Proposing a Process Reference Model for Telemedicine Systems

Rodrigo Araujo Barbalho[1], Christiane Gresse von Wangenheim[2]
[1]Aluno do Programa de Pós-Graduação em Ciência da Computação – PPGCC – UFSC, Florianópolis, Brasil
[2]Professora Adjunta do Departamento de Informática e Estatística da Universidade Federal de Santa Catarina – UFSC, Florianópolis, Brasil

Resumo: Telemedicina pode ser definida como o uso da tecnologia da informação, comunicação e medicina para fornecer cuidados médicos em locais onde a distância é um fator crítico. Embora esses sistemas estejam sejam utilizados no mundo todo, ainda não existem modelos de qualidade para guiar o desenvolvimento desses sistemas. Nesse sentido, um modelo de maturidade e capacidade de processos de software (MMCPS) poderia auxiliar não apenas o desenvolvimento de novos sistemas, como também a avaliação dos já existentes. Como primeiro passo para a criação de um MMCPS para sistemas de telemedicina, um modelo de referência de processos (MRP) é apresentado neste artigo baseado na norma ISO/IEC 12207, integrando processos da norma ISO/IEC 21827 e ISO/IEC 15504-10 para criar um modelo mais seguro e com menores riscos, devido ao aspecto crítico do domínio. A definição e avaliação desse modelo de referência são apresentadas neste artigo.

Palavras-chave: Telemedicina, Segurança, Segurança computacional.

***Abstract**:* Telemedicine can be defined as the use of information technology, communication and medicine to provide medical cares in places where distance is a crucial matter. Although these systems are widespread used around the globe, there is still no quality standard defined to guide the development of these systems. In that way, a software process capability maturity model (SPCMM) would help not only the development of new systems as the evaluation of the already existing ones. As a first step towards the objective of creating a SPCMM for telemedicine systems, a process reference model (PRM) is presented on this paper using as base the ISO/IEC 12207, integrating processes from ISO/IEC 21827 and ISO/IEC 15504-10 to create a more secure and safe reference model, due to the critical aspect of the domain. The definition and evaluation of this reference model is presented on this paper.

***Keywords**: Telemedicine, Safety, Computer Security.*

Introduction

Telemedicine can be defined as the "delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities."[1].

Telemedicine systems basically offers two types of services: synchronized, which requires simultaneously the participation of two or more parties using telephones, or audio or video conference[2]; and asynchronized, where clinical data, such as images, videos, audio or text files are gathered in one location and sent to another for further evaluation by a health care provider[3]. They are also known as store-and-forward systems, because the information is stored locally for further sending to a different location.

Asynchronous telemedicine systems are usually used for tele-diagnosis, exam results, and continuous education of health care providers[4]. Tele-diagnosis is increasingly being used in specialist fields of medicine, in which corresponding diagnostic findings data (mainly images) can be transmitted digitally, such as tele-radiology, tele-cardiology, or tele-dermatology. If compared to synchronized telemedicine projects, asynchronous telemedicine projects require a less complex infrastructure to be implemented what makes them cheaper to be implanted.

These systems are widespread used around the globe with some of them with more than millions consultations made so far. The development of these systems remains a challenge considering their potential impact on human health[5]. For example, mixed-up patient's examination results could bring a patient to death, Personal Health Records (PHR) must be protected from unauthorized personnel. And yet, there is still no standard or software process model specified for the development of those systems[6,7].

A Software Process Capability Maturity Model (SPCMM) would help the development of these systems, to evaluate the existing ones and enhance the quality of provided services[8]. SPCMM are the gathering of best practices from the expertise of certified software engineers. Nowadays there are a lot of SPCMM spread and in usage for mostly all kind of systems, such as the CMMI, the ISO/IEC 15504, SSE-CM, among others. The Process Assessment Model from ISO/IEC 15504, has two dimensions: the capability dimension and the process dimension, composed by one or more Process Reference Models (PRM).

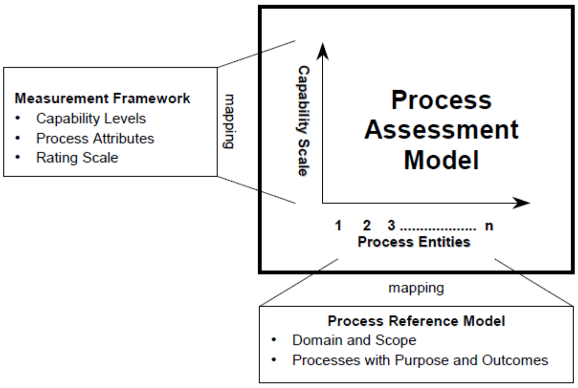

Figure 1: Process Assessment Model relationships. (ISO/IEC 15504-2)

Although quality models are usually built on a flexible way in order to be applied to as many contexts as possible, usually its appliance requires a customization based on requirements from the specific domain[9]. "Since the quality of the model will affect the quality of creations that are guided by these models it is important to reflect upon the process of model construction"[10], and the definition of the model structure is essential as from it depends how the best practices for the domain will be represented on the developed SPCMM[11], since SPCMM are based on reference models to define what should be done. In this context, this paper presents the process of how a PRM is being customized to serve as a base for a tailored SPCMM for telemedicine systems.

Method

Phase 1: Mapping Process

On previous work[12], a classification was made to define the most important quality aspects for telemedicine systems, based on quality criteria from ISO/IEC 25010. Security and Safety were classified as essential aspects for this domain. So, in order to build a more secure and safe PRM, the processes from ISO/IEC 21827 and ISO/IEC 15504-10 were mapped for processes on the reference model. As result of the mapping, base practices from the safety and security processes have been incorporated to the customized PRM.

Each base practice from the base models were double checked in order to verify that there was no process on the PRM, already capable of performing it. After the verification a proceeding was established to define what would be done to the matched and no-matched base practices. For each base practice from ISO/IEC 21827 and ISO 15504-10 a similar task or activity was sought on ISO/IEC 12207, in order to avoid repeated processes, activities or tasks on the PRM. If there was a match and if necessary, a note was added to the referenced process on the PRM in order to provide clearance about the implementation of the base practice. During the mapping process three possibilities of matching between base practices and activities/tasks were identified:

1. **No match** between base practices and activities/tasks. In this case, a new process was incorporated to the PRM, entirely as described on the source;
2. **Partial match** between some base practices from a process and activities/tasks from the PRM. In this case, a check was made to identify similar processes that could aggregate the missing base practices, if there was none, so a new process was created with the missing base practices as activities;
3. **Full match** between all base practices from a process and activities/tasks from the PRM. In this case, if necessary a note was added in order to provide information about the implementation focusing on security or safety. **Figure 2** presents the workflow of the defined process.

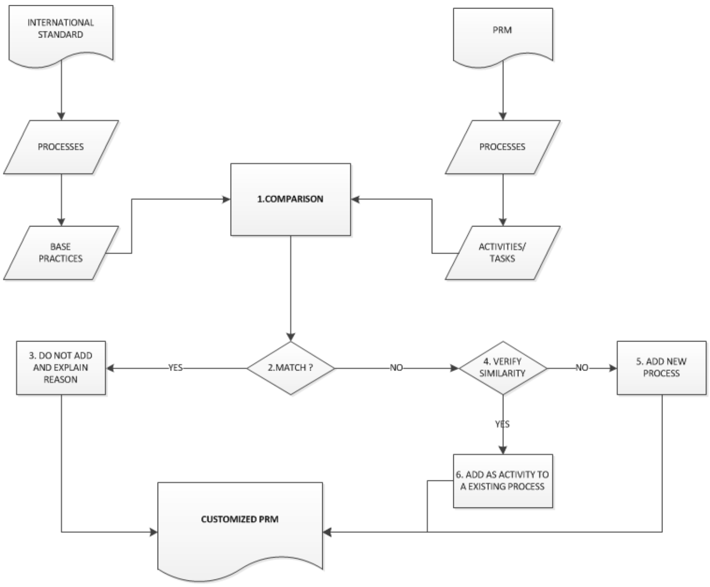

Figure 2: Workflow of mapping process

After the mapping, the processes and base practices were added to the PRM as necessary. Each new process or base practice included is described according to the processes description of ISO/IEC 12207 in order to maintain consistency between models. A group was created for the Security and Safety Processes and positioned over the System Context Processes and Software Specific Context as it is believed that these processes must be implemented and controlled during the entire development life cycle. **Figure 3** presents the processes from ISO/IEC 12207, with the new processes added after the mapping process.

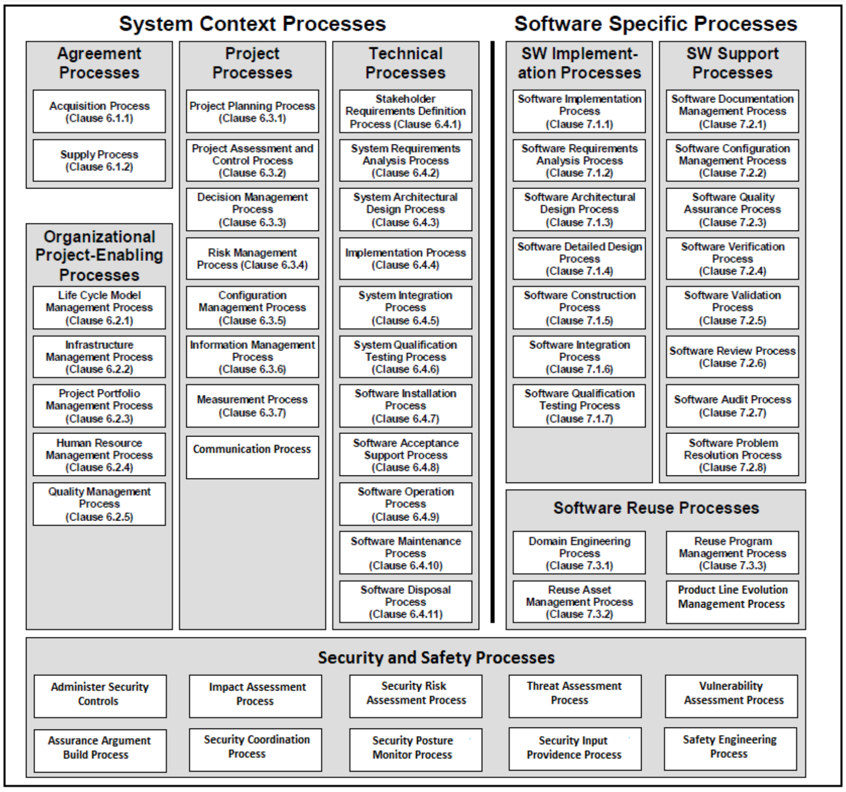

Figure 3: Customized PRM with Security and Safety Processes. Adapted from ISO/IEC 12207 (2008)

Phase 2: Evaluation of the customized PRM

In order to validate the proposed PRM a survey was made, in portuguese language, with participants of two telemedicine projects in Brazil. This evaluation was made online, through a Google Form. Through e-mails, each participant received the proposed PRM with the definition of the processes so they could read it, and classify the processes based on their experience on developing telemedicine systems.

For the classification of the processes a scale was defined where each process would be classified as: **essential**, **important**, **desirable** or **irrelevant** to the context telemedicine domain. The objective of the survey was to classify the process into importance levels presenting how much they are considered important in the context of telemedicine projects. The definition of these levels will help to build the maturity levels of the SPCMM for telemedicine projects, so the first levels will focus on processes considered more important.

Results

The average time of working on telemedicine projects was 6,6 years, among participants who provided this information. As a result of the evaluation process, the processes were classified into importance levels, by the participants. No process was classified as Irrelevant and so the column that should represent these processes was removed from Table 1. Some processes had the same number of votes classifying them in two different levels. In these cases, the process was inserted on the highest level of importance.

Table 1: Classified Processes

Classified Processes		
Essencial Processes	**Important Processes**	**Desirable**
Infrastructure Management	Aquisition	Project Portfolio Management
Quality Management	Supply	Configuration Management
Project Planning	Life Cycle Management	Product Line Evolution Management
Risk Management	Human Resource Management	Software Disposal
Measurement Process	Decision Management	Software Operation
Communication Process	Project Assessment and Control	Software Verification
Stakeholders Requirements Definition	Software Acceptance Support	
System Requirements Analysis	Software Qualification Testing	
System Architectural Design	Software Documentation Management	
Implementation	Software Configuration Management	
System Integration	Software Review	
System Qualification	Software Audit	
Software Installation	Domain Engineering	
Software Maintanance	Information Management	
Software Implementation	Reuse Asset Management	
Software Requirements Analysis	Reuse Program Management	
Software Archtectural Design	Administer Security Controls	
Software Project	Security Risk Assessment	
Software Construction	Threat Assessment	
Software Integration	Vulnerability Assessment	
Software Quality Assurance	Security Input Providence	
Software Validation	Build Security Assurance Argument	
Software Problem Resolution	Security Coordination	
Impact Assessment	Safety Engineering	
Security Posture Monitor		

Discussion

The mapping process required hard work, first because no defined process for mapping base practices and activities/task or even two different processes was found. So the mapping process had to be defined from the core. Another difficult was because of the differences between models. ISO/IEC 21827 and ISO 15504-10 used base practices to describe the activities on their processes, as ISO/IEC 12207 works with activities/tasks within their processes. The mapping between base practices to activities/tasks was quite an effort.

Other problem is the low number of successful telemedicine projects in Brazil, and so the short number of possible participants to evaluate the model. Most telemedicine projects are experimental with less than a thousand exams/consultations performed. Even harder is to find developers who worked on these projects. The choice of the projects was because the higher number of performed exams/consultations through a specific platform.

Conclusion

Health sector system requires special attention due to the critical aspect of the domain. This customized PRM is a step forward to propose a SPCMM specifically for this kind of system aiming at the building of more secure and safe telemedicine systems and the supply of high quality services for general population. As future work more important aspects shall be incorporated to this PRM in order build a more adapted SPCMM for the telemedicine/health domain.

The processes classified on this research will be split in maturity levels in order to help organizations on focusing on most important processes and also making them capable of evaluating the maturity of their development process.

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Contato

Rodrigo Araujo Barbalho, mestrando no programa de pós-graduação em Ciência da Computação, Universidade Federal de Santa Catarina (UFSC), pesquisador do Grupo de Qualidade de Software (GQS). Telefone: (48) 3721-9516. E-mail: rodrigo.barbalho@posgrad.ufsc.br

Christiane Gresse von Wangenheim, professora do programa de pós-graduação em Ciência da Computação da Universidade Federal de Santa Catarina (UFSC), coordenadora do Grupo de Qualidade de Software (GQS). Telefone: (48) 3721-9516. E-mail: gresse@inf.ufsc.br.