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SeReM^2 - A Meta-Model for the structured Definition of Quality Requirements for Electronic Health Record Services

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Abstract

Quality assurance is a major task with regard to Electronic Health Records (EHR). Currently there are only a few approaches explicitly dealing with the quality of EHR services as a whole. The objective of this paper is to introduce a new Meta-Model to structure and describe quality requirements of EHRs. This approach should support the transnational quality certification of EHR services. The Model was developed based on interviews with 24 experts and a systematic literature search and comprises a service and requirements model. The service model represents the structure of a service whereas the requirements model can be used to assign specific predefined aims and requirements to a service. The new model differs from existing approaches as it accounts for modern software architectures and the special attributes of EHRs.

Keywords:

Electronic health record, Service, Quality, Requirements, Meta-model

Introduction

The idea of comprehensive Electronic Health Record had its origin in the early 90s and was first - amongst others - discussed by Waegemann (see e.g. [1]). Since that time a great number of projects and efforts were dedicated to the development of this basic idea. This fact has still not changed but the recent past shows that more and more of the research that was conducted is introduced in real life environments. Particularly Scandinavian countries are on the cusp of introducing EHR systems or at least parts of it (e.g. Denmark [2, 3]).

The success of such an EHR introduction is – apart from the mere technical questions – strongly dependent on the definition and fulfillment of a variety of different requirements on a functional and non-functional level. The definition respectively the coordination of such requirements is extremely difficult. This is due to several factors such as different norms and standards, legislation, different strength or heterogeneity of stakeholders within a country etc.

The general question in this context is: How can the quality of EHR services be defined? Basically, quality can be defined as the degree to which a set of inherent characteristics fulfills requirements (technocratic definition) [4]. But the actual definition and characterization of EHR quality poses a problem, as the large heterogeneity in existing requirements or tacit knowledge makes it difficult to define a consolidated set of characteristics that has to be fulfilled.

As the conceptual design and prototypical implementation were in the center of interest till the recent past, there aren't many initiatives so far that focus on the quality neither of EHRs nor on quality of EHRs as a whole. Quality approaches such as the ones from CCHIT [5] or EuroRec [6] have a very strong functional focus; the IHE again solely focuses on interoperability. Other more generic approaches such as FURPS+ [7] or the ISO 9126 [8] do not account for the specific requirements of EHRs.

The paper presents a Meta-Model to describe and structure quality requirements for EHR services. The model serves as a basis during/after requirements engineering as well as for potential quality certifications. It should increase, amongst others, transparency and comparability between systems and aims at an increase of the quality of requirements description and structure. Furthermore, potential users should be supported during the selection process of different EHRs. The approach also accounts for the particular characteristics of modern EHRs such as service oriented architectures, heterogeneous requirements, different vendors or interoperability.

Methods

The Meta-Model for quality requirements that is described in this paper was developed as part of an extensive research project that started in 2007 with the aim to support transnational quality certification of EHR services. The Meta-Model is part of a comprehensive framework including a large requirement repository (> 1200 EHR specific requirements), a language to formally represent the structural model, a thesaurus and a model to categorize requirements, a process model etc. To develop the model an expert survey and literature analysis in the middle of 2008 was conducted.

Data collection - Literature analysis

To collect all relevant publications for the data analysis PubMed, IEEExplore, Google and ACM Digital Library were used. The search was targeted towards publications on software quality and software certification with regard to electronic medical records in general.

The following initial list of keywords or keyword combinations was used: software, quality, software engineering, certification, software model, Health Record, Standards, EHR certification and EHR quality. This initial list of keywords was obtained by selecting relevant MeSh-Terms. Through the analysis of the documents found during the process further keywords and document sources were discovered and subsequently used. In total 400 sources were found of which 63 sources were relevant for this work.

Data collection – Expert survey

The expert survey was designed as qualitative problem-centric interviews. 50 Experts from the domains of legislation, standards, norms, data security, industry and science were initially selected. An expert was defined as a person that works in the field of clinical information systems for more than 3 years and is actively involved in the development (design/implementation) of Electronic Health Records. In total, 26 experts all over Europe (special focus on German-speaking and English-speaking countries) were questioned about general as well as detailed requirements regarding quality certification of EHR services. We applied the concept of theoretical saturation to both, the literature analysis as well as the expert survey, meaning that we stopped the research as the analysis of interviews and documents did not yield fundamentally new results.

Data analysis

Documents that were retrieved were analyzed by two independent reviewers. In the first step documents were roughly judged regarding quality and content. This was done by selecting scientifically published (peer-reviewed conferences, journals etc.) documents only and analyzing their abstract. Reviewers afterwards discussed their results to match all discrepancies in selection that occurred.

Selected documents as well as the results from the expert survey were analyzed in detail. Techniques of qualitative content analysis as described e.g. in [9] or [10] were used to derive quality requirements for EHR services.

Results

The following paragraphs describe the different elements and sub-models of the Meta-Model as well as general Meta-Model constraints. The Meta-Model is divided in two interdependent sub-models, a service model and a requirements model. This separation better reflects/distinguishes the structure of a service from its requirements. The service model is therefore used to describe the structure of an EHR service, whereas the requirements model is used to structure the requirements of EHR services. It is important to notice that the Meta-Model is not aiming at the definition or selection of specific requirements for an EHR service, but rather as a method to structure requirements.

Initial Situation and Model Constraints

To be able to represent EHR services, their structure and requirements using a Meta-Model the actual complexity of EHR services with regard to their structure had to be reduced resulting in different constraints, definitions and relations.

Summarizing these results a service is defined as an application program that runs on a (hardware) device using different communication means and transmitting various content by these means. Services may use other services to provide certain functionality. For this purpose services communicate with other services bi-directional, exchange information and compute information. Infrastructure neither communication infrastructure nor devices are of interest with regard to the current Meta-Model. Also Services that are needed to execute EHR services (e.g. operating system) are not part of the Meta-Model.

Service Model

The Service Model is used to describe the EHR service with its basic structural components aiming at the later, structured assignment of requirements. The Service Model defines an EHR service as the sum of the services that it consists of respectively that it uses to provide certain functionality. It is not regarded as a monolithic entity (see Figure 1). Such an approach is particularly important for the representation of applications that are based on service-oriented architectures where services may use different and sometimes even changing services in different physical or logical locations to provide functionality.

The root element of the Service Model is a certain service. Different structural elements and sub-elements (such as Application-Logic-Element, User-Interface-Element etc.) are assigned to this root element depending on the components a service consists of. All possible Elements that may be assigned are displayed in Figure 1. These structural elements are used as containers to assign different elements from the requirements model and subsequently specific requirements (see Requirements Model below). All structural elements of the service sub-model are categorized either as external or internal visible from the viewpoint of the service.

When a specific service is modeled using the service model not all of the structural elements need to be used. This is solely dependent on the requirements that are modeled for a service (see chapter Example of use). Figure 1 describes the Service Model and contains all structural elements defined (see also Figure 2).

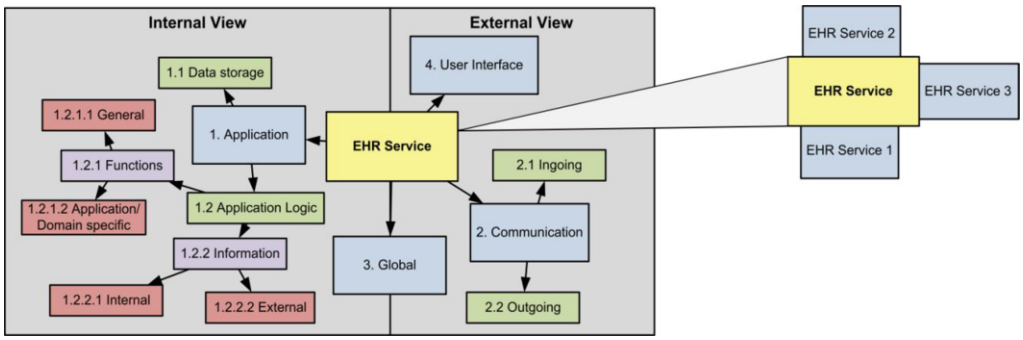

Figure 1 - Service Model

The EHR Service consists of / uses different services to provide its functionality (in this case three). The Arrows define a hierarchical order within the structural elements of the model. Colors represent the hierarchical layers. All structural elements are either part of the internal or external view except the Global-Element

Requirements Model

Whereas the service model describes the structure of a service, the requirements model describes and structures specific requirements that were selected for a certain EHR service. The basic idea of the Requirements Model is to define requirements on different levels of abstraction and to link dependent requirements.

The model consists of four basic elements: quality objectives, generic requirements, implementations and metrics. These elements are mainly determined by the content they represent and their sensitivity with regard to change during lifetime of a service. See Figure 2 for the elements of the Requirements Model and their relationships.

Quality objectives

These elements mainly have two functions they define long lasting objectives regarding the quality of a service and they are used to group generic requirements and other quality objectives. Quality objectives can be assigned to more than one other quality objective if applicable. A Quality objective needs to have at least one generic requirement to be assigned.

Generic Requirements

A generic requirement is used as a container for actual requirements that are assigned to an EHR service.

The main purpose is to describe a certain requirement with the objective of stating what has to be implemented / fulfilled by the service. One or more implementation elements can be assigned to a generic requirement. If a generic requirement has no implementation elements assigned then it is necessary to assign at least one metric.

Implementations

Implementation elements contain rules or references to certain existing rules such as standards or norms which describe how generic requirements must be implemented. Every implementation element must link to at least one metric element.

Metrics

Metrics are again rules or references to rules that in this case describe procedures how requirement elements respectively implementation elements can be checked for their fulfillment. Metrics do always have a certain type. So far a metric may be of one of the following types: value, presence, rate and combined type.

Sensitivity regarding the change of Requirements

As all elements were described regarding content and structure so far it is also of major importance to reflect the elements against the background of change during the lifecycle of an EHR service.

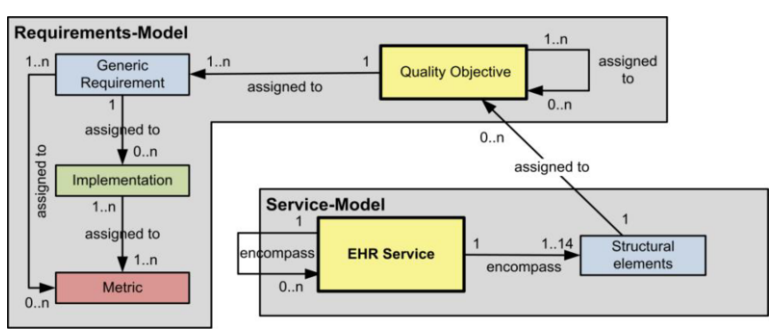

Figure 2 – Summary of all Elements and Interdependencies

With regard to requirement changes quality objectives are intended to face much smaller changes over time therefore they are highly suitable to describe medium and/or long-term aims. Generic requirements are subject to greater changes and represent medium-term aims. Implementations are suitable to describe the current state of the art and subsequently short-term aims. Figure 3 illustrates this matter schematically.

The requirements model, the service model and their interdependencies are summarized graphically in Figure 3.

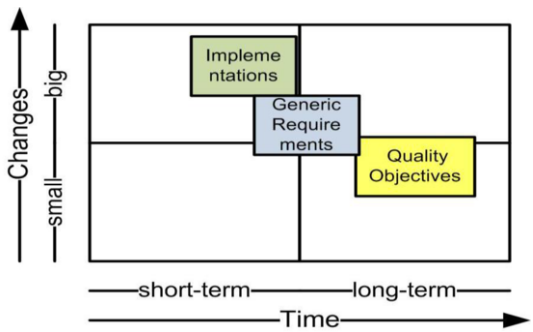

Figure 3 - Requirement Model Elements in Dependence of Time and Change

Example of Use

To illustrate the use of the Meta-Model a brief example is shown in Figure 4 and Table 1. The EHR service that is modeled is a Diabetes Diary which features a glucose meter import service, a web portal for additional data entry / display and a chart service to plot the results gathered as well as other services not mentioned here (see Figure 4). The services that compose the diary are not offered by the same organizations. The diary and the web portal belong to organization C, the chart service is offered by organization A and the Import service by organization B who also offers the glucose meter.

The import service which is displayed in the figure in detail as part of the diary does not make use of all structural elements of the service model. As the import service doesn't have a user interface or doesn't store data the corresponding structural elements are not modeled for the service.

Other services offered by the diary do have a user interface such as the web portal service. Therefore the structural element 'User Interface' is modeled for the portal service. Table 1 contains exemplary and randomly selected user interface requirements for such a service taken from the requirements repository which was also established as part of this project. The requirements are structured according to the requirement model (QO – Quality Objective; GR – Generic Requirement; IP – Implementation). Table 1 points out that all requirements used have a unique, service-independent ID to identify them.

The unique and service-independent identification is especially important for the comparison and consolidation of different services and their requirements.

Table 1 – Exemplary and randomly selected requirements for the User-Interface-Element of the Portal Service
(Legend: QO – Quality Objective GR – Generic Requirement; IP – Implementation)

Requirements Web Portal Service User Interface
QO - The interface should be user friendly (UI57)
GR - The user interface should be context sensitive (UI12)
QO - Forms should be user friendly (UI32)
GR - Forms should be structured (UI39)
GR - The user interface should be consistent (UI19)
IP - Icons should be unambiguous and conform to industry standards (UI86)
IP - The fonts should be consistent and easily readable (UI124)
IP - Screen item placement should be predictable (UI432)
GR - The user interface should be customizable (UI213)
IP - Font size should be customizable (UI17)
IP - Icon placement should be customizable (UI83)

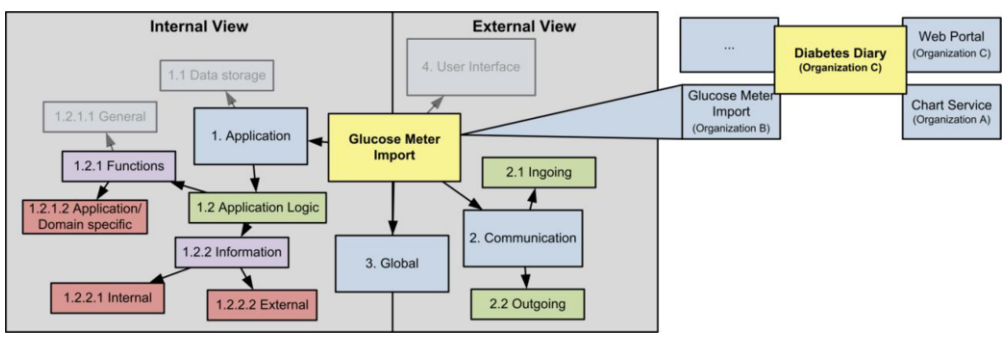

Figure 4 - Brief Example for the Service Model of a Diabetes Diary Service
Structural elements colored in grey (e.g. User Interface) are not used / applicable for this service

Discussion

SeReM^2 as presented in this paper is a Meta-Model that supports quality assurance as well as requirements engineering during the lifecycle of an EHR service. In comparison to existing EHR specific certification approaches such as the ones from the CCHIT [5] or EuroRec [6] or general software quality approaches e.g. Dromey [11], Boehm [12], FURPS+ [7] or the ISO 9126 [8] our approach features significant differences/advantages.

Complex structures and increased transparency

In general it is easier to represent complex service structures especially those based on service-oriented architectures. Interdependencies of different services that provide certain functionality are transparent.

It is not necessary to mix requirements of different services. Composed services can clearly be separated in terms of their requirements but not completely separated.

The afore mentioned approaches do not regard a service as the sum of different other services and therefore do not or only in a limited way offer these possibilities.

Better maintenance and comparability of requirements

Due to the classification of requirements in different levels of granularity the change process during the lifecycle of a service is better supported. Requirements can be discussed and changed on different levels improving the integration of different stakeholders in the definition and maintenance of requirements.

Comparison of different services and their requirements is supported as requirements are more structured. This is particularly true as requirements are split in different levels.

Existing approaches mainly categorize requirements but do not differentiate within requirements.

Selected further advantages

The model supports the inheritance of requirements for different services. This is the basis for requirements patterns for specific services such as web portal service. The model can be used to represent both, the requirements and the attributes of a service.

Limitations and drawbacks

So far the Meta-Model was used to model and structure requirements for a system run by the TILAK (Tyrolean Federal Hospitals) which is used by general practitioners to retrieve doctor's letters, laboratory and radiology findings. It is also used as a basis for the development of an EHR certification approach within ProRec Austria and is used to model requirements for the selection of specific EHR services by the Wiener KAV (Vienna Hospitals Association). So far all tests were successful but to fully proof the model more tests especially with complex systems are indicated.

At the moment there is also little tool support to implement the model for real system. The majority of the modeling tasks have to be carried out manually.

The approach does not support the user with guidelines regarding the categorization and actual structuring of specific requirements.

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