Certification of Service-oriented eHealth Platforms

Derivation of Structured Criteria for Interoperability and Expandability

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Abstract: Certification of interoperability is an important quality measure, which can foster the success of eHealth projects. Often these projects test and certify interoperability for specific purposes. The achievement of long-term interoperability is often not in the scope of these projects. In this paper we describe the importance of expandability for the long-term interoperability. Further we show, how a structured criteria catalogue for the certification process can be derived for these two quality factors.

1 INTRODUCTION

1.1 Certification of eHealth Solutions in Integrated Care Regions

More and more complex and expensive therapies as well as quality issues of localized care due to a shortage of healthcare professionals are typical issues the healthcare is faced with. Furthermore, the need for cost efficiency is a challenge that has to be mastered by the healthcare systems in Europe. One important influencing factor for this development is the demographic change, which leads to more morbidity (Gröne and Garcia-Barbero, 2001). In Germany for example, in the rural areas the average age of the population is rising while the availability of primary and secondary care decreases (Greß and Stegmüller, 2011, pp. 11, 14, 20). To face these problems an often-discussed approach is the establishment of integrated care. The goal is to enhance the quality and efficiency of patient treatment and the patients quality of life, in particular for patients having complex and long-term health problems, which are treated by multiple healthcare providers. The result of the integration of multiple healthcare providers is called “integrated care” (Kodner and Spreeuwenberg, 2002). Several players must work together in different subjects. Gröne and Garcia-Barbero notice that this integration of players is significantly driven by telemedical technologies on different layers of granularity (citizen, professional teams, health care systems) (Gröne and Garcia-Barbero, 2001). Telemedical projects aim to improve the communication between actors in the healthcare. Several regional telemedical projects in Germany have been initiated in the last years (e.g. see (Plischke et al., 2014), (Audebert et al., 2004)).

When implementing telemedical platforms communication standards can foster interoperability by defining a language that can be interpreted by different information systems. However, eHealth-platforms usually aim to implement a specific subset of a communication standard, e.g. to share patients demographics data. Later in the lifetime of such platforms new data exchange needs may become important and new implementers want to implement services based on platforms. Thus, an interoperable eHealth-platform with many participators has to be flexible concerning new requirements and technologies – it must be sustainable. In particular, if it is designed as a basic infrastructure, which allows implementing services by 3rd-party developers, requirements exist, which have not been recognized yet. These aspects are addressed by the term expandability. Risks that affect expandability may arise from complex extensibility mechanisms, proprietary interfaces, expensive business models and lock-in effects (Hilley, 2009). To counter these risks conformity assessment through a neutral party can be an appropriate method (Sunyaev and Schneider, 2013). The attestation from the third-party assessment is called certification (DIN Deutsches Institut für Normung e.V., 2005, p. 17).

To sum up, risks affecting the interoperability and expandability of an eHealth-platform can be countered by methods of certification. When de-

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scribing a certification method as an artifact, one part will be a structured catalogue of criteria. It enables a measurable and objective determination of properties that has to be fulfilled by a certification subject to achieve a high degree of the quality factors. However, when we started to design the artifact, it was not clear how to achieve criteria that indicate the factor achievement. In this paper, we focus on the question how criteria that measure the degree of interoperability and expandability of eHealth solutions can be determined. Therefore the following subquestions are formulated:

(I) What is the role of interoperability and expandability for an eHealth-platform?
(II) How can criteria be determined, that allows an evaluation of these quality factors?

We aim to design a framework, which defines layers of interoperability that are connected with quality factors. First we describe how interoperability and expandability are interrelated and that expandability is a necessity for interoperability in a long-term view. We discuss actual interoperability models of European studies concerning interoperability certification. Third we propose a framework, which allows a structured derivation of conformity criteria based on interoperability models. We contribute to the evaluation of platform expandability, by showing that these interoperability layers can also be useful to structure conformity criteria. Finally, for demonstration purposes, we present a resulting criteria catalogue, which was defined in a specific project.

1.2 Demonstration

In an EU-funded project a regional healthcare platform for Eastern Saxony is developed. The main objective of this project is to improve the care of patients in rural and structurally weak areas. One important objective to the platform is, that it must be open and allows 3rd-party providers to implement projects based on the platform or to connect their own software with the central platform.

The original vision according to this objective is to provide an infrastructure for future healthcare projects in saxony. The platform hides the technical eHealth-infrastructure and allows project initiators to focus more on issues of intersectoral care and less on technical issues. Health solution implementers can use it as a framework for the development of innovative eHealth solutions. Obstacles in project initiations should be reduced by the platform.

Additional, three sample projects are developed initially for the platform (see figure 1). These sample applications and the platform are certification objects. In this paper, we refer to the platform to demonstrate the defined certification scheme and to describe the principles of the proposed criteria model. The certification of the platform should verify, whether the vision is achieved by the implementation of the platform. The certification of applications determines whether the applications are using the components of the platform as intended. This is intended to steer the growth of the ecosystem around the basic platform.

2 RELATED WORK

Existing works in the field of eHealth-certification addresses mainly the requirements of the users concerning electronic health records rather than to address the openness as a factor for 3rd-party developers as an enhancer of functionality and quality of;

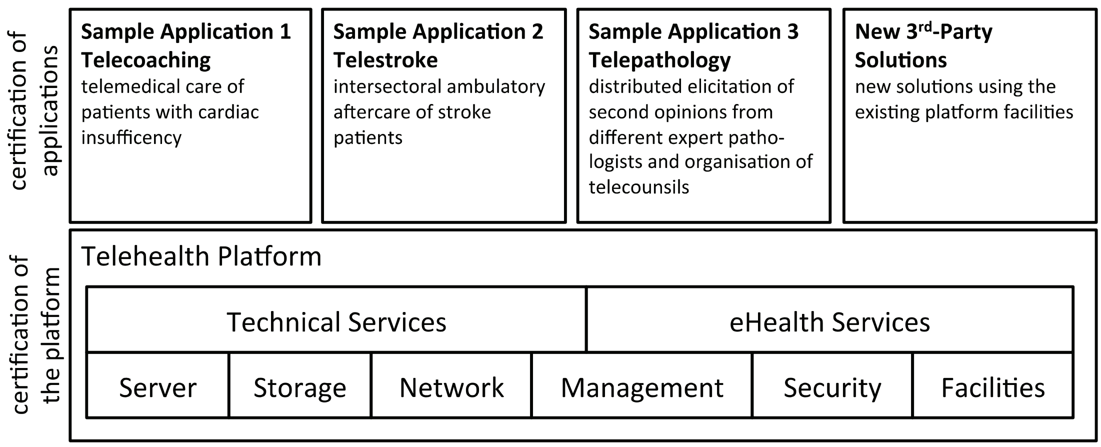

Figure 1: Scheme of the platform infrastructure and the description of the three sample applications.

service (De Moor et al., 2008; Hörbst et al., 2009; Hörbst and Ammenwerth, 2010a). Furthermore existing approaches focus primarily on the interoperability between eHealth-systems (Hörbst and Ammenwerth, 2010b; Toroi et al., 2007). Evaluation of interoperability in the context of eHealth is well operationalized by testing systems and procedures, e.g. the IHE Connectathon (IHE Europe, 2014) or the ONC HIT Certification Program (Office of the National Coordinator for Health Information Technology, 2012) are based on computerized testing routines. There exists also a set of studies concerning eHealth interoperability and testing of interoperability in Europe (HITCH - Healthcare Interoperability Testing and Conformance Harmonization, Antilope - Advancing eHealth Interoperability, EHR-Q, etc.), which face the problem of how a certification of eHealth services can be disseminated in a harmonized European way. However, it is harder to find some work that explicitly faces expandability (or its synonym extensibility) of eHealth systems (no results for "allintitle: ehealth expandability" or "extensibility" at Google Scholar). One explanation for this gap could be that eHealth-systems are interpreted as monolithic systems by the certification approaches.

Independent from the eHealth-domain, there are some approaches that define a component based view of software (Alvaro et al., 2005). These certification approaches focus on the reuse of individually certified software components. 3rd-party providers primary play the role of component deliverers. Alvaro differentiates between two ages of certification: the age of mathematical and test-based models and the age of techniques and models that predicts quality requirements (Alvaro et al., 2005). The evaluation methods in current eHealth certification programs can be assigned to the first age.

3 METHODS

3.1 Interoperability and Expandability and Their Impact to eHealth-Platforms

Existing quality factor models systematize different aspects of software quality to dedicated quality factors. These factors represent a specific set of attributes that a software product has to fulfill (e.g. maintainability, usability, etc.). An often-cited model is the factor model of McCall, which contains eleven quality factors. This model contains an interoperability quality factor and a flexibility factor. A specific attribute, which is assigned to the flexibility factor, is expandability (McCall et al., 1977). The factor model from Deutsch and Willis describes expandability as a dedicated factor (Galin, 2004, p. 45). However, interoperability and expandability are defined as follows:

- IEEE defines interoperability as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" (IEEE, 1990, p. 42).
- Expandability is the ability to adapt to future requirements resulting from enhancements in functionality, broadening of service to new target groups and improvements in service and usability (Galin, 2004, p. 45).

Expandability and interoperability are interrelated. Expandability is a necessary prerequisite for interoperability. Interoperability can be given for a specific snapshot of a system. This system, for example, might be able to communicate with an unrestricted set of systems for a specific purpose (e.g. sharing lab results). Hörbst and Ammenwerth identified that this purpose-specific view when defining interoperability requirements could be found often in literature (Hörbst and Ammenwerth, 2010a, p. 329). According to the same system, in a long term view, the interoperability maybe worse, if new needs for information exchange emerge and the system can't be extended to fulfill these needs. This dependency is depicted in figure 2.

The degree of interoperability is defined by the quotient of the number of electronic implemented information exchanges and the number of requirements that specify the need for electronic information exchange. If a system has a worse expandability the reaction time span between a new requirement regarding information exchange and its finished implementation is very long. Meanwhile other new requirements can come up and reduce the degree of interoperability more and more. An expandable system can react to new requirements very quickly. The time span between event and measure is much smaller, when the expandability is good.

It may be argued that interoperability is given, if the system considers all future information exchange needs by implementing all known interoperability standards. Apart from the impracticability of this approach even in this case, interoperability is only given for a specific set of information exchange needs that is considered by the implemented interoperability standards at a specific point in time. If there are new communication partners (e.g. a new authori-

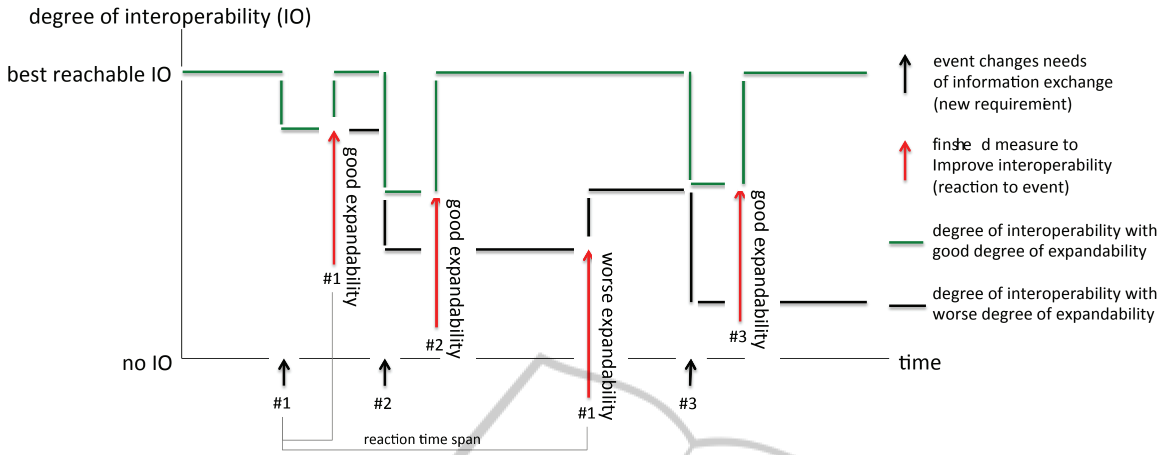

Figure 2: Dependency between the degree of interoperability and the degree of expandability accumulated over time.

ty was implemented) or new communication needs (e.g. new measure methods that lead to new data structures) which aren't considered in existing standards, the interoperability is reduced to the interactions defined by the existing standards. Furthermore, it is difficult to predict which of the implemented interoperability functions are really needed. This could lead to excessive efforts with small solution-relevant outcome.

In the opposite direction expandability can be improved by a good interoperability. If an eHealth platform has well-organized interoperability mechanisms, for example established and well documented data models taken from interoperability standards, the implementation of platform extension is facilitated. 3rd-party implementers for example can reuse already implemented interfaces to connect to existing platform components.

3.2 Structuring with Interoperability Layers

An often-used approach to structure the view on interoperability between two or more systems, is to describe a layered model defining layers of interoperability. There are existing interoperability frameworks, which are dedicated to the structuring of eHealth interoperability. One is the eHealth European Interoperability Framework (eEIF). It defines four layers of interoperability: legal, organizational, semantic and technical interoperability (European Commission and Deloitte & Touche, 2013, p. 14). Another three-layer model containing an Application, Logical and Technical Layer (ALT-Model) is defined by the HITCH-project. Additionally an organizational layer is mentioned, but not considered in the model (Coorevits et al., 2011, p. 12). The Antilope project synthesizes different interoperability models, inter alia the eEIF interoperability model. It defines the following layers of interoperability: Legal and Regulatory, Policy, Care Process, Information, Applications, IT Infrastructure (van Pelt and Sprenger, 2013, p. 11). The Antilope model is the newest of the three described models. For a detailed explanation of the several models we refer to the mentioned references. We selected the ALT-model as basis of our framework. In the following, the layers are defined in the context of conformity assessment and it is shown, how they can be matched to the Antilope interoperability model. Even if the organizational layer is not in the scope of the ALT-model, the framework considers it.

Organizational Layer: A conformity assessment on the organizational layer has to ensure, that the platform provider and the 3rd-party implementer conforms to a legal and organizational context, which allows an information exchange or a comprehensive use of provided functionality. Compared to HITCH's organizational layer, which focuses on quality of care, in this paper the organizational Layer focuses on measures between the platform provider and the 3rd-party implementer. Indirectly this also aims at quality of care, because those measures ensure a seamless handling of care aspects. In the Antilope interoperability model this layer is referenced by "Legal and Regulatory" and "Policy".

Application Layer: On this layer, it must be ensured that platform provider and 3rd-party implementers are able to support integrated care processes. HITCH addresses presentation and functionality at this layer. This must support the care process. In a conformity assessment, it must be assured, that the functionality for the interaction between platform and third party products is given. In the Antilope interoperability model this layer conforms to "Care Process", but with the view to a concrete system as a certification subject, which has to support this process.

Logical Layer: This layer aims at concepts and principles that have to be understood by 3rd-party implementers and the platform providers. This layer can be associated with the ANTILOPE-layers "Information" and "Application". On this layer it must be evaluated, whether concepts specified by a standard, technical rules or by the platform are implemented in a transparent way and whether they are interpretable by the both stakeholders. On this layer also the design decisions of the platform and implementation of those decisions has to be evaluated.

Technical Layer: On this layer, it must be evaluated that the both sides abide technical framework conditions. This focuses on technical specifications and on the transparency and right use of implementation mechanisms. This layer is associated with the Antilope interoperability layers "Application" and "IT Infrastructure".

3.3 Framework to Structure the Criteria Catalogue

Existing certification approaches describe criteria for existing interoperability functions but not for the extension of interoperability. Our proposed framework addresses this methodological gap. Figure 3 illustrates our framework.

A bilateral view is the foundation of the framework. On the one hand, there is the platform, which provides interoperability and expandability mechanisms and on the other hand there is a 3rd-party implementer, which wants to add new components to the platform or to interconnect his own product with the platforms interoperability mechanisms. The two quality factors are interconnected with the layers of the ALT-model from HITCH. Even if the ALT-model doesn't specify the organizational layer in detail (Coorevits et al., 2011, p. 13), we use this layer in the model to describe organizational aspects concerning the conformity assessment. For example the contracting is an organizational aspect. The selection of the layer models is driven by the following factors that refer to resulting criteria catalogues:

- expected volume of the resulting catalogue
- expected complexity and practicability of the use of the criteria in an evaluation processes
- expected ability of formalization of the resulting criteria
- expected precision of the resulting criteria

The intersection of a quality factor and an interoperability layer describes an aspect that has to be evaluated in an assessment process. The question marks identify that these points have to be specified in detail. One important use of these intersections is to categorize the different certification criteria. A criterion defines a requirement that a system has to fulfill in a verifiable way. Other instances of this interconnection-model can help to describe the subjects of certification and the certification methods. In HITCH the least is already done for the interoperability quality factor.

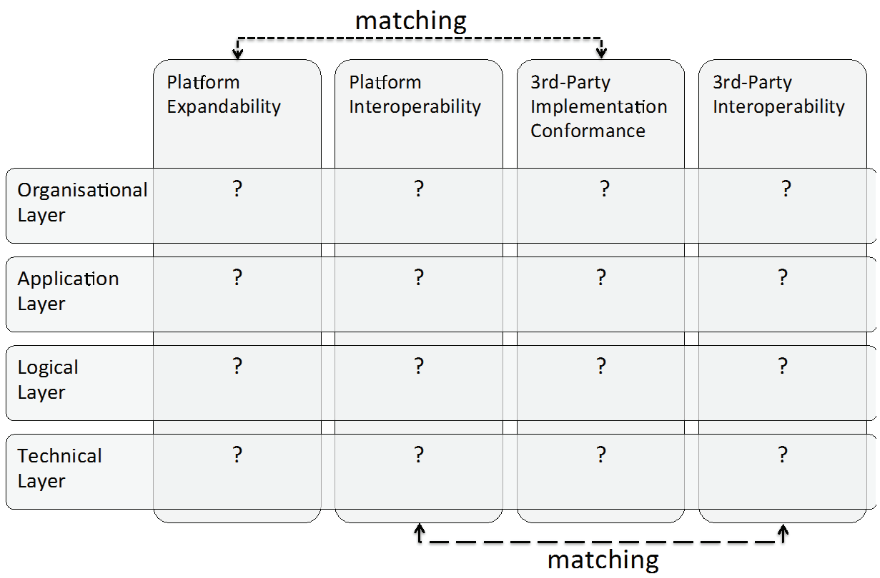

Figure 3: Scheme for the assignment of criteria to the quality factors of expandability and interoperability.

The bilateralism is depicted by the "matching"-arrows. The certification of the platform expandability is the opponent of the certification of implementation conformance of a 3^{rd}-party implementer. These two pillars address the risks mentioned in the introduction of this paper. The implementer of the platform is evaluated concerning the expandability of the platform and the 3^{rd}-party implementer is assessed concerning its valid use of the extension mechanisms. This matching can be called asymmetric, because there is a provide-use-relationship between the certified actors. For the quality factor interoperability the two actors are evaluated regarding a valid implementation of an interoperability mechanism, for example an interface. These mechanisms are specified in an, ideally standardized but also proprietary specification. Both, the platform and the implemented component of the 3^{rd}-party implementer must be conforming to this specification. This matching can be called symmetric.

3.4 Semiformal Model for the Scheme

The derivation of criteria is a central step when describing a specific certification process. Hence, in the following we describe a structure, in which the criterion is embedded. This structure forms the basis for a derivation method and shows how the scheme shown in section 3.3 is considered in a formalized model. Figure 4 shows the concepts that are associated with the criteria. A criterion results from realization scenarios, which are formulating solution approaches for a specific use case. Realization scenarios can be referenced to standards like IHE-profiles (Integrating the Healthcare Enterprise). This scenario oriented methodology is taken from the Antilope project (van Pelt and Sprenger, 2013, p. 6 f.).

The quality factors interoperability and expandability are indirectly referenced with the criterions by quality objectives. These quality objectives are specific subordinated goals that have to be achieved for a good quality factor fulfillment. The criterion is associated with a specific requirement from the requirements specification. The standards, referenced in the realization scenarios must also be referenced by specific criteria that are derived from the scenarios. A criterion could have subordinated criteria. The subordinated criteria specify conditions that are necessary for the fulfillment of the parent criterion. A subordinated criterion must be on the same or a lower layer of the specified certification scheme.

In the provided scheme the layers are represented by the enumeration and associated to the criterion with an attribute. The layers are ordinal:

Organizational > Application > Technical > Logical

Criteria can also reference other criteria, to show dependencies. These dependencies specify no subordination or precondition. They are informative. The definition of criteria associated with the quality factor interoperability is depending on a specific domain. In section 3.1 we stated, that the degree of interoperability could only be determined for specific purposes. Insofar the definition of use cases for interoperability is always driven by a domain context.

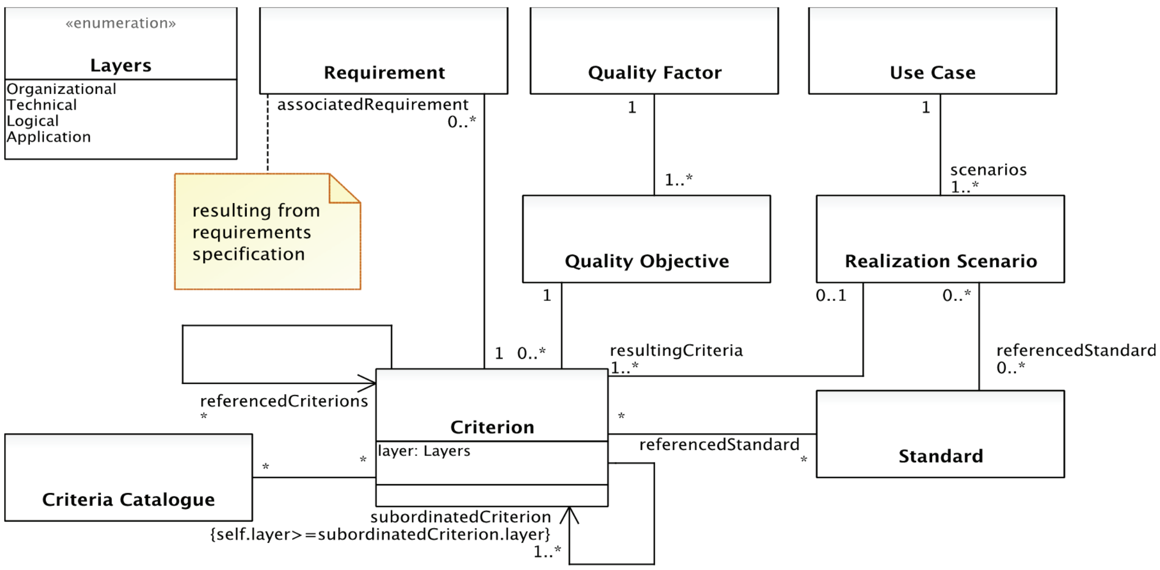

Figure 4: Criteria-model for the certification framework.

4 RESULTS

In the following we demonstrate the use of our framework with a small set of criteria. In the context of our project, described in section 1.2, we defined a set of subordinated quality objectives, which support the achievement of expandability and interoperability (see table 1).

Table 1: Quality objectives derived for the demonstration platform.

Expandability	Interoperability
Performance	Performance
Transparency	Transparency
Reusability	Usability
Conformity to Standards	Conformity to Standards
Security	Reactivity
Market accessibility	Consistency
Framework behavior	Legal compliance
Legal compliance	

Another concept, we specified, are realization scenarios, which are derived from a use case. The scenarios profile the prospective expandability aspects to specific expandability cases. In the following a simple scenario is shown:

A 3rd-party implementer wants to transmit patient data from a patient registry to the platform. For this purpose an HL7v2 (Health Level Seven Version 2) message (ADT A01) should be used. An adapter for receiving these message types isn't implemented yet. He implements a component, which is able to receive messages from this type and to modify the internal data.

Table 2: Example criteria for expandability.

Criterion	Layer	Quality Objective
API and interface-specification must be available to a 3rd-party implementer without specific constraints.	Organizational	Transparency
The data hold in the platform must be accessible for read and write to new components.	Application	Reusability
The extension-mechanism of the interface layer for import-interfaces uses the following patterns: Bridge, Decorator, Adapter, Template Method	Logical	Framework behavior
A mapping-language allows the configuration of interfaces.	Technical	Reusability
All SOAP-service-interfaces are specified with WSDL.	Technical	Framework behavior

Considering of the quality goals for the platform, now criteria can be derived and assigned to each layer. For example the criteria in Table 2 have been derived based on the described scenario. All criteria in the following table address expandability aspects.

For expandability, the layers of the framework are instantiated as follows: The criteria on the organizational layer ensure, that the context of the technical platform is designed in a way, that the 3rd-party implementer is not hampered. Criteria on the application layer describe basic principles that are expected when extending the technical platform. It addresses the general application behavior towards expandability. This is similar to functional requirements. Criteria on the logical layer address architectural principles. In the example specific design patterns that target on the problem fields reusability, flexibility and abstraction from implementation are referenced (Gamma, 1995). Criteria on the technical layer define expected technology aspects.

Table 3 shows an exemplary set of criteria, which describe the requirements for the implementation conformance of third party applications. These criteria ensure that the ecosystem of the platform is designed in a homogenous structure. To foster the use of established standards, the second criterion defines that the use of established standards is obligatory. This criterion should prevent the ecosystem from being overwhelmed with new proprietary interfaces.

Table 3: Example criteria for implementation conformance of 3rd-party application.

Criterion	Layer	Quality Objective
It must be documented, which services of the base platform are used.	Organizational	Transparency
Implementation of new external interfaces considers international and national standards.	Application	Conform. Standards
Services of the platform had to be referenced always via a central naming service.	Logical	Framework behavior

Interoperability criteria can be derived as shown in (Coorevits et al., 2011, p. 14 ff). The use cases and realization scenarios are derived as shown in (van Pelt and Sprenger, 2013). In table 4 we show a small subset of the derived interoperability criteria. Our domain context for which criteria was derived was the generic inter-institutional sharing of documents. As basic use case and scenarios we reused the Antilope-defined use case and scenarios from use case 4b (van Pelt and Sprenger, 2013, p. 32 ff.).

Table 4: Example criteria for interoperability.

Criterion	Layer	Quality Objective
1. A template for an interoperability agreement must exist, in which the stakeholders are obliged to implement interoperability standards.	Organizational	Legal compliance
2. The system must be able to receive and store documents from other systems	Application	Reactivity
3. The system must be able to send stored documents to other systems.	Application	Reactivity
4. The system must be able to act as IHE actor "Document Repository".	Logical	Conform. Standards
5. The system must support the IHE transaction ITI-41.	Logical	Conform. Standards
6. The system implements registry response defined in ebRS.	Technical	Conform. Standards

The derived criteria are also formulated in the context of our defined quality objectives. The example also shows criteria that are in a hierarchic relationship. For example, the second criterion is the parent criterion for the fourth criterion, which in turn is the parent for the fifth. The fifth is the parent of the sixt.

5 DISCUSSION

We demonstrated how established interoperability layer models can structure conformity criteria and that these models can also be applied for expandability. The other newer interoperability models weren't used for the structuring for the following reasons. We haven't selected the eEIF model, because its views are too organization-oriented. There are two layers representing legal and organizational interoperability and only two layers (semantic and technical) that represent information system aspects. The differentiation between logical and technical aspects would have become difficult. The model from Antilope was not selected because through its six layers a criteria catalogue had lead to many nearly equal criteria that overlap in their definition space. For example the first criterion in t ^ able 3 can be assigned to "Legal & Regulatory" and also to "Policy". The resulting catalogue would have become too voluminous due to redundant criteria. If necessary, the layers of Antilope can be adapted. To ensure the adaptability of the Antilope interoperability model, the mappings are defined in this paper. In the following definition of the framework layers, a reference to the Antilope layers is also given.

It was necessary to redefine the layer of the organizational view in the context of expandability. In the ALT-model the organizational layer is only outlined with the terms "continuity and quality" (Coorevits et al., 2011, p. 14). It aims at the care process. Our definition of the organizational layer more focuses on the organization between the stakeholders of an eHealth-project. Nevertheless the quality of care results is affected by the properties of this layer, e.g. if the stakeholders of the project define the need for a privacy agreement that enables the data exchange of patient relevant data in a legally conformant way.

A resulting question from our work is which evaluation methods are adequate to use with the gathered criteria. The evaluation methods build another part of the artifact certification. The three studies described in section 2 define assessment processes for interoperability and functionality of eHealth software products. It can be found, that the layers are not recognized in the specified assessment processes. Only HITCH provides how the testing can be structured by the ALT-model (Coorevits et al., 2011, p. 14). If only interoperability for specific information exchanges should be tested, this may be sufficient. In this case the criteria derived with our framework can be used as acceptance criteria in a test plan (Bruun-Rasmussen and Johansen, 2013, p. 16 f.). If interoperability in the long-term view should be certified, there is one problem: Because of the future aspects of this view, there are no specific components that can be tested. Even other expandability aspects (extension of other non-interface-related platform components) are not testable. In such a cases other evaluation methods, like inspections have to be done. There are different scenario based inspection methods for such problems that seem appropriate, e.g. ATAM (Kazman et al., 2000) or QADA (Henttonen et al., 2007). In the next steps we plan to analyze different methods for architecture evaluation.

As part of a larger design artifact, we evaluated the framework only in an artificial evaluation with the shown demonstration (Alturki et al., 2011). We demonstrated that the framework aligns with the eHealth-context. Further research has to be done answering the question, whether the framework also is applicable for non-eHealth-Solutions.

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