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The Critical Role of Hospital Information Systems in Digital Health Innovation Projects

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Abstract—Societal demand and political support still drive researchers and practitioners to work in numerous initiatives to create Digital Innovations (DI) in healthcare. Despite all support, the problem of unsuccessful or not-satisfying translation of project outputs into the healthcare reality remains. One critical aspect is the integration of a DI into evolved Hospital Information Systems (HIS). As DI projects often are conducted in practice research consortia, such projects can provide close insights into real-world settings. Therefore, a rigor analysis is necessary, which we perform using the Action Design Research approach that helps to analyze the role of HIS in DI projects for healthcare. The main contribution of this paper is the detailed description of a context-specific framework for the formalization of learning plus a systematic presentation of enablers and barriers of DI projects in healthcare. The framework matches both a project management perspective by considering different stages of a DI project and an interoperability perspective as an overall key factor for successful implementation.

Keywords—Action Design Research; Digital Innovation; Hospital Information and Application Systems; Interoperability; Integrated Care

I. INTRODUCTION

Digital transformation in the healthcare sector is mainly driven by the implementation of Digital Innovations (DI) in care settings. Such DI projects aim to improve the quality of care, the efficiency as well as the access to medical treatment [1]. Despite all actions, the problem of unsuccessful or not-satisfying translation of project outputs into the healthcare reality remains [2], [3]. Not many project outputs achieve a positive productivity or a wide spreading market introduction. Several research papers with sociological nature or information system background have been already raised the critical question why such projects fail in implementation or what is necessary for their success [1]–[6].

Significant progress has been made in the exploration of success factors and barriers in the integration of healthcare projects but the role of Hospital Information Systems (HIS) for DI is still under-researched. As HIS are central to the information management in care settings and consequently influence the success of DI in this domain, further research efforts are needed in this area.

HIS consist of different actors and application systems, which might be affected by a DI. For example, the main application system in clinical care is the clinical

documentation system [7]. DI often consume data from or provide data to the different application systems. A poor integration into existing systems and workflows can have a negative impact on the perceived utility [4], [8]. Even if a specific technological artifact seems to be useful for a specific purpose, its use may be impractical in every-day-routine due to incompatible behaviors or cultural expectations [9].

Consequently, integrating DI into an existing HIS is a task which requires both technical efforts and the consideration of the socio-technological context. Hospitals manage their information systems in different ways and disparate application systems are combined in various complex permutations. Besides the technical integration, DI also need to be integrated into a social system of professional care processes with different actors and organizational restrictions. This leads to very heterogenous implementation contexts which makes the provision of generalized guidelines for the improvement of DI integration in HIS to a difficult task.

Existing research rather focus on a retrospective outcome-oriented investigation than take a dynamic perspective on how the HIS influences DI projects. Observations of practical projects can provide useful insights how the socio-technical context (the HIS) influences the integration of DI project through all project stages. These insights may lead to important entry points for the improvement of DI integration.

Based on a practice-oriented research methodology, this paper contributes formalized barriers and enablers which have been experienced in concrete DI projects. Further, this paper also shows how these barriers and enablers have been systematically identified and formalized. Therefore, the following research question is addressed: *Which enablers and barriers of HIS influence the success of DI projects in the healthcare and how can they be systematized?*

This paper is structured as follows: section II sets out the state of the art. In section III we explain the research method in more detail and focus on the theoretical background of a proposed framework to formalize learning according to Action Design Research (ADR). Afterwards, an overview of three of our current research projects is given before section IV discusses the observed acceptance effects, ambiguities and tensions. A brief discussion of our findings is presented in section V. Finally, section VI formulates the conclusion of our research work and gives an outlook on further research.

II. STATE OF THE ART

In the course of digitalization, the term ‘digital innovation’ is increasingly used in literature. FICHMAN ET AL. (2014) define DI ‘as a product, process, or business model that is perceived as new, requires some significant changes on the part of adopters, and is embodied in or enabled by IT.’ [17, p. 330]. CIRIELLO (2018) specifies the term IT in more detail by referencing to digital technology platforms that serve as a means or end in intra- or cross-organizational scenarios. DI differ from common innovations due to the use of digital technologies. Digital technologies have inherent characteristics that can change the nature of common innovations [11]. The characteristics are data homogenization, editability, reprogrammability, distributedness and a self-referential nature [12]–[14], which contribute to more open and flexible layered architectures [15]. The resulting DI have two central characteristics: generativity and convergence [16]. While the generativity is the capacity of a technology for unprompted changes [17], convergence means that non-digital artifacts get digitized [16].

HIS, as a pool of various existing digital technologies, provide an infrastructure for new digital technologies. Consequently, they can drive innovation in healthcare if they are developed to achieve generativity and convergence. In order to support all groups of people involved in clinical routine and daily work processes, the integration of the all application systems in the hospital has to be ensured. Against this background the concept of interoperability was established. By interoperability we mean ‘the ability of two or more systems or components to exchange information and to use the information that has been exchanged’ [26, p. 20]. Interoperability is realized in hospitals via data exchange mechanisms such as the use of a communication server, communication standards (HL7, DICOM, EDIFACT) or contextual integration [19], [20]. Interoperability occurs at different levels of the HIS. Consequently, the integration of digital technology may be influenced by interoperability-specific barriers [21].

Such barriers have already been described in detail in numerous research papers. While the majority of the authors are approaching the topic via literature research, the second strand of research is based on case studies especially interviews. For example, MAIR ET AL. (2012) address factors that promote or impede the e-health implementation on the basis of an explanatory systematic review. Determinants which influence a successful telemedicine implementation were identified by BROENS ET AL. (2007). Whereas OBSTFELDER ET AL. (2007) explore characteristics of successfully implemented telemedical applications. Within the context of an inductive theory-building process comprising two qualitative studies, URUEÑAA ET AL. (2016) identify organizational capabilities that e-health innovation projects require. In contrast, MURRAY ET AL. (2011) aim to explore and understand the experiences of implementers of e-health initiatives using semi-structured interviews.

We contribute to this existing research base by adding results from a more design-oriented research perspective. We observed barriers and enablers on a concrete level while being

involved in dynamic development processes in different stages of our DI projects. The researchers’ involvement in design interventions creates knowledge throughout an alternative methodological approach that enriches the existing body of research in that field.

III. METHOD

A. Application of Action Design Research

Enablers and barriers can be observed in organizational as well as technological settings and in the interplay of both. They can be seen as outcome of technology-in-practice-situations. However, not every enabler or barrier occurs explicitly as such if an expert is asked for naming them. Some may occur implicitly in behavioral patterns and latent social relationships [9].

Furthermore, not every enabler or barrier is relevant in each DI project stage. In particular, if the barriers and enablers will be the base for prospect design principles a deep knowledge about the design context is required [22]. One possible approach to generating knowledge is to go into the real field of action – a hospital. Consequently, we gain knowledge by participating in DI projects and analyzing them during their lifecycle and in their original socio-technical context.

Our research follows the ADR method. ADR starts from the fundamental position that artifacts are created in an organizational context and their design is influenced by researchers’ intent [23]. ADR can be used to gain generalized findings from an interpretivist perspective on socio-technological systems and can particularly be used to identify barriers and enablers in their context [24].

We apply the ADR method in three integrated care DI projects which are introduced later on. Figure 1 shows the instantiation of the different ADR stages for our research objective. On that note, it outlines our research agenda. The insufficient translation of DI project outputs into the healthcare reality forms the problem context (*ADR Stage 1 – Problem Formulation*). The research problem results from interoperability issues while integrating DI into existing HIS. We aim to identify enablers and barriers that influence the integration of DI into existing HIS. The HIS and its organizational capsule can be seen as the environmental context of an artifact that is created in a DI project. We systematize this context by defining different perspectives on HIS. In order to achieve a comprehensive picture, we apply an existing layer model from the field of interoperability.

In *ADR Stage 2 – Build, Intervention and Evaluation* the researchers act as participants in three projects. These projects aim to create DI for cross-institutional healthcare settings with different project consortia configurations. Considering that the found barriers and enablers should address a class of problems, we act in the projects as architects for interoperability and as researchers, who reflect the problem-solving activities in this role [23]. During the research projects, we iteratively participated in the integration efforts to launch the created DI in the clinical contexts. Thus, we were involved in discussions and processes of solution finding of HIS related topics. We created organizational as well as

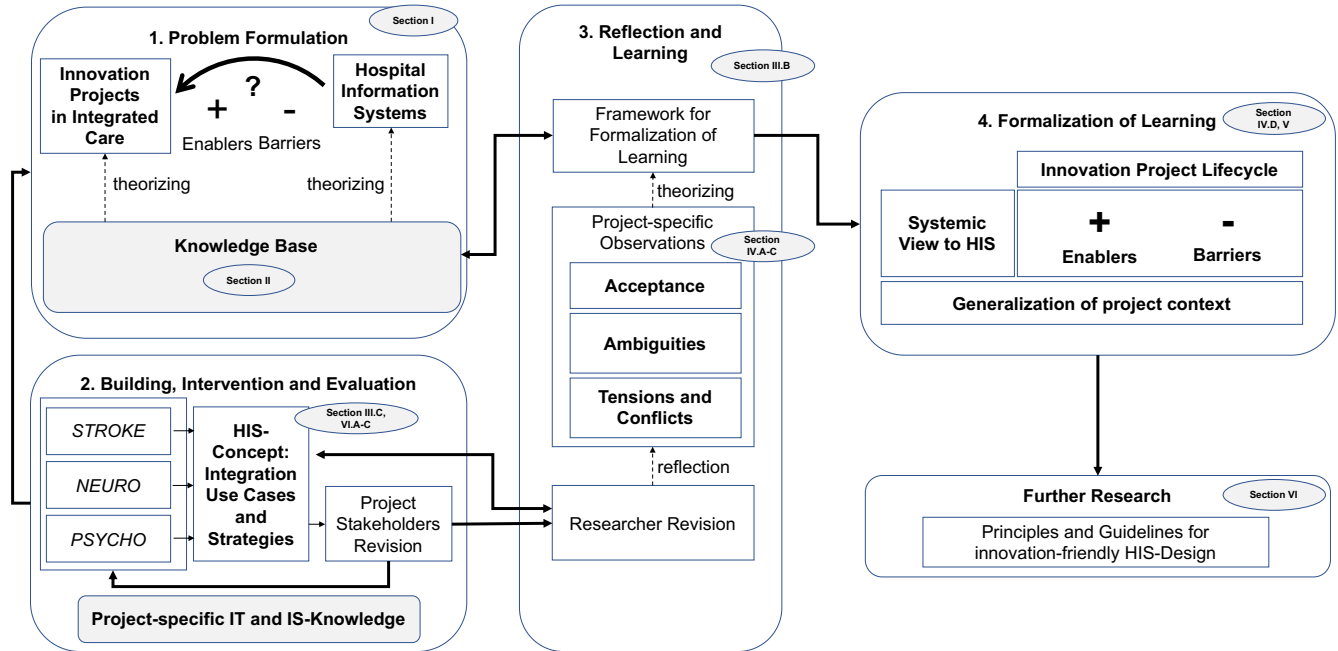


Figure 1. Research design, adoption of ADR method of SEIN ET AL. (2011)

technical concepts shaped through information system models and applied them for the concrete HIS of the project contexts. The information system models were discussed and revised in joined board meetings with the practitioners from the project consortia (see Table 1). The remarks of the project partners on the concepts and semi-formal models were recorded in protocols, notes and e-mail traffic (project documentation). The information system models consisted of use cases and strategies. These describe how a concrete aspect of a DI project could be integrated into existing business processes as well as into the application system environment.

In *ADR Stage 3 – Reflection and Learning* we analyzed the project documentation iteratively and classified the observations we made according to *acceptance effects*, *ambiguities* and *tensions*. We define *acceptance effects* as positive commitments of the practitioners regarding a proposed HIS integration conception. The acceptance of an integration use case or strategy (black boxes, e.g. ‘A1’) leads to design decisions (see Figure 2). These decisions transform the use cases and strategies (A1, B2, X1 in the figure) into

concrete system instantiations and to the integration of the DI into the HIS. If specific use cases and strategies were to imprecise from the practitioners point of view, they had to be refined. Consequently, we define *ambiguities* as discussion points that occurred in the revision meetings which lead to a more specific proposal for a HIS integration conception (B1 → B2 in the figure). A rejection of use cases and strategies by the practitioners lead to tensions which require the need for new integration use cases and strategies. We define *tensions* as issues that lead to a rejection of a specific part of the system concept and triggered a new proposal for a HIS integration conception (C1 → X1).

Finally, the observations are systematized by a theory-based framework containing the generalized barriers and enablers formulated on the basis of acceptance effects, ambiguities and tensions. The barriers and enablers are assigned to the combination of interoperability-specific views on HIS and DI project stages (*ADR Stage 4 – Formalization of Learning*).

B. Framework for Formalization of Learning

The framework we have developed is presented in Table II and considers two dimensions that are theoretically explained as follows. One dimension focuses on the different interoperability-specific views which can be applied to HIS. The other one focuses on life cycle stages of DI projects.

We adapted the interoperability-specific views on HIS from an existing interoperability framework. In the context of eHealth, several interoperability models have already been established, e.g. the ALT-Model, the eHealth European Interoperability Framework (eEIF) and the Antilope Model. While the ALT-Model focusses on application, logical and technical layer, eEIF regards the layers legal, organizational, semantic and technical interoperability. The Antilope Model is a refinement of the eEIF and contains six layers: legal and

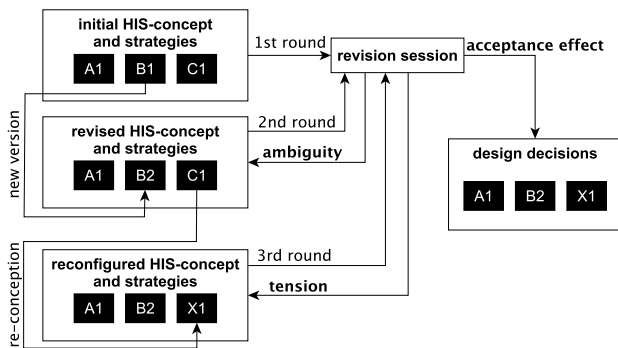


Figure 1. Instantiation of the build, intervention and evaluation-cycles

regulatory, policy, care process, information, applications, IT infrastructure [25]–[27]. We use the layers of the Antilope Model as it fits best to our research intention. On the one hand, it is based on an already established framework and is consequently accepted in the community with regard to its validity. On the other hand, the Antilope Model, as an extension of eEIF, provides a more granular view on healthcare interoperability. Below, the six layers are explained in more detail:

- Legal and regulatory: regional, national and international constraints due to laws and regulations
- Policy: definition of (contractual) agreements; purpose of cooperation, regulation of responsibilities, shared values and vision
- Care process: consideration of integrated supply routes and processes with regard to the required information
- Information: definition of the data model including the data elements and their links
- Applications: the way in which information is exchanged, integrated and processed
- IT-infrastructure: standards and protocols [28].

To determine the horizontal layers of the matrix, we focus on stages of a DI project lifecycle. Depending on the maturity of a project, different enablers and barriers can be identified in the collaboration of the project participants. According to PINTO AND PRESCOTT (1988) a project can typically be subdivided into four project stages mentioned below. For a detailed breakdown, explanation and separation of these project stages, we also consider the argumentation of MUNNS AND BJEIRMI (1996) who add the two factors ‘time’ and ‘parties involved’ [29].

- Conceptualization stage: determining of goals/project mission
- Implementation stage: definition of procedure to accomplish the goal

- Execution stage: planning becomes reality/delivery of the final ‘project result’
- Termination stage: use by customer/resolution of project [30].

Yet, all three projects are still running and did not reach the execution stage. Hence, only the first two stages are listed in the matrix to formalize project observations.

C. Practice Setting for Build, Intervention and Evaluation

As research group, we are currently involved in various projects and initiatives in the field of digital health and telemedicine. Our project partners are medical experts, technology partners like software developers, information management facilities of the hospitals and project management facilities. Some of them, in particular a medical case record provider and the local university hospital, participate in several projects with us. Three of these projects have been chosen as explanatory use cases for this ADR-based study. On the one hand, all three projects have in common that they aim to the development of at least one DI in healthcare for an integrated care setting, its diffusion into the healthcare reality and therefore its integration into the existing information system landscape with one or more HIS. As a common DI, all projects aim to integrate a disease-specific case record with an existing telehealth platform for interorganizational exchange scenarios. On the other hand, each project is connected to a specific disease and requires a different problem-solving approach and other IT artifacts in particular. Thus, the selected projects match generally the described problem area while they differ in their internal structures and how they are affected by the HIS. The three projects are introduced below and summarized in Table I.

In a past project with medical members of an existing stroke network, a reference application for information and communication technology supported care of acute strokes in a clinical context was developed. In context of this past project, a digital telehealth platform was developed as a technological basis for future applications. The three projects

TABLE I. DIGITAL INNOVATION PROJECTS AS RESEARCH BACKGROUND FOR STAGE 2 OF ADR

| Name | Project Description | | | |
|--------|--|---|-----------------------|---|
| | Care Innovation | Information System Artifact | Medical Domain | Participants |
| STROKE | Improving aftercare management by integrating general practitioners | Integration infrastructure for application systems of physicians | Stroke Aftercare | <ul style="list-style-type: none"> · Medical experts from university hospital · General practitioner · Physicians from care center · Provider of stroke aftercare documentation system and integration platform · Communication server provider |
| NEURO | Patient engagement into care processes by an integrated patient portal | Patient portal, interorganizational case record | Neurological Diseases | <ul style="list-style-type: none"> · Medical experts from university hospital · Provider of neurological documentation system · Provider of clinical documentation system · Provider of case record system · Information systems department of university hospital · Developers of patient portal |
| PSYCHO | Cross-institutional information, communication and knowledge sharing between medical experts via a digitized network | Interorganizational case record, integrated professional tools, Mobile Apps for intraclinical assesment | Psychological Care | <ul style="list-style-type: none"> · Medical experts from multiple hospitals · Provider of clinical documentation system · Provider of case record system · Information systems department of university hospital · Mobile app developers |

use parts of this platform to implement DI for the healthcare sector.

Project STROKE aims to the informational connection between the platform with its stroke-specific services and systems of General Practitioners (GP) as well as specialists in ambulatory aftercare. It uses the outcomes of the past project mentioned above to innovate the care process by providing an integrated information flow between case managers and GPs. Center of this communication scenario is a stroke-specific Clinical Document Architecture (CDA) document which is collaboratively used by all involved care providers of the stroke aftercare.

Project NEURO deals with the development of an integrated care portal for patients with a chronic neurological disease. The main goal is to create a better connection between professionals and their patients as well as (informal) supporting care providers. Thus, patients and relatives will be better supported in managing their chronic illness. Portal users get access to their medical records and are able to use individual, context-sensitive services e.g. reminder features for medication or for therapeutic exercises and specific questionnaires.

Project PSYCHO aims to an improvement of the interorganizational treatment of psychotraumatological diseases. Modern information and communication technology will be used to optimize the communication of all involved professionals even over relatively long distances. As a result, case specific documentation will be available across institutions. Additional tools and procedures for standardized screening and diagnostic will be developed and evaluated.

IV. OBSERVED ACCEPTANCE EFFECTS, AMBIGUITIES AND TENSIONS

In the following, we explain different activities that were conducted in different DI project stages and describe the resulting observations we identified during revision sessions. One activity may lead to multiple observations. Further, we justify our decision whether these observations have been interpreted as a barrier or an enabler. Therefore, we clarify whether the observation was experienced as an *acceptance*, *ambiguity* or *tension* (see Figure 2). *Acceptances* indicate enablers while *tensions* indicate barriers. *Ambiguities* are seen as something in between and have to be discussed more in detail to elucidate how they effected the DI project. Different observations may lead to the same barrier or enabler. Finally, the described enablers and barriers are formalized represented in Table II. The explanation follows the order of the introduced projects. Content-related overlaps are indicated and generally reasoned by the parallelism of the project's work tasks.

A. Project STROKE

Activities: To face different technological conditions on the side of the GPs that have to be integrated, we conceptualized a stage model of digital integration of GPs. Four stages represented four different integration levels into the integrated care scenario. The full integration enables a structured communication of electronic documentation. The minimal integration is realized via an easy-accessible web-

frontend for the GPs. We described communication scenarios as well as information and documentation flow charts for each level. Further, we specified an electronic stroke passport as an interface specification between the documentation systems of the GPs and the case management documentation software. This passport was specified based on the CDA standard [31]. The stage model as well as the CDA interface specification were presented and discussed with the project partners, doctors and the case managers as part of a review process.

The realization of the integration levels mentioned above required extensions or changes of an existing integration platform which interacts as the technological basis (output of a former project). Furthermore, existing documentation software at the GPs office has to be integrated with the documentation software of the case managers, which is located in the HIS. The integration has been made via a central platform infrastructure. Therefore, negotiations with the provider of the established stroke aftercare documentation system and of the case record system have been conducted which unfold technological possibilities and needed efforts.

Observations: The proposed stage model has received a high acceptance both by the technical providers as well as the medical experts. The medical experts from the university hospital also mentioned that the suitability of the intended digital integration is a crucial factor for the further support by themselves as well as by higher hospital management. Additionally, meetings with GPs and other resident neurologists of the ambulatory aftercare confirmed the assumption that an approach for different digital integration levels is needed because the maturity of the digital infrastructure differ between the GPs.

The hospitals' information systems department is not the physical owner of the integration platform. In addition, the use of the existing platform to reach the project's goals was set as a duty. In fact, there was a high dependency on the provider of the existing stroke aftercare documentation system and the integration platform. This led to the tension, that the provider had problems in separating the integration development tasks from the tasks to extend the existing aftercare documentation system with new features. This results in a slowdown of the conception process.

The case managers that use the existing aftercare documentation system stated that the system suffers from many issues like impractical graphical user interfaces, missing integration with other operative application systems and a very sticky bug-fixing by the provider. Unfortunately, proper corrections have not been realized so far. Thus, they rated the existing system as inconvenient and clumsy. The realization of the proposed concept should include the correction of these issues. Thus, the rather negative experience of the case managers with the technology provider leads to negative perception of the proposed integration concepts.

The technical documentation of the integration platform and the aftercare documentation system were available and described the interfaces. However, the existing interfaces did not fit directly to the GPs' application systems. Unfortunately, the technical documentation did not explain how the platform

can be extended by new interfaces or adapters which fit to the GPs application system interfaces.

In addition, the cooperation with the aftercare documentation system providers is characterized by complex contractual conditions. The offered service is characterized by a high price and little transparency which impedes the cooperation between science and industry. Further tensions grow from the general technological possibilities and their financial affordability.

Last but not least, all negotiations with the aftercare documentation system and integration platform provider were highly time consuming because detailed technological knowledge was only accessible via individual employees and their availability was also limited. Additionally, the provider assigned a subcontractor to realize the integration into the GPs application systems. The project consortium could only communicate with the subcontractor indirectly via the platform provider which also had a delaying effect.

B. Project NEURO

Activities: One key feature of the patient portal is the patient's access to his or her individual medication plan. The patient should be able to get both an overview of all prescribed medication and a today's medication plan. Therefore, we proposed the implementation of a CDA-based implementation guide¹ for medication plans. This standard is based on consensus of a national committee of physicians and includes the human-readable representation as a table as well as structured data. We suggested the use of this standard to the medical experts as well as to the neurology documentation system provider and the patient portal developers.

Another use case describes the communication of patient-tasks between a clinical documentation system for neurological diseases and the patient portal. In order to achieve a common interface between these systems, we proposed the use of HL7 FHIR² as standard for the data exchange. We created a detailed interface specification. Therefore, we had regular communication with the senior developer of the neurological documentation system provider. We created examples and explained how we ensure genericity of the interface concept. The specifications contained diagrammatical representations (UML component and sequence diagrams) how the tasks, e.g. answering a digital questionnaire, should be transferred.

In this project (and also in project PSYCHO) we provided a concept to create an interorganizational case record. This concept comprises use cases that describe the actions of partners in a cross-institutional healthcare network. The concept also comprised interface definitions that reference the IHE XDS.b-standard, which is a standard for sharing documents through a repository-based infrastructure [32]. The central repository of case record provider supports this standard as well as HL7 Version 2-based communication.

Observations: The use of the nationwide standard for medication plans into the intended patient portal was

accepted, even highly appreciated, by the medical experts from the university hospital. General background of this observation is that the realization of the mentioned medication plan is political demanded on a national level and well known by the medical experts. The fitting CDA technical standard for the medication plan is available through the HL7 user group. The use of this standard offers therefore advantages from multiple perspectives especially in the context of a sustainable interoperability with different HIS. The medication plan standard is not disease-specific. Thus, it can also be used in future projects. Otherwise, the implementation of the medication plan CDA specification was not available in the participating documentation systems. Consequently, we proposed an integration adapter which is able to receive different formats (proprietary as well as FHIR) that represent medication data and integrate them into the patient portals medication plan representation.

While reviewing our concepts with the provider of the neurological documentation system, the senior developer accepted the specification without the need for revision. He saw the use of the CDA-standard for medication plans and of HL7 FHIR as an opportunity to improve the interoperability of his own product. The examples allowed the provider to create an own test environment with sample data and led to a better understanding of the specification.

Principally, the conceptualized use cases for the interorganizational communication have been accepted by the information systems department, the management and the medical experts of the university hospital. They gave their organizational commitment to implement these use cases. However, the technological specification, the proposed IHE XDS.b-based interorganizational case record concept, was rejected by the information systems department of the hospital because they are currently revising their IT-management strategy and haven't made decisions regarding new interfaces so far. Additionally, the inflexibility of the existing clinical documentation system to deal with new interfaces constituted another tension with the same result: The initial interface concept of using IHE XDS.b-standard was not realizable. Consequently, we only were able to deal with existing interfaces of the clinical documentation system and that only allows HL7 Version 2 MDM-messages for document sharing. Hence, we had to revise the concepts and specify an MDM-based solution for document communication which finally led to a positive commitment of the information systems department regarding feasibility.

Two more tensions have been experienced while developing an interface concept for the interorganizational information exchange. First, the information systems department was highly restricted in its resources and capabilities. Thus, it was limited in the creation of own interfaces by customization functionalities the existing system may offer. Second, we experienced a lack of available knowledge about the clinical documentation system in its breadth and detail. Consequently, we had to make assumptions how the clinical documentation system and its

¹ http://wiki.hl7.de/index.php?title=IG:Patientenbezogener_Medikationsplan_Plus

² Health Level 7, Fast Healthcare Interoperability Resources, <https://www.hl7.org/fhir/>

existing interfaces are designed. Some of those had to be corrected late in the discussions which results in late reconfiguration efforts.

C. Project PSYCHO

Activities: As mentioned above, we provided for PSYCHO (as well as for NEURO) a concept for an interorganizational case record. Within this concept we explained that medical documents need to be transferred on IHE ITI XDS.b-basis. In other words, we technologically specified how structured and non-structured documents have to be accessed and added. Thus, we proposed a document-based information exchange for the healthcare professionals.

Early in the conceptualization stage of the project, we collaboratively organized a focus group workshop with our medical project partner to which we invited multiple psychotraumatological care provider from different institutions. All of them are experts in our care scenario but have different roles within the care process. Together, we discussed and specified the interorganizational care process as well as particular stages. Additionally, we talked about medical and therapeutic documents as content for the central case record. Thereby, we identified various documents, defined whether those should be structured documents or not and discussed their priority for the project scope. Results have been documented and used in further work.

Besides improvements of the professional communication and collaboration, PSYCHO also aims to innovative telemedical scenarios to ease the access for the patients to psychotraumatological treatment. Therefore, we summarized multiple telemedical alternatives in a concept for online therapy. We added context specific details, use cases and activity diagrams to specify the different options. The concept included for example web-based video appointments in different settings, an online application for writing therapy and a software tool to support standardized structured interviews.

Another part of the project is the development of supporting mobile apps for the professionals. One app offers digital questionnaires for the patients which they may have to fulfill just before an appointment in a psychological department of the care network. For these apps, we provided guidelines how interfaces should be implemented. During the discussion with the information systems department, we had to clarify the position of the apps in the overall HIS architecture and in a further round we had to describe the communication flow between the apps and the clinical documentation system. Furthermore, we had to integrate a use case and process model to explain how the apps are used in a practical setting.

Observations: While reviewing the concept of the interorganizational case record, the medical experts expected that this also comprises the export and import of structured data in particular from and into the clinical documentation system. However, the provider of the clinical documentation system does currently not provide an interface to read and write machine-readable documents. As a consequence, we added a two-staged approach which prioritized first the

physical integration of human-readable documents through an interorganizational infrastructure and second a concept for reading and writing machine-readable documents based on CDA. This observation was experienced as an ambiguity because on the one hand different interpretations of the project scope needed to be aligned which caused extra efforts. On the other hand, the resulting refinement of the concept offers future advantages.

With a look of the conducted focus group workshop, only positive feedback has been identified. The feedback includes the acceptance of the interorganizational health care processes as well as the defined and primary prioritized documents, e.g. a doctor's letter with disease specific attributes. Furthermore, we observed a high commitment and motivation of all participants for the project in general and for further collaboration. This acceptance is needed when the concepts have to be realized and enabled for all members of the interorganizational care process. The realization has to be suited for all involved care providers and thus it has to fit in their HIS. Even though this acceptance is a quite strategic and social observation it is seen as a necessary aspect to ensure the interoperability of the DI project with involved HIS.

In the context of the proposed concept for online therapy, we made different observations. The legal circumstances for web-based video appointments are currently in change. In fact, some scenarios we wanted to support with this technology were not realizable from a legal status quo perspective but may be possible soon. This uncertainty was a reason of rejection for both the information systems department and possible service provider. Hence, we observed this aspect as a tension. The included alternative of an online application for writing therapy represents another ambiguity. In the initial project conception, this was not even mentioned by the medical project partner. It occurs pretty much spontaneously and caused additional efforts of specification and coordination. On the other side, this alternative enhanced the portfolio of online therapy. This leads to an observed acceptance. The broad range of alternatives brought advantages for the project. The project consortium was able to select and prioritize the alternatives that should be implemented. Furthermore, when recognized that one or more alternatives could not be realized other alternatives could get in the scope. Thus, the overall goal of creating DI to support the specific care process in different phases with different technological approaches could be guaranteed despite all difficulties.

After the discussions about the mobile app, multiple ambiguities have been observed. They all have in common that they resulted in additional efforts but which, at the end, enabled the continuity of the app development. First, the role of the mobile app in the care scenario as well as in the technical infrastructure was unclear to the managers of information systems department. Additionally, an unknown questionnaire service already exists within the HIS which almost led the managers of the information systems department to a rejection of the intended app. Therefore, we had to create a clear role description, a list of requirements for the implementation and UML sequence diagrams to clarify the scenario. Second, the assumptions of the medical experts

TABLE II. FRAMEWORK FOR FORMALIZATION OF LEARNING

| Interoperability-specific views on HIS | DI project stages | |
|--|---|---|
| | Conceptualization | Implementation |
| Legal and regulatory | E: Prominent use of standards required by law B: Legal uncertainty | |
| Policy | E: Professional users engagement E: Openness for new DI artifacts B: Missing interface strategies B: Divergent DI project interpretation | B: Contractual dependency to technology provider B: Insufficient collaboration with subcontractor B: Prejudices of future users B: Misconception of organizational collaboration |
| Care process | E: Concerted definition of care process with involved care providers | |
| Information | E: Concerted definition & prioritization of case record content with involved care providers | B: Faulty data models in existing systems |
| Applications | E: Suitability for various technological conditions E: Range of alternatives to reach goals B: Inflexibility of existing systems | B: Uncertain role of application within information system landscape |
| IT-infrastructure | B: No or outdated standards in existing systems | E: Proposal and use of established standards B: Technical lock-in effect |

Legend: E: Enabler; B: Barrier

about the cooperation with the information systems department did not fit the reality. This was reasoned on one side by ambitious expectations about the technology as well as about the information systems department capabilities and on the other side by a lack of transparency about them during the initial conception round. Hence, we had to mediate the expectations of the medical experts with the capabilities of the information systems department. However, there were internal directives and organizational behaviors that impeded the progress. Third, one intended feature of the app is an export function of a fulfilled and analyzed questionnaire. But currently, the clinical documentation system is not able to import structured data from apps. Therefore, we had to specify a fall-back option in a new integration use case. Fourth, our provided implementation guidelines dealt with communication standards that were not known to the app developers. Hence, we had to introduce them before we could integrate them into the implementation work.

D. Formalization of Observations

At this point, the principle and illustrating examples are given how we formalized our project observations and how we integrated them into the proposed framework. The observations mentioned above have been interpreted by three researchers independently. Each researcher decided whether he or she interprets the observation as acceptance effect, ambiguity or tension as it is methodologically described in section III.A. (ADR Stage 3). Further, each researcher summarized the essential reason for this decision. Thereby, they pay particular attention to the balance between a concrete naming of the observation and the required level of abstraction. Afterwards, a group session was conducted to build a consensus out of the individual results and to eliminate redundancies. The group session was especially necessary for the decision whether an *ambiguity* was interpreted as an

enabler or a barrier. Additionally, the group decided in league about the allocation to the interoperability views. At the end, eight enablers and twelve barriers have been identified, named and integrated into the proposed framework (see Table II.)

One illustrating example is given by the enabler ‘prominent use of standards required by law’ that we experienced in the conceptualization stage of the project NEURO while proposing the use of a standardized medication plan. Even though a law which set it as a general duty does not exist in particular, the use of this standard is nationwide demanded by multiple medical regulations. Thus, a prominent positioning of this topic in our concept reasoned a high commitment of our medical project partners. An allocating to the layer ‘IT infrastructure’ could have been also possible. However, the researchers stated that the crucial reason of acceptance in this context was the regulatory demand and not the standard itself. This reasoned the classification into the layer ‘Legal and regulatory’.

Providing further examples, we had to experience *tensions* multiple times that resulted from legacy issues in existing systems. These issues affected our work negatively in both conceptualization and implementation of the specific DI. Thus, barriers according to existing (technical) systems are stated in both columns of our framework. In more detail, we differentiated these barriers because they address different interoperability aspects. Consequently, a faulty data model of a software artifact was allocated to the view ‘Information’, the inflexibility of an application system to define new interfaces to the view ‘Applications’ and no or obsolete standards used to the view ‘IT-Infrastructure’. Surely, a generalization of these observations to an overall barrier like ‘issue with technical circumstances’ would be correct. However, we argue that the closer consideration offers advantages for the practical usage of our results as well for further research.

V. DISCUSSION AND LIMITATIONS

Our framework for formalization of learning clearly highlights the value that results from the application of ADR. A summary of the observations from three different DI projects facilitates the identification of a multitude of possible barriers and enablers at various levels of interoperability. In addition, our findings are characterized by a high practical relevance – without neglecting the generalization of the results (see section VI. D.).

However, our results should be viewed in the light of some limitations. On the one hand, the limitations of this work can be attributed to the research method including the selection of the three dedicated projects. On the other hand, limitations arise for the interoperability framework used.

We have shown how an ADR-based research method can be used in HIS-integration projects and proposed a conceptual model how barriers and enablers can be identified. Yet, a repeated methodological criticism of ADR is a limited extent of objectivity and validity of the results [33], [34]. Although these limitations have to be considered when assessing our research achievements, the methodological advantages and their concrete design in our research setting have to be emphasized. With the help of ‘only’ three projects we can gain a broad spectrum of knowledge. In addition, we would like to point out that our findings are based exclusively on what we have observed in the course of the three projects. Insofar, no claim can be made to completeness regarding all conceivable barriers and enablers [35]. All DI projects are currently in progress, whereas none of the three projects is yet in the project stage of execution or termination. Thus, our framework for formalization of learning cannot be finalized at this moment with content for all essential innovation project stages (see section V).

We identified a range of enablers and barriers of DI in HIS with our instantiation of ADR. According to our understanding that both HIS and DI are socio-technical constructs, these are not exclusively technological. Therefore, the systematization via the Antelope Model helped to achieve different views to our DI projects. However, the interoperability framework did not provide an explicit view to social aspects without a technology relation. Therefore, it was difficult to classify such social observations, e.g. ‘insufficient collaboration’, in our framework. Furthermore, a few observations, e.g. ‘insufficient technical documentation about existing system,’ could not be allocated into the framework as they do not fit into one single layer of the Antelope Model. An extension of the model plus an analysis using a social theory could improve the understanding of this kind of effects, that also occur when integrating DI into HIS.

Considering the generativity of the HIS, the integration of DI can be seen as unprompted change. The range of barriers and enablers shows that the generativity depends both on adequate technology selection as well as to anticipate social and organizational effects. For example, the prospective planning of integration strategies and corresponding interfaces for unanticipated DI projects may support innovators integrating their solutions into the HIS. Particularly, platform-oriented approaches can help to

develop DI-friendly HIS, because these approaches directly propose openness and evolvability [36].

VI. CONCLUSION

HIS stay an important hub for healthcare information processing even in interorganizational care provision. Therefore, DI has to be integrated into these complex systems, consisting of different information processing actors and application systems. Based on an ADR approach our paper shows which barriers and enablers may occur. We show, how barriers and enablers can be gained from a practice setting and we identified a non-exclusive set of those, which we observed in our projects.

Our research contributes to theory by formalizing existing barriers and enablers from a practical setting. Researchers can use them to organize new research agendas. For example, the barriers and enablers can be used to describe semi-structured interview guidelines. Furthermore, design oriented-researchers can use them to generate problem classes and describe the environmental context of a designed artifact that addresses a specific problem class. Furthermore, the enablers and barriers can help to describe descriptive design knowledge. For example, they can be used in pattern languages to identify design problems and solutions.

For practitioners, the barriers can help to identify issue points at an early stage in DI projects. Enablers can help them to create an innovation-friendly environment for DI projects in hospitals. Hospital managers and CIOs can use the barriers and enablers as a qualitative benchmarking-indicators and to describe strategic measures that address barriers and utilize enablers as templates for own project set-ups. The results of the three projects can help new DI projects to avoid unintended effects.

In further research the analysis of enablers and barriers in the execution and termination stage is necessary. The next steps are to check the findings against experts’ opinion in the form of an interview. In doing so, our leading objective is to identify a weighting of barriers and enablers as well as to consider their interaction. An interesting question might be whether there are conflicting goals between the individual barriers and enablers. In a concluding step we plan to derive recommendations and guidelines for the DI-friendly implementation of HIS.

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