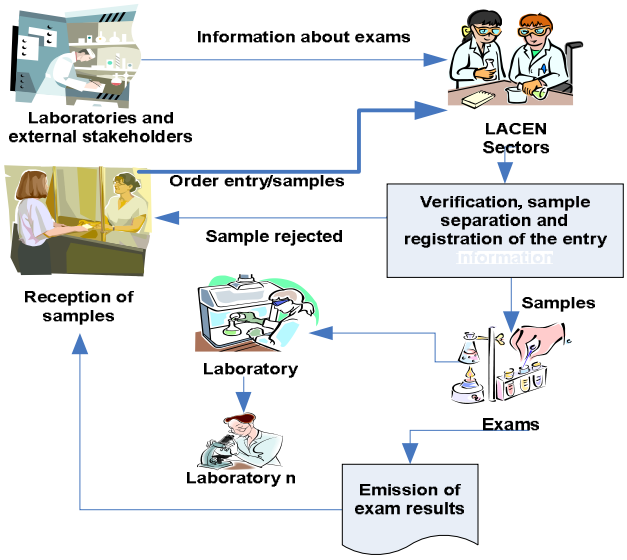

Figure 4. Sample extract of business process of LACEN

During the interviews, also a vocabulary of the application domain was elicited, creating a glossary as part of the requirements document.

Validation of the business process and vocabulary of each sector. We organized validation sessions with 2-3 representatives of each sector of the LACEN during which we step-by-step presented and discussed the process, as elicited in the interviews. Errors or missing information were corrected until we obtained a version formally approved by the stakeholders.

Business process analysis. One of the objectives of the project was to establish a system for an integrated and uniform business process among all sectors of LACEN. Therefore, we included a step in which we analyzed and unified the elicited business processes of each sector. Inconsistencies were solved in cooperation with representatives of the respective sectors and senior management of the LACEN.

Validation of the unified business process. We validated the unified business process with senior management of the LACEN. Therefore, the unified business process was presented in a validation session and discussed. In the end, the process was formally approved by senior management.

Modelling of the business process diagram. Then, we modelled the business process more formally, adopting a customized notation based on UML [13] using Enterprise Architect (EA) [14] (Figure 5). Besides the formalization of the business process, this activity also served to understand in more detail the structure and dynamic of the institution's processes. At this moment, we focused on understanding the processes in place, without the usage of an information system. The detailed documentation of the business process permitted its systematic analysis and the identification of improvement opportunities.

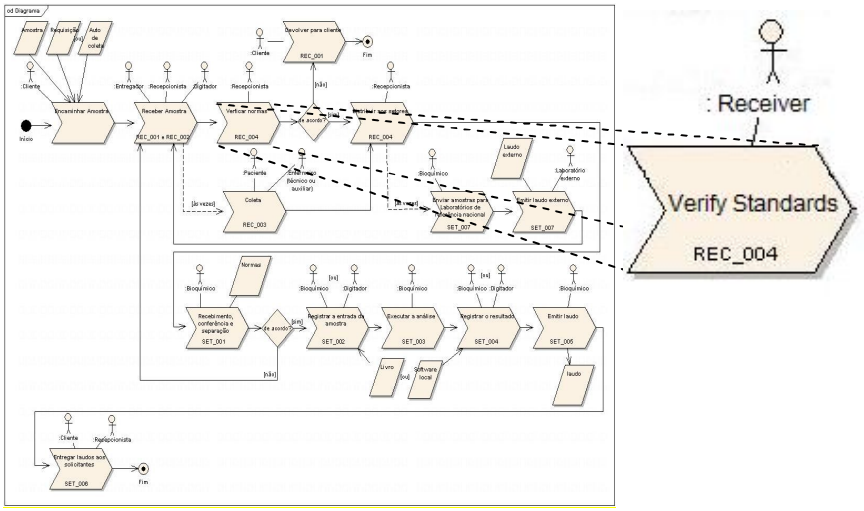

Figure 5. Sample of the business process of LACEN

Requirements elicitation. Based on the modelled business process, we begun to elicit functional and non-functional requirements of the system to be developed, considering the identified improvement opportunities. Requirements and business rules were documented in a textual form using a customized template of EA.

Use case development. Then, we grouped the functional requirements per functionality and started to develop use cases based on the information elicited earlier. Once all requirements were mapped to use cases, a use case diagram was developed providing an overview on the scope of the system. All use cases were initially described high-level and, later on, refined detailing the main flow, alternatives and exceptions.

User-interface prototyping. In parallel to the refinement of the use cases, we also prototyped the user-interfaces of the system in accordance to the event flows defined in the use cases. The objective of the prototyping was to facilitate the validation of the future system by the stakeholders.

Validation of use cases and user-interface prototypes. This has been done in two steps. First internally by a validation of software process engineers of the CYCLOPS Group throughout the whole development process, analyzing the conformance of the process and artefacts with respect to the defined process as well as the correctness and consistency of the requirements, business rules, use cases and user-interface prototypes. In a second step, the use cases and user-interface prototypes have been presented to the principal representatives of each sector and senior management of the LACEN and their formal approval was obtained after some small adjustments.

As result of the requirement development a formally approved requirements document was completed, which served as input to the second stage of the project, covering design, codification, tests and deployment of the system.

3 Lessons Learned

In general, the requirements development process as described in Section 2 worked well in the LACEN project. Applying the process, we observed various lessons learned:

Capturing the "big picture". Organizing the initial workshop, was not sufficient to assure that a general view and context of the system to be developed was captured. Therefore, we are including an additional step after the workshop, involving a more thorough characterization of the institution(s) in which the system will be implanted as well as profiles of its future users. We also added requirement elicitation sessions with senior management and sponsors of the respective institution(s).

Group interviews. A specific characteristic of the LACEN project was the prior inexistence of a de-

fined unified process. In this context, the realization of group interviews allowed to discuss and solve inconsistencies or conflicts immediately with the involved parties. Only in cases where conflicts could not be resolved directly, senior management had to be involved together with the representatives of the respective sector(s).

Involvement of senior management. Their involvement, when necessary, and their consistent way of decision and motivation for the unification of the processes has been essential for the definition of a uniform processes to which all sectors are committed.

Non-functional requirements. Our approach has shown to be adequate for the elicitation of functional requirements related to the actual business process in place. However, we also observed two shortcomings. The approach did not sufficiently help to elicit non-functional requirements – a typical difficulty in this domain [5]. Therefore, we included a specific step for the elicitation of non-functional requirements using a checklist based on [15].

Innovation. We also experienced difficulties in modelling a system that meet users' needs regarding the actual process in place while at the same time proposing an innovative technological solution. Therefore, we are also integrating the consultation of technology experts in the health care domain to complete the requirements development.

Documentation. In general, the format and contents of the requirements documentation was adequate, but we observed the need to also document the relationship (dependency) between requirements, a data dictionary for user-interfaces as well as the navigation flow between interfaces.

Step-wise validation. Realizing first the validation of the business process and later on the validation of the use case and user-interface prototypes, was experienced as beneficial as it helped to identify errors early and concentrated the involvement of the users to the validation of parts of the processes of their sector. We also experienced the realization of validation meetings with an analyst and users as essential. It would not have worked, if we had simply asked the representatives to review the documents individually.

Formal approval. During the later steps in the requirements development and especially during the implementation of the system, we experienced the formal approvals we obtained as essential for negotiation each time a change request came up with significant impact on the project baseline.

Involvement of future users. We also experienced the close involvement of future users as one of the key factors of success. The initial workshop helped to provide an understanding of the project and to create a friendly climate. The active participation during the elicitation and validation contributed to obtain a better understanding of the requirements.

4 Conclusion

In this paper, we present our experiences in developing requirements for a new CLIS. The project has also served as a pilot for the deployment of a defined requirements development process in alignment with CMMI-DEV, ISO/IEC 15504 and MPS.BR for the development of new systems in the CYCLOPS group. In order to establish the requirements development process at the CYCLOPS group, we used the ASPE-MSC approach [16], which, based on the descriptive modelling of the process in place, identifies strengths and weaknesses and guides the improvement in alignment with reference models, such as, CMMI or ISO/IEC 15504. Our experiences show that such a hybrid process improvement approach, using descriptive and prescriptive techniques, facilitates SPI by strengthening the existing process and culture, instead of trying to adopt a generic process top-down. We experienced the objectives/purpose and practices/outcomes as defined with regard to the requirements process by CMMI-DEV, ISO/IEC 15504 and MPS.BR as adequate. All three models provide a consistent view, which is defined on a level sufficiently abstract to be tailorable to a specific environment. On the other side, we noticed a lack of more concrete guidance, which maps practices/outcomes of reference models or standards to alternative processes, techniques and/or tools to satisfy these requirements.

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Authors' CVs

Jean Carlo Rossa Hauck

Jean Carlo Rossa Hauck is SEPG manager of the CYCLOPS Research Group at the Federal University of Santa Catarina (UFSC). His research interests are in software process improvement and project management. He received his M.Sc. in Computer Science from the Universidade Federal de Santa Catarina and is a PhD student of the Graduate Program in Knowledge Engineering and Management at the Federal University of Santa Catarina. Contact him at UFSC - EGC, Campus Universitário 88049-200 Florianópolis/SC, Brazil; jeanhauck@egc.ufsc.br

Maiara Heil Cancian

Maiara Heil Cancian is system analyst of the CYCLOPS Research Group at the Federal University of Santa Catarina (UFSC). Her research interests are software process improvement and project management. She received his B.Sc. in Computer Science from the Universidade do Vale do Itajaí (UNIVALI) and is a master student of the Graduate Program in Automation and Systems at the Federal University of Santa Catarina. Contact her at UFSC - CTC-DAS, Campus Universitário 88049-200 Florianópolis/SC, Brazil; maiara@telemedicina.ufsc.br

Christiane Gresse von Wangenheim

Christiane Gresse von Wangenheim is a professor at the Universidade do Vale do Itajaí (UNIVALI) and consultant at Incremental Tecnologia. Her research interests are software process improvement, including project management. Previously, she worked at the Fraunhofer Institute for Experimental Software Engineering. She received a PhD in Production Engineering at the Federal University of Santa Catarina (Brazil) and a PhD in Computer Science at the University of Kaiserslautern (Germany). She's also a PMP - Project Management Professional and Assessor of the Brazilian Process Improvement Model MPS.BR. She's a member of the IEEE Computer Society, the Project Management Institute, and the Working Group ISO/IEC JTC1/SC7/WG24—SE Life-Cycle Profiles for Very Small Enterprises. Contact her at UNIVALI, Rod. SC 407, Km 04, 88122-000 São José/SC, Brazil; gresse@gmail.com

Aldo von Wangenheim

Aldo von Wangenheim is a Professor for Medical Informatics and Telemedicine at the University Hospital of Federal University of Santa Catarina and his research interests are in the areas of medical image analysis for diagnosis support and large-scale telemedicine frameworks for public health. He studied Computer Sciences at the Federal University of Santa Catarina – UFSC in Brazil and obtained his Ph.D. in Computer Sciences from the Industrial Mathematics Ph.D. Program at the University of Kaiserslautern, Germany. Contact him at UFSC - CTC-INE, Campus Universitário 88049-200 Florianópolis/SC, Brazil; awangenh@inf.ufsc.br

Richard H. de Souza

Richard H. de Souza is a master student of the Graduate Program in Computer Science at the Federal University of Santa Catarina. His research interests are in software process improvement and requirement management. He received his B.Sc. in Computer Science from the Universidade do Vale do Itajaí (UNIVALI). Contact him at UFSC -CTC-INE, Campus Universitário 88049-200 Florianópolis/SC, Brazil; richardhenrique@gmail.com