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Governance Guidelines for Digital Healthcare Ecosystems

Martin BENEDICT[a,1], Hannes SCHLIETER[a]
[a] *Dresden University of Technology, Chair of Wirtschaftsinformatik, esp. Systems Development, Dresden, Germany*

Abstract. Advanced Information and Communication Technologies (ICT) solutions are the key instrument to enable modern integrated care. They are not limited the traditional boundaries. Moreover, their aim is to provide medical care at the right point, in the right manner, at the right time without technological, institutional boundaries or integration issues, esp. for comorbidity treatment cases. Open digital ecosystems enabled by eHealth platforms can help to create a prospering eHealth environment. However, the creation of digital ecosystems in the health care domain is an ambitious task. The conditions how an open system can be achieved are often consented in complex projects, but they are not often scientific questioned. Conducting an action design research process, the paper contributes 13 guidelines for implementing eHealth platforms by reflection of the work in an EU-funded infrastructure project, which can be used as input for further research to provide generic guidelines for eHealth ecosystem projects.

Keywords. eHealth platform, digital ecosystems, governance

1. Introduction

Information technology in healthcare is faced with new technological trends. For example, cloud services can foster the development of intelligent healthcare solutions. In particular, small enterprises can outsource basic technology and focus on their core competencies [1]. However, in the last years the adoption of cloud technology in healthcare was not as progressive as in other branches. Privacy concerns and interoperability issues are significant hurdles for adoption of cloud technology in healthcare [2]. Other obstacles are lock-in-effects, a lack of trust by the users, legal issues [3] and opacity of follow-up costs [4].

The paradigm of community clouds can address these problems by providing a controlled environment that allows the definition of constraints for cloud member participation [5]. A community cloud is a cloud, which can be accessed exclusively by a specific range of members with shared concerns [6]. For example, in such environment a rigorous privacy infrastructure and legal agreements can be introduced to address the privacy issues and to improve the trustworthiness of the applications. Even if the participation may be constrained by rules, a community cloud environment may be open for new members.

A digital ecosystem can be achieved by establishing a community cloud [7]. A digital ecosystem is an environment of entities ("digital species" and components) that interacts, depends or corresponds on other entities. It is metaphor for the digital

[1] Corresponding Author: Martin Benedict, Dresden University of Technology, Chair of Wirtschaftsinformatik, esp. Systems Development, 01062 Dresden, E-Mail: martin.benedict@tu-dresden.de

equivalent of natural ecosystems. A main aspect besides the traditional understanding of IS artifacts is that a digital ecosystem contains rules and self-organizing mechanisms that enable a more dynamic development of the system (evolutionary approach) [8]. According to Briscoe and Marinos, in digital ecosystems members can be coordinators (i.e. meta repositories), producers (i.e. providers of services) and consumers (i.e. users of services) at the same time [7]. The success of a digital ecosystem depends on the ability to gain and obtain a "critical mass" of members [8]. An initial platform can provide the basic components for an infrastructure [9] and a seed of useful services that can be used by consumers that forms the "critical mass" of "digital species". In the specific case of the healthcare domain, we call this type of environments open eHealth-platforms.

eHealth-platforms provide the environment for services and components that enable the realization of medical applications for intersectoral treatment and information sharing between different actors of healthcare. These platforms additionally provide fundamental sets of communication and documentation services. They are inherently expandable systems that facilitate the development of healthcare services and not only provide domain specific services as a static set. Expandability on different layers and the ability to cooperate with other ICT systems (interoperability) are main quality factors to form and guarantee an open eHealth ecosystem [10]. In addition to these factors, reusability in terms of discoverability, business commonality, standard conformance, modularity [11] also helps producers to contribute to the platform with own services and software solutions.

Taking a view on the ICT maturity of health care systems in Europe for example, it can be stated that the degree of implantation is extremely different and depends on multitude factors like national security policies, reimbursement systems or the degree of nation-wide regulation of the health care sector. Despite this, concerning the topics European funding programs such as Horizon 2020 or EICT-projects, there is a trend towards the development of innovative, intersectoral treatment solutions based on eHealth-solutions. However, in particularly in Germany, the past shows that provider specific ICT-solutions lead to heterogeneous ICT landscapes and a lot of conflicts once different solutions should cooperate, or other providers wants to consume basic services.

According to the outlined concept of an open eHealth platform, there are no implementations of prospering digital ecosystems in healthcare in a wide range. Especially, when we exclude platforms, which are prescribed by law. So, we want to contribute by evaluating common practices of system engineering in a complex settings and by extraction of guidelines (in terms of lessons learned) that can be adapted in similar project contexts, or can help the administrative setting up standards, or evaluate projects in this area. Therefore, we reflect the participation within a EU-funded project on building an eHealth platform for Eastern Saxony (Germany) following an action design research (sec. 2). Hence, we formulated the following research question:

RQ: What are useful governance guidelines to cover the development and utilization process of an open eHealth platform?

2. Methods

2.1. Research Method & Outline

The article is dedicated to the design oriented branch of information system research (ISR) [12]. In detail, the findings results of an action design research (ADR) process, in which the research process is an inherently interwoven activity of building the IT artifact [13]. In comparison to typical Design Science approach, ADR are slightly more oriented on organizational relevance at the cost of technological rigor.

According to Sein et al. [13], ADR process is typically structured in the stages of Problem Formulation (1); Building, Intervention and Evaluation (2); Reflection and Learning (3); and Formalization of Learning (4). The paper addresses these stages as follows: The problem and motivation (1) is given in section 1 by a brief introduction. In further course of the method section, we illustrate the case example, which is used as real world project setup for gaining findings (2). Afterwards, we extract and reflect the learning (3) in section 3 and explicate governance guidelines (4). The paper ends with a short summary and an outlook on the further research.

2.2. Background – Case Example

As case example, we are directly involved in an EU-funded project by a project partnership. The project purposes to implement a regional healthcare platform for Eastern Saxony. Concerning the public interest of the platform, the main objective is to improve the care of patients in rural and structurally weak areas. This platform shall also provide an open infrastructure that allows 3rd-party providers to implement projects based on the platform, to connect their own software products, or extend the functionalities. Therefore, the platform hides the technical 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. Thus, the platform shall enable a digital ecosystem for eHealth services.

The technical and organizational barriers to entry and to participate should be reduced systematically to overcome the obstacles for the realization of additional eHealth-solutions. Primary objective is not to provide or implement final applications, but to generate a coherent environment for such solutions (sec. 1). To confirm functionality of the platform in principle, three sample projects are developed initially for the ecosystem (see Figure 1). The development of the sample projects and the foundational platform (the environment) is decoupled through different independent business units.

The foundational technology can be used to implement services and solutions. The sample projects also help to build a set of seed-services and they also deliver themselves reusable services. To achieve a critical mass on services, all of them must be designed that they address the quality factors mentioned in section 1. In general, seed services can be classified as documentation (i.e. a document repository), communication (i.e. a service for VOIP, internal messages) and supportive services (i.e. a service for clinical pathways).

As a research institute, we are involved since the first draft of the application. We are an independent research partner in a consortium of a big national telecommunication provider and a management organization of a regional health care network as well as a

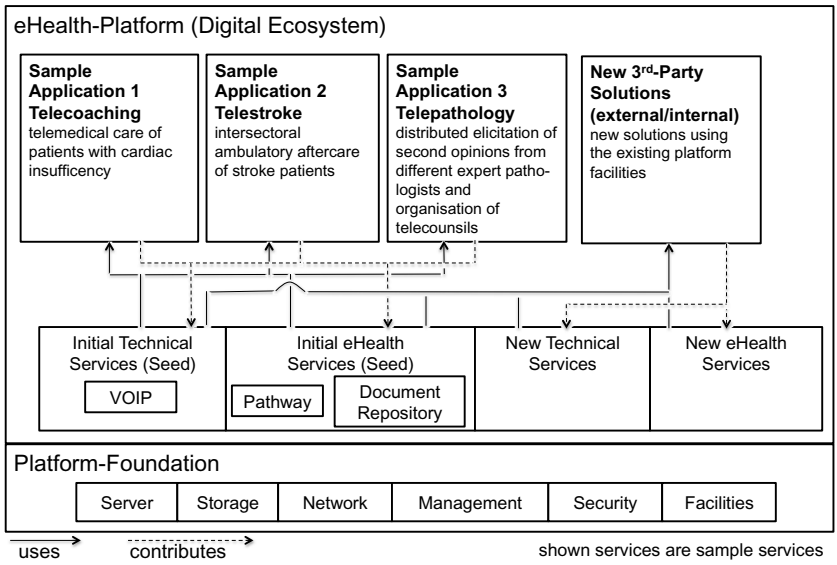

Figure 1: Structure of the eHealth-platform

university hospital. Our project tasks are to ensure the openness of the platform, to develop instruments supporting the participation on the ecosystem [14], and to design and cover the develop of ICT-supported pathway system helping to define internal and intersectoral process standards [15]. So, we are responsible to develop an accessible infrastructure that leads to a real eHealth ecosystem within the region of Saxony. Thus, a major task of our institute is keeping the representation of the interests of the public stakeholders that do not directly participate in the project, but which will have a benefit from the resulting platform in the future. It can be said, that our project role can be named as open systems advisor (in the following "advisor").

3. Results - Governance Guidelines for an Open E-Health Ecosystem

After presenting the case example and the underlying methodical approach, in the further course, particular the lessons learned of participation in a research are extracted and reflected. By describing different governance measures and deriving generic rules of technical governance, we focus on giving an outcome, which will foster similar work on building digital ecosystems in health care sector.

Figure 2 illustrates the major stages of building the infrastructure within the project context and its utilization (June 2015) in a simplified manner. All stages are covered by assessment or support activities that shall lead to an open (in terms of interoperability and expandability [10]), easily accessible platform. The different edges in Figure 2 show the typical governance process including related artifacts. The first edge (left side) represents artifacts, which we provide to the project partner for implementation. The second edge (middle) represents the deliverables of the project stages that are checked and evaluated (3rd edge) by our research institute.

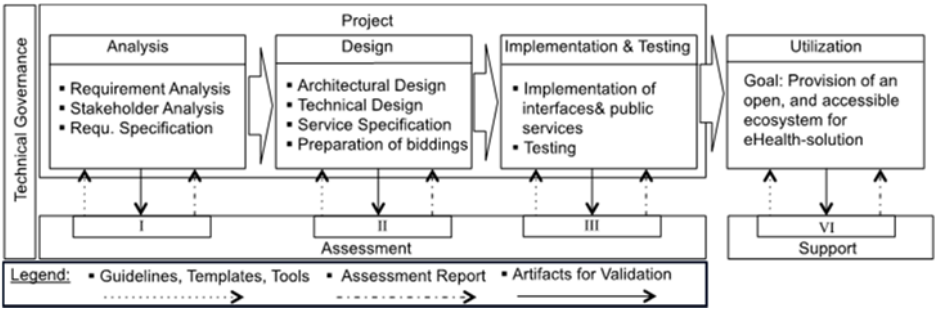

Figure 2: Technical Governance – outline of the governance interactions

Initial Governance Measures

As depicted in Figure 2, the governance measures covers permanently the building process. Therefore, it is common practice to explicate roles in a comprehensive project handbook, which contains rules for interaction, responsibilities and the organizational structure.

Governance Guideline 1 define the advisor role: Although, the creation of functional project units is not very innovative. We conclude that the implementation of an independent project unit responsible for ensuring openness (the advisor role), and a board with sufficient influence prevent the building a nonviable ecosystem (from technical viewpoint). These two instances implement transparent processes for discussion of issues like evaluation results, change requests or design decisions. These two roles are responsible to reflect the voice of 3rd-party providers, uninvolved healthcare facilities and citizens. The competencies and the possibility for influencing project decision should be formalized in an agreement document. Basic characteristics of these instances are: (1) neutrality, (2) low commercial dependencies to other stakeholders, (3) technical expertise in software- and eHealth-technology and a (4) sense for business-it-alignment.

3.1. Analysis Governance (I)

The analysis encloses the requirements engineering that generates the product specification and the system specification. Both types are developed for the sample applications and for the foundational platform. There is a requirements flow between the specifications of the sample applications and the requirements specification of the foundational platform.

The requirements elicitation is done in cooperation of end users or their representatives with requirements engineers of the responsible sample application developer. These two parties are interested in achieving a well-working application that supports the business cases of the end-users. Services realize the business functions specified in the business cases. The end-users and the requirements engineer do not necessarily consider similar generic business cases, that can be supported by a specific type of a service that may result from the elicited requirements. If the developers of the platform and the applications have interdependencies (i.e. requirements engineering for all parts is done by one company), the boundaries between the ecosystem entities may become blurred.

Governance Guideline 2 generalize requirements: The flow of requirements from application to platform specification must be reviewed for generic formulation.

Example Measures: (1) review for fine-grained referring standards (i.e. not only referring IHE (Integrating the Healthcare Enterprise) as standard but referring specific profiles and the specific actors), (2) review for universality of domain ontology models, (3) review for utility of functional requirements (i.e. does a address book service only allow one telephone number)

Governance Guideline 3 observe requirements elicitation: The requirements elicitation should be accompanied. References to business relevant standards should be given and end-user specific business cases should be enhanced with generic formulations from which generic functional requirements can be derived.

Governance Guideline 4 formulate 3rd-party objectives and requirements: Objectives and requirements of potential 3rd-party developers should be documented.

Example Measures: Usage of goal oriented requirements engineering [16] for formulation of objectives of 3rd-party providers

3.2. Design Governance (II)

The architectural specification defines technology decisions and fundamental principles of service implementation. Ferronato states that ecosystems need an enhanced architecture that considers the self-organizing aspect [9]. For a good adoption of the seed-services, it is important that they can be easily accessed and used as templates for further services. These objectives primarily depend on architectural decisions (i.e. central business model repository etc.). Furthermore, it is important, that architectural decision does not hinder 3rd-party-providers from using other technologies.

Governance Guideline 5 Review of the architectural specification: The architecture should be inspected for architectural patterns that foster expandability, flexibility and reusability. Constraints concerning interface design (i. e. documentation of interfaces, comprehensive data models) should be reviewed. The impact of architectural decisions for the 3rd-party-provider should be checked. The review should lead to claims (normative) and recommendations (informative) that have to be considered by the platform developer.

Example Measures: (1) use of a formal architecture review method (i. e. ATAM [17]) with scenarios from analysis phase, (2) identification of applied patterns (i.e. for distributed systems [18]), (3) formulation of change requests for architectural changes, (4) review of interface specification for discoverability [19]

Governance Guideline 6 Review universality of domain and message models: Check for realization of standardized domain and message information models and inspect the universality of these models in reference to the generic business cases.

Governance Guideline 7 Sensitize stakeholders for exchange context issues: Generate an understanding of the issues for interoperability (i.e. unknown communication partners, no possibility for bilateral negotiation).

3.3. Implementation Governance (III)

It is necessary to have an objective evidence for the openness of the platform. This fosters planning security for 3rd-party providers. Furthermore good solutions should be reusable by 3rd-party developers.

Governance Guideline 8 Introduce a certification program for the platform: A certification method should be introduced that enables an objective evaluation of the openness of the platform [10].

Example Measures: (1) The certification program should consider existing quality evaluation methods, (2) define own test cases, (3) define a certification process that includes a review of the architecture.

Governance Guideline 9 Review of artifact templates for reuse: Solution artifacts (i.e. document templates) should be reviewed if reusability is ensured.

Governance Guideline 10 Inspect developers test cases: The test-cases of the platform developers should be inspected, if they can be reused as evidence for openness.

3.4. Utilization Governance (IV)

The main questions in the stage of utilization are: how can we provide helpful instruments that foster the participation of additional organizations to the platform, and how do we assure the compliance with the objectives for openness? Since the beginning of the project, we decide to conduct a model driven design process consequently [14]. The method we applied is build for software solutions in eHealth. Therefore, we adapted the principles of a Model Driven Architecture (MDA) in our context. In particular, we add domain specific views and model elements as well as a comprehensive Computer Independent Model (see [14]).

Additionally, we develop a certification procedure, which all extensions (ecosystem entities) have to pass through [10]. With this certification, we define a minimum standard for interoperability and implementation conformance that we expect by all participants and define a quality label for entities of the ecosystem. Thus, prospective 3rd-party-developers can be assured that if their program shall cooperate with some existing services, it will be possible and assured.

A special issue is the handling and integration of existing legacy systems in the ecosystem. Therefore a phased plan is developed that allows classifying the maturity of a legacy system concerning their interfaces, exchange formats, documentation quality. With every update or extension of the legacy system, it can be used to derive necessary steps that integrate it deeper into the ecosystem.

Governance Guideline 11 Provision of implementation guides: It is helpful to support the access to the platform by giving a comprehensive tool chain (i.e. MDA [14]) as well as a documentation or specific development guides.

Governance Guideline 12 Provision of a transparent review process (i.e. certification): including a quality label for interoperable entities in ecosystem.

Governance Guideline 13 Strategy for legacy systems: It is recommended to define strategies for handling legacy systems within the ecosystem.

4. Discussion and Conclusion

In the paper, we focused on the presentation of different governance guidelines that have been reflected a real-world setting. They should be transferable and helpful to avoid incorrect measures in similar projects. However, from an idealistic viewpoint, it can be stated that the described guidelines are mostly consented knowledge, esp. for complex project settings, but they are also often not questioned from a scientific position. This, the paper contributes, based on the learning oriented ADR-method, by critically reflecting which consented knowledge is applicable for the development of an open eHealth platform in a descriptive way. Therefore, in further research, our contribution

can be used as an input for describing generalized rules for setup of eHealth platforms in quantitative empiric research project.

The practical contribution lies primary in the possibility to use the guidelines for similar project constellations. The project hasn't finished yet, so a final retrospective measurement of success is pending. Further research has to be done additionally by formalizing the stakeholder model and connecting the guidelines to this model. We plan to add specific governance methods to the guidelines as we have shown already in the exemplary measure.

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