Rethink Digital Health Innovation – Understanding Socio-Technical Interoperability as Guiding Concept

by

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Prolog

"Verbunden werden auch die Schwachen mächtig."
aus "Wilhelm Tell" von Friedrich Schiller

"Wir sind nur so stark, wie wir vereint sind und so schwach, wie wir getrennt sind."
Albus Dumbledore in "Harry Potter und der Feuerkelch" von J.K. Rowling

"Der Humor ist der Regenschirm der Weisen."
Erich Kästner

Liebe Leserin, Lieber Leser,

in den letzten fünf Jahren hatte ich das Privileg, mich unterschiedlichsten Themen durch die Brille der Wissenschaft widmen zu können. Meistens waren diese Themen mit der Frage verbunden, wie man mit aktuellen, digitalen Technologien die gegenwärtige und zukünftige Gesundheitsversorgung verbessern kann. Dieses Privileg, wenngleich es durchaus Phasen gab, in denen ich es nicht als eines empfinden konnte, besticht meines Erachtens nach durch zwei Aspekte. Einerseits - auch wenn es pathetisch klingen mag - ist es die Freiheit, sowohl zeitlich als auch inhaltlich wenigen (bis keinen) Grenzen ausgesetzt zu sein. So war es mir möglich, vielen Einzelfragen nachzugehen, ihre Zusammenhänge zu untersuchen und diverse Perspektiven einnehmen zu können. Andererseits erwächst aus dieser zeitlichen und inhaltlichen Freiheit eine individuelle Qualifizierung, die weit über die Fachinhalte eines Promotionsthemas hinausragen. Neben der Aneignung konkreten Wissens über den Themenbereich „Digitalisierung im Gesundheitswesen", konnte ich zahlreiche, weitere Kompetenzen ausbauen, welche ich ohne den Weg der Promotion nicht in vergleichbarem Maß hätte stärken können. Darunter zähle ich insbesondere Kenntnisse der Wahrheits- und Wissenschaftstheorie, die Fähigkeit, Multiperspektivität und Interdisziplinarität zu organisieren sowie das Balancieren von Relevanz und Rigorosität in allen Tätigkeiten. Gerade die letztgenannte Waage ist ein vieldiskutiertes Thema meiner Disziplin der Wirtschaftsinformatik (oder eben auch des Information Systems Research). Während diese Dissertation in Ihrer Gesamtheit nach einem angemessenen Gleichgewicht sucht, möchte ich in diesem Prolog die Seite der „Relevanz" als besonderen Aufhänger nutzen und zwar in doppelter Hinsicht.

Zunächst ist es mir ein erstes Anliegen, in möglichst verständlicher Form mein Promotionsthema und wesentliche Erkenntnisse meiner Arbeiten zusammenzufassen. Denn das Weltgeschehen der vergangenen fünf Jahre hat mich für den Kommunikationsauftrag der Wissenschaft sensibilisiert. Ich empfinde es daher als besonders relevant, jeder Leserin und jedem Leser meine Erkenntnisse zugänglich zu machen, insbesondere denjenigen, die mit weniger

Vorwissen in meinem Themengebiet ausgestattet sind. Also, worum geht's?

Diese Dissertation sucht nach einem theoretischem Grundgerüst, um komplexe, digitale Gesundheitsinnovationen so zu entwickeln, dass sie bessere Erfolgsaussichten haben, auch in der alltäglichen Versorgungspraxis anzukommen. Denn obwohl es weder am Bedarf von noch an Ideen für digitale Gesundheitsinnovationen mangelt, bleibt die Flut an erfolgreich in der Praxis etablierten Lösungen leider aus. Dieser unzureichende Diffusionserfolg einer entwickelten Lösung - gern auch als Pilotitis pathologisiert - offenbart sich insbesondere dann, wenn die geplante Innovation mit größeren Ambitionen und Komplexität verbunden ist.

Dem geübten Kritiker werden sofort ketzerische Gegenfragen in den Sinn kommen. Beispielsweise was denn unter komplexen, digitalen Gesundheitsinnovationen verstanden werden soll und ob es überhaupt möglich ist, eine universale Lösungsformel zu finden, die eine erfolgreiche Diffusion digitaler Gesundheitsinnovationen garantieren kann. Beide Fragen sind nicht nur berechtigt, sondern münden letztlich auch in zwei Forschungsstränge, welchen ich mich in dieser Dissertation explizit widme.

In einem ersten Block erarbeite ich eine Abgrenzung jener digitalen Gesundheitsinnovationen, welche derzeit in Literatur und Praxis besondere Aufmerksamkeit aufgrund ihres hohen Potentials zur Versorgungsverbesserung und ihrer resultierenden Komplexität gewidmet ist. Genauer gesagt untersuche ich dominante Zielstellungen und welche Herausforderung mit ihnen einhergehen. Innerhalb der Arbeiten in diesem Forschungsstrang kristallisieren sich vier Zielstellungen heraus: 1. die Unterstützung kontinuierlicher, gemeinschaftlicher Versorgungsprozesse über diverse Leistungserbringer (auch als inter-organisationale Versorgungspfade bekannt); 2. die aktive Einbeziehung der Patient:innen in ihre Versorgungsprozesse (auch als Patient Empowerment oder Patient Engagement bekannt); 3. die Stärkung der sektoren-übergreifenden Zusammenarbeit zwischen Wissenschaft und Versorgungpraxis bis hin zu lernenden Gesundheitssystemen und 4. die Etablierung daten-zentrierter Wertschöpfung für das Gesundheitswesen aufgrund steigender bzgl. Verfügbarkeit valider Daten, neuen Verarbeitungsmethoden (Stichwort Künstliche Intelligenz) sowie den zahlreichen Nutzungsmöglichkeiten.

Im Fokus dieser Dissertation stehen daher weniger die autarken, klar abgrenzbaren Innovationen (bspw. eine Symptomtagebuch-App zur Beschwerdedokumentation). Vielmehr adressiert diese Doktorarbeit jene Innovationsvorhaben, welche eine oder mehrere der o.g. Zielstellung verfolgen, ein weiteres technologisches Puzzleteil in komplexe Informationssystemlandschaften hinzufügen und somit im Zusammenspiel mit diversen weiteren IT-Systemen zur Verbesserung der Gesundheitsversorgung und/ oder ihrer Organisation beitragen.

In der Auseinandersetzung mit diesen Zielstellungen und verbundenen Herausforderungen der Systementwicklung rückte das Problem fragmentierter IT-Systemlandschaften des Gesundheitswesens in den Mittelpunkt. Darunter wird der unerfreuliche Zustand verstanden, dass unterschiedliche Informations- und Anwendungssysteme nicht wie gewünscht miteinander interagieren können. So kommt es zu Unterbrechungen von Informationsflüssen und Versorgungsprozessen, welche anderweitig durch fehleranfällige Zusatzaufwände (bspw. Doppeldokumentation) aufgefangen werden müssen. Um diesen Einschränkungen der Effektivität und Effizienz zu begegnen, müssen eben jene IT-System-Silos abgebaut werden. Alle o.g. Zielstellungen ordnen sich dieser defragmentierenden Wirkung unter, in dem sie 1. verschiedene Leistungserbringer, 2. Versorgungsteams und Patient:innen, 3. Wissenschaft und Versorgung oder 4. diverse Datenquellen und moderne Auswertungstechnologien zusammenführen wollen. Doch nun kommt es zu einem komplexen Ringschluss. Einerseits suchen die in dieser Arbeit thematisierten digitalen Gesundheitsinnovationen Wege zur Defragmentierung der Informationssystemlandschaften. Andererseits ist ihre eingeschränkte Erfolgsquote u.a. in eben jener bestehenden Fragmentierung begründet, die sie aufzulösen suchen.

Mit diesem Erkenntnisgewinn eröffnet sich der zweite Forschungsstrang dieser Arbeit, der sich mit der Eigenschaft der „Interoperabilität" intensiv auseinandersetzt. Er untersucht, wie diese Eigenschaft eine zentrale Rolle für Innovationsvorhaben in der Digital Health Domäne einnehmen soll. Denn Interoperabilität beschreibt, vereinfacht ausgedrückt, die Fähigkeit von zwei oder mehreren Systemen miteinander gemeinsame Aufgaben zu erfüllen. Sie repräsentiert somit das Kernanliegen der identifizierten Zielstellungen und ist Dreh- und Angelpunkt, wenn eine entwickelte Lösung in eine konkrete Zielumgebung integriert werden soll. Von einem technisch-dominierten Blickwinkel aus betrachtet, geht es hierbei um die Gewährleistung von validen, performanten und sicheren Kommunikationsszenarien, sodass die o.g. Informationsflussbrüche zwischen technischen Teilsystemen abgebaut werden. Ein rein technisches Interoperabilitätsverständnis genügt jedoch nicht, um die Vielfalt an Diffusionsbarrieren von digitalen Gesundheitsinnovationen zu umfassen. Denn beispielsweise das Fehlen adäquater Vergütungsoptionen innerhalb der gesetzlichen Rahmenbedingungen oder eine mangelhafte Passfähigkeit für den bestimmten Versorgungsprozess sind keine rein technischen Probleme. Vielmehr kommt hier eine Grundhaltung der Wirtschaftsinformatik zum Tragen, die Informationssysteme - auch die des Gesundheitswesens - als sozio-technische Systeme begreift und dabei Technologie stets im Zusammenhang mit Menschen, die sie nutzen, von ihr beeinflusst werden oder sie organisieren, betrachtet. Soll eine digitale Gesundheitsinnovation, die einen Mehrwert gemäß der o.g. Zielstellungen verspricht, in eine existierende Informationssystemlandschaft der Gesundheitsversorgung integriert werden, so muss sie aus technischen sowie nicht-technischen Gesichtspunkten „interoperabel" sein.

Zwar ist die Notwendigkeit von Interoperabilität in der Wissenschaft, Politik und Praxis bekannt und auch positive Bewegungen der Domäne hin zu mehr Interoperabilität sind zu verspüren. Jedoch dominiert dabei einerseits ein technisches Verständnis und andererseits bleibt das Potential dieser Eigenschaft als Leitmotiv für das Innovationsmanagement bislang weitestgehend ungenutzt. An genau dieser Stelle knüpft nun der Hauptbeitrag dieser Doktorarbeit an, in dem sie eine sozio-technische Konzeptualisierung und Kontextualisierung von Interoperabilität für künftige digitale Gesundheitsinnovationen vorschlägt. Literatur- und expertenbasiert wird ein Rahmenwerk erarbeitet – das Digital Health Innovation Interoperability Framework – das insbesondere Innovatoren und Innovationsfördernde dabei unterstützen soll, die Diffusionswahrscheinlichkeit in die Praxis zu erhöhen. Nun sind mit diesem Framework viele Erkenntnisse und Botschaften verbunden, die ich für diesen Prolog wie folgt zusammenfassen möchte:

1. Um die Entwicklung digitaler Gesundheitsinnovationen bestmöglich auf eine erfolgreiche Integration in eine bestimmte Zielumgebung auszurichten, sind die Realisierung eines neuartigen Wertversprechens sowie die Gewährleistung sozio-technischer Interoperabilität die zwei zusammenhängenden Hauptaufgaben eines Innovationsprozesses.

2. Die Gewährleistung von Interoperabilität ist eine aktiv zu verantwortende Managementaufgabe und wird durch projektspezifische Bedingungen sowie von externen und internen Dynamiken beeinflusst.

3. Sozio-technische Interoperabilität im Kontext digitaler Gesundheitsinnovationen kann über sieben, interdependente Ebenen definiert werden: Politische und regulatorische Bedingungen; Vertragsbedingungen; Versorgungs- und Geschäftsprozesse; Nutzung; Information; Anwendungen; IT-Infrastruktur.

4. Um Interoperabilität auf jeder dieser Ebenen zu gewährleisten, sind Strategien differenziert zu definieren, welche auf einem Kontinuum zwischen Kompatibilitätsanforderungen aufseiten der Innovation und der Motivation von Anpassungen aufseiten der Zielumgebung verortet werden können.

5. Das Streben nach mehr Interoperabilität fördert sowohl den nachhaltigen Erfolg der einzelnen digitalen Gesundheitsinnovation als auch die Defragmentierung existierender Informationssystemlandschaften und trägt somit zur Verbesserung des Gesundheitswesens bei.

Zugegeben: die letzte dieser fünf Botschaften trägt eher die Färbung einer Überzeugung, als dass sie ein Ergebnis wissenschaftlicher Beweisführung ist. Dennoch empfinde ich diese, wenn auch persönliche Erkenntnis als Maxim der Domäne, der ich mich zugehörig fühle - der IT-Systementwicklung des Gesundheitswesens.

So möchte ich an dieser Stelle zum zweiten, mir sehr relevanten Anliegen überleiten: der Danksagung an meine Unterstützerinnen und Unterstützer insbesondere der vergangenen fünf Jahre, ohne die ich weder die Orientierung noch die Kraft gefunden hätte, diese Arbeit zu

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Ich danke euch von Herzen.

Proloque

“United even the weak become powerful.”
from ”Wilhelm Tell” by Friedrich Schiller

“We are only as strong as we are united and as weak as we are divided.”
Albus Dumbledore in ”Harry Potter and the fire goblet” by J.K. Rowling

“Humor is the umbrella of the wise.”
Erich Kästner

Dear reader,

Over the past five years, I have had the privilege of working on a wide variety of topics through the lens of science. Mostly, these topics have been related to the question of how modern digital technologies can be used to improve current and future healthcare. This privilege, although there were phases when I could not perceive it as one, stands out in my opinion due to two aspects. On the one hand - even if it may sound pathetic - it is the freedom to be restricted by only a few (to no) limits in terms of time and content. Thus, I could explore many individual questions, examine their interrelationships, and take on diverse perspectives. On the other hand, this freedom resulted in an individual qualification that went far beyond the specific realm of a doctoral thesis. In addition to acquiring concrete knowledge about the topic of ”digitalization in healthcare”, I was able to promote numerous other competencies that I would not have been able to strengthen to a comparable extent without taking the path of a doctoral student. Among them, I count in particular knowledge of the theory of truth and science, the ability to organize multi-perspectivity and interdisciplinarity, and balancing relevance and rigor in all activities. Especially the latter weighing is a much-discussed topic in my discipline of Information Systems Research. While this dissertation as a whole is searching for an appropriate balance, I would like to use the side of ”relevance” as a special hook in this prologue in two respects.

First, I would like to summarize my dissertation topic and the main findings of my work as comprehensibly as possible. The world events of the past years have made me more aware of the communication mandate of science. I therefore consider it particularly relevant to make my findings accessible to every reader, especially those with less foreknowledge of my subject. So, what is it all about?

This dissertation seeks a theoretical framework for developing complex digital health innovations so that they have a better chance of diffusion success into everyday health care practice. Although there is neither a lack of demand nor a lack of ideas for digital health innovations, there is, unfortunately, no flood of solutions that have been successfully established in healthcare practice. This insufficient diffusion success of a developed solution - often pathologized as ”pilotitis” - is particularly apparent when the planned innovation is associated with greater ambition and complexity. Heretical counter-questions will immediately come to the mind of the experienced critic. For example, what should be understood by complex digital health innovations and whether it is even possible to find a universal formula that can guarantee the successful diffusion of digital health innovations? Both questions are not only justified but ultimately lead to two research threads that I explicitly address in this dissertation.

In the first block, I will delineate those digital health innovations that are currently receiving particular attention in literature and practice due to their high potential for improving healthcare and their resulting complexity. More specifically, I examine the dominant goals associated with digital health innovations and related challenges. Within the work in this research thread, four objectives emerge: 1. supporting continuous, collaborative care processes across diverse care providers (known as inter-organizational care pathways); 2. actively involving patients in their healthcare processes (known as patient empowerment or patient engagement); 3. strengthening cross-sectoral collaboration between science and healthcare practice, up to learning healthcare systems; and 4. establishing data-centered value propositions increasing availability of comprehensive and valid data sources, new processing methods (keyword artificial intelligence), and numerous usage possibilities. Therefore, this dissertation's scope is less focused on stand-alone, clearly definable innovations (e.g., a symptom diary app for complaint monitoring). Rather, this dissertation addresses those innovation projects that pursue one or more of the objectives mentioned above, add another technological piece of the puzzle to complex health information system landscapes, and thus contributes to improving healthcare and/or its organization in interaction with various other IT systems.

In addressing these objectives and associated system development challenges, the problem of fragmented health IT system landscapes came into focus. This is understood as the unpleasant state that different information and application systems cannot interact with each other as desired. This leads to discontinuities in information flows and care processes, which, otherwise, have to be covered by additional, error-prone efforts (e.g., double documentation). To counteract these restrictions on healthcare effectiveness and efficiency, these IT system silos must be eliminated. All of the objectives mentioned above are subordinate to this defragmenting effect in that they want to bring together 1. different healthcare providers, 2. healthcare teams and patients, 3. science and healthcare practice, or 4. multiple data sources and modern processing technologies. However, this leads to a complex ring closure, as, on the one hand, the digital health innovations discussed in this paper are looking for defragmentation of health information system landscapes. On the other hand, it is exactly the existing fragmentation of the target environment that causes the limited success rate of these innovation projects.

This gain in knowledge opens up the second research thread of this thesis, which deals intensively with the property of ”interoperability”. It examines how this property should be central in innovation projects in the digital health domain. Simply speaking, interoperability describes the ability of two or more systems to perform common tasks in conjunction with each other. It thus represents the central aim of the identified objectives and is the linchpin when a developed solution has to be integrated into a specific target environment. From a technically dominated perspective, the aim is to ensure valid, performant, and secure communication scenarios to eliminate the aforementioned discontinuities in information flows between technical subsystems. Interoperability is also highly relevant for digital innovations in general due to their unique characteristics. They are often characterized by distributed value creation (interaction with other systems and services is essential for their added value) and combinability (different value creation through different system interactions). Thus, ensuring interoperability is crucial to releasing the intended value proposition of a digital (health) innovation in practice.

However, a purely technical understanding of interoperability is insufficient to encompass the various diffusion barriers to digital health innovations. For example, the lack of adequate remuneration opportunities within the regulatory environment or an inadequate fit for the particular healthcare process are not exclusively technical problems. Instead, a basic mindset of the Wirtschaftsinformatik discipline comes into play. It understands information systems - including those of the healthcare sector - as socio-technical systems and thereby always views technology in the context of people who use it, are influenced by it, or organize it. If a digital health innovation that promises benefits by aforementioned objectives has to be integrated into an existing health information system landscape, it must be ”interoperable” from both a technical and a non-technical point of view.

The need for interoperability is well known in science, politics, and practice, and positive movements in the domain toward more interoperability can also be observed. However, on the one hand, a technical understanding dominates, and, on the other hand, the potential of this property as a leitmotif for innovation management remains largely unused. This is precisely where the main contribution of this dissertation picks up, proposing a socio-technical conceptualization and contextualization of interoperability for future digital health innovations with complex objectives. Literature- and expert-based, it elaborates a framework - the Digital Health Innovation Interoperability Framework - that aims to support innovators and innovation promoters to increase the likelihood of diffusion into practice. Now, there are many findings and messages associated with this framework, which I would like to summarize for this prologue as follows:

1. To guide the development of digital health innovations in the best possible way toward successful integration into a specific target environment, realizing a novel value proposition and ensuring socio-technical interoperability are the two main interrelated tasks within the innovation process.

2. Ensuring interoperability is a management task that must be actively addressed and influenced by project-specific conditions and external and internal dynamics.

3. Socio-technical interoperability in the context of digital health innovations can be defined across seven interdependent levels: Legal and regulatory; Policy; Care and business process; Use of innovation; Information; Applications; and IT-Infrastructure.

4. To ensure interoperability on each of these levels, strategies have to be defined in a differentiated way, which can be located on a continuum between compatibility requirements on the innovation side and the motivation of adjustments on the target environment side.

5. The pursuit of increased interoperability promotes both the sustainable success of single digital health innovation and the defragmentation of existing health information system landscapes, thus contributing to the improvement of the healthcare practice.

Admittedly, the latter of these five statements carries the tinge of conviction rather than being the result of scientific reasoning. Nevertheless, I find this, albeit personal, conclusion to be a maxim of the domain I belong to - healthcare information systems development.

Thus, at this point, I would like to move on to the second subject that is very relevant to me: the expression of gratitude to my supporters, especially during the past five years, without whom I would have found neither the orientation nor the strength to write this thesis. To the highest degree, I would like to express my thankfulness to the following people and groups.

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List of Abbreviations

ADR	Action Design Research
CAF	Clinical Adoption Framework
Con-#	Contribution (no. #)
DOIS	Design-Oriented Information Systems
DH	Digital Health
DHI	Digital Health Innovation(s)
DHIIF	Digital Health Innovation Interoperability Framework
DSR	Design Science Research
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HIS	Health Information System(s)
HISR	Health Information Systems Research
HIT	Health Information Technology
IEEE	Institute of Electrical and Electronics Engineers
IS	Information System(s)
ISR	Information Systems Research
MS	Multiple Sclerosis
NASSS	Nonadoption, Abandonment, Scale-up, Spread, and Sustainability [Framework]
P#	Paper (no. #)
ReEIF	Refined eHealth European Interoperability Framework
RO#	Research objective (no. #)
RQ#	Research question (no. #)

Part I
Synopsis of the Doctoral Thesis

1 Introduction

1.1 Background

When I started studying in 2011, we discussed in a basic course called ”Einführung in die Wirtschaftsinformatik” (Engl. introduction to business informatics) the central object of our discipline: socio-technical information systems (IS) of industry, trade, service sector, and administration that also progressively permeate the private life of people (Ferstl and Sinz, 1998). Today, this permeation process reached a level where digitalization crosses all areas of society so that the concept of a digital life becomes an interwoven reality. Especially for the healthcare domain, this concept and its realization by modern health information systems (HIS) have the potential to revolutionize our healthcare system (Hess et al., 2014). Since 2017, I have had the honor to be a proactive part of that change. Within these five years of design-oriented Health Information Systems Research (HISR), I experienced dynamics of the Digital Health (DH) domain regarding new concepts of healthcare delivery, technological progress, hindering diffusion issues of Digital Health Innovation (DHI), increasing relevance of interoperability as key property, and political efforts to overcome a historically fragmented state of HIS landscapes. With apologies for this extended introduction, I'd like to highlight those streams that motivated my research sustainably and introduce recent contributions that have built the focal point of my investigations.

Defragmentation of Health Information landscapes. In recent years, the demand for seamlessly collaborative and synergetic health systems has become of vital importance to enhance healthcare quality and efficiency. However, practice and science still attest an insufficient convergence between the interwoven ideal and the status quo of health systems and their information systems (IS) landscapes (Agha et al., 2017; Auschra, 2018). Professional stakeholders and patients strive for opportunities to overcome existing information and communication burdens. This pursuit of defragmentation becomes obvious, e.g., in the following observations: First, conventional care regimes get enhanced to inter-organizational collaborations where different healthcare providers, professions, and further actors form a patient's care team (Auschra, 2018; Müller-Mielitz et al., 2017). Such approaches of integrated care (Valentijn et al., 2013) or care networks (Richter and Schlieter, 2019) might be guided by consented process definitions that lead to improved patient pathways (Richter and Schlieter, 2021, 2019). Consequently, the concept of value-based healthcare (Berwick et al., 2008; Porter and Teisberg, 2006) can finally be implemented in healthcare practice. Second and in addition to professional collaborations, the role of patients within their treatment becomes more proactive. Enabled by health information technology (HIT), patients get increasingly involved, empowered, and engaged at different stages of their personal pathways to improve individualization, care quality, and efficiency (Castro et al., 2016; Cerezo et al., 2016; Fumagalli et al., 2015; Walker et al., 2017). Third, the realm of integrated approaches extends from focusing on primary healthcare delivery to more complex collaboration networks, including the secondary and tertiary healthcare sectors. Multiple disciplines of science (e.g., medicine, public health, or IS), public administration, insurances institutes, and business management strive for inter-connected HIS to improve their effectiveness and efficiency (Auschra, 2018; Schlieter et al., 2012; Valentijn et al., 2013). Fourth, the rise of artificial intelligence (AI) applications and other data-centered approaches promotes as well as requests technological and organizational defragmentation. The increased maturity of methods and techniques requires access to multiple sources of valuable data and promotes testing and implementing a broad variety of data-centered value propositions (He et al., 2019; Secinaro et al., 2021; Xiao et al., 2018). Moreover, results of such applications need to be communicated to one or more receiving systems, where different stakeholders might benefit from them. In summary, these four observations motivated me to contribute to this defragmentation progress by developing distinct DHI within research projects and the scientific investigation on how such DHI shall be designed, developed, and implemented.

The challenge of DHI diffusion. Within my work, I experienced that the successful diffusion of DHI into practice remains a tough challenge for innovators. Even today, the term ”Pilotitis” is frequently used to express the pathogenic issue of the DH domain that mature DHI pilots can be realized, but their integration into healthcare practice often fails (Egermark et al., 2022). Especially Germany performed insufficiently in creating a beneficial digitalized healthcare system, as an international comparison study revealed a few years ago (Thiel et al., 2018). Unfortunately, the phenomenon has been well known for a long time, but DHI projects still have a high failure rate, especially when a DHI project's ambition reaches a high level (Cresswell and Sheikh, 2013; Mair et al., 2012; Standing et al., 2018). Those high ambitions may relate to the high complexity and/or novelty of a DHI's intention to address the fragmented status quo of HIS landscapes. In the end, the application of new HIT to establish new paradigms of healthcare delivery (e.g., value-based healthcare) within inter-organizational care settings rarely results in successfully integrated and sustainable DH solutions.

Prior research on the diffusion issue. Paradoxically, HISR already investigated the extent and complexity of reasons for diffusion failure and conceptualized what sustainable DH adoption requires. For instance, comprehensive lists of barriers and enablers for DHI diffusion were derived (Kowatsch et al., 2019; Schreiweis et al., 2019). Complementing such consolidations, other disciplines provide conceptualizations for evaluating DH adoption retrospectively from a top-down perspective. In this context, the Clinical Adoption Framework (CAF) (Lau and Price, 2017a) and the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability

(NASSS) framework (Greenhalgh et al., 2017) are widely recognized in DH practice and research. As both contributions had a decisive influence on the perspective of this dissertation, they are briefly introduced here. Lau and Price (2017a) comprise in their CAF three conceptual dimensions. On a micro-level, the authors distinguish beneficial factors about technological quality, usage quality, and net benefits. They saw the need for extending this perspective (Lau et al., 2011) to capture meso (people, organization, implementation) and macro factors (governance, standards, funding, trends) for providing a holistic evaluation framework (Lau and Price, 2017b). van Mens et al. (2020) applied CAF for patient access to EHRs and enhanced it by specifying sub-categories, making it more tangible for other DH evaluation objects.

The NASSS framework of Greenhalgh et al. includes several questions about illness specificity, technology, characteristics of value proposition, human-centered adopter systems, involved organization(s), the wider (institutional and societal) context, and the interaction and mutual adaptation between all these domains over time (Greenhalgh et al., 2017). The NASSS framework focuses on a DHI's path from the integration phase to its post-market usage and further evolution. But doing that, it implicitly indicates relevant and interrelated aspects that require consideration in earlier stages of DHI design and development, ensuring a DHI's sustainable diffusion. Thus, a rich body of knowledge on DHI diffusion has already been contributed over recent years. It consolidates the vast number of relevant aspects and provides a structure for retrospective evaluation. These contributions differ in detail but confirm each other for most aspects, their multi-perspectivity, and their general socio-technical realm. But with respect to each work's value, guidance for DH practitioners to manage the diffusion challenge is limited. There is still a lack of support on how innovators shall handle the complexity to improve DHI management and increase diffusion probability. Especially with a scope on ambitious, defragmenting DHI, prior research – to the author's knowledge – does not provide concepts or managing aids that lead to interoperable and easy-to-integrate DHI.

Views on Digital Health Innovation. The knowledge base of diffusion in the DH domain and the professional experience gained by research projects refined the initial understanding of DHI as a research object. Three interrelated views shape the conceptual basis of this thesis (see Figure 1): 1. DHI as a novel artifact providing one or more particular value propositions referring to one or more HIT; 2. DHI as a process with a longitudinal view on how an DHI artifact is developed and integrated into a target environment; and 3. the wider DHI project context comprising the specific target environment (status quo of technological, organizational, and legal conditions) as well as the DHI's organizational background (e.g., innovator's status, structure of consortia, or funding conditions). Those views indicate the extent and complexity of aspects that reason limitations of universality when investigating DHI. Thus, this thesis claims not to elaborate, a generically valid method that guarantees successful integration of all future DHI.

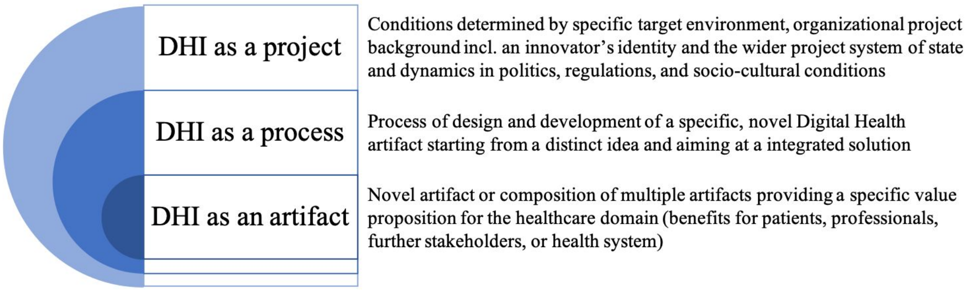

Figure 1: Interrelated views on DHI guiding theorization within the doctoral thesis

Instead, it aims at a conceptual construct to rethink the design and development of future DHI for defragmented healthcare and bridge the stated views on DHI.

A plea for focusing on socio-technical interoperability. The era of digital innovations reasons an increased relevance of interoperability for IS research and development in general (Hodapp and Hanelt, 2022). Especially digital innovations' unique characteristics of being variously combinatorial and, thus, providing multiple value propositions by distributed components lead to a demand for interoperability within smaller or larger IS contexts (Henfridsson et al., 2018; Yoo et al., 2012, 2010). Traditionally, interoperability is broadly understood as a technical ability describing the "degree to which two or more systems, products or components can exchange information and use the information that has been exchanged" (IEEE, 2022). But within the last decade, selected research contributions motivated a broader, inclusive view on interoperability as a key property that should be managed as an organizational and informational issue (Allen et al., 2014). These articles argue, e.g., for new model-based approaches to enhance interoperability in next-generation enterprise information systems (Zacharewicz et al., 2017), step forward to interoperability evaluation models including business process perspectives (da Silva Serapião Leal et al., 2019; Liu et al., 2020; Rezaei et al., 2014), and discuss economic implications on benefits, trade-offs, or competition (Kerber and Schweitzer, 2017). But despite these single contributions, ISR still faces conceptual, scoping, and methodological issues, as a recent study presents (Hodapp and Hanelt, 2022). Here, the authors especially highlight the need for socio-technological perspectives that account for the role of digital technology and the corresponding organizational interactions. They conclude with a research agenda that underpins this thesis' domain-specific motivation as it asks for a contextualized theorization of interoperability that describes its co-evolution with strategic rationales in digital innovation and its counteracting impact on fragmentation.

Interoperability in the HIS domain. Analogous, the traditional interpretation of interoperability as an ability between two or more technical systems to exchange and use information is also in the healthcare world still dominant (HIMSS, 2020; International, 2021; Zeinali et al., 2016). Technical properties, e.g., semantics and syntax, are at the focal point of discussion to ensure different communication scenarios. National and international committees (e.g., HL7 and IHE) strive to increase technical standardization, reduce inconsistencies in information flows, and pave the path toward defragmented HIS landscapes. Under the consideration of the multitude of non-technical aspects that determine a DHI's adoption (Kowatsch et al., 2019), practice and academia partly broadened their interoperability understanding and postulated more inclusive approaches for the healthcare domain. Only a few contributions conceptually discuss the balance between technical, organizational, and economic perspectives on interoperability (Kuziemsky and Peyton, 2016; Kuziemsky and Weber-Jahnke, 2009; Milosevic and Bond, 2016; Stegemann and Gersch, 2019; Thun, 2021; Zeinali et al., 2016). These articles stimulate the conceptual progress in HISR but the potential for improvements remains. Especially diffusion and adoption theory for DHI, the innovator's management perspective, and current technical as well as political dynamics shall be considered in particular to promote conceptualization and contextualization efforts. From a German point of view, the roadmap toward an interoperable health system in Germany in 2025 published by pertinent organizations (Heitmann et al., 2020a,b) and a European consented interoperability framework as a basis for national interoperability strategies provide insights on required efforts in that regard.

A European framework on interoperability in healthcare. In 2015, the European Commission's working group "eHealth Network" published the Refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2015). It is intended to support activities in the context of interoperability between different healthcare organizations and related standardization challenges. It provides a consented language, supports communication and decision-making processes, and offers six distinguished interoperability perspectives (see Figure 2). In more detail, it differentiates technical (Information, Application, IT-Infrastructure) and non-technical levels of interoperability (Legal and Regulatory, Policy, Care Process) and provides further explanation of each level (see also Appendix C).

Over recent years, the ReEIF has been established in policy-making, research, and practice. For example, the WHO endorses its member states its adoption within their national eHealth strategies to support all involved stakeholders from innovation to implementation (Peterson et al., 2016). HISR applied it in selected contributions, e.g., to derive a framework for the digital transformation of the Greece health system (Kouroubali and Katehakis, 2019) or to propose a reference architecture for future digital ecosystems for primary care (d'Hollosy et al., 2018). The eStandard initiative also built on the ReEIF and provided recommendations for eHealth deployment projects (eStandards, 2017). However, its applicability to the context of DHI dissemination remains unclear, as it originally focuses on interoperability between organizations.

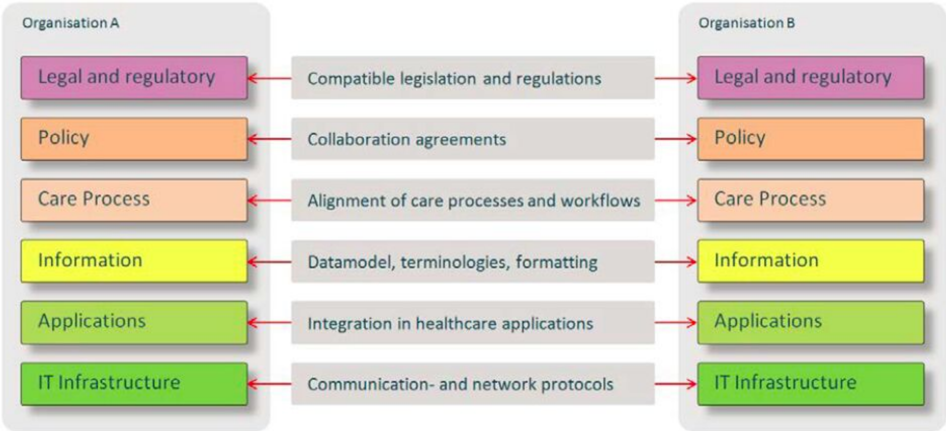

Figure 2: Levels of interoperability according to ReEIF (eHealth Network, 2015)

On the other hand, future defragmenting DHI may explicitly aim at inter-organizational healthcare settings. For this reason, the ReEIF was chosen as an initial delineation aid within this dissertation. Further investigations addressed the question of how the ReEIF can conceptually be enhanced to suit the context of a DHI's integration into healthcare practice (see section 2.2).

Interoperability within the political healthcare agenda in Germany. Additionally, the increasing relevance of interoperability is visible in the political and regulatory progress. Health systems on regional, national and international level seek more inter-organizational and intersectoral collaboration to improve healthcare accessibility, quality, and efficiency. Politics became more ambitious regarding issues of limited technical connectivity and insufficient openness of existing HIS landscapes that inhibit the establishment of DHI-friendly HIS environments. Thus, ensuring interoperability is central to current political and regulatory activities. In Germany, multiple legal acts have been recently passed that either directly or indirectly force healthcare actors to more interoperability. To the date of this thesis, the following acts[1] commonly contribute to that aim by establishing organizational structures, empowering legal and independent bodies to define standardization procedures, and promoting or determining the implementation of technical standards:

- October 2021: Health-IT-Interoperability-Governance-Regulation (dt. GIGV Gesundheits-IT-Interoperabilitäts-Governance-Verordnung)
- October 2021: Health-IT-Interoperability-Regulation (dt. GIV Gesundheits-IT Interoperabilitätsverordnung)

[1] A brief overview on how the listed acts strengthen goals of standardization and interoperability is given in Appendix D

- June 2021: Digital-Healthcare-And-Nursing-Modernization-Act (dt. DVPMG Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz)
- October 2020: Hospital-Futures-Act (dt. KHZG Krankenhauszukunftsgesetz)
- April 2020: Digital-Health-Application-Regulation (dt. DIGAV Digitale Gesundheits-anwendungen-Verordnung)
- December 2019: Digital-Care-Act (dt. DGV Digitale-Versorgung-Gesetz)

1.2 Subject and Motivation

The different background aspects described in section 1.1 motivated the design and conduction of a research agenda. Two different research threads gained my scientific attention in particular.

Thread A – Challenge of design, development, and implementation of DHI in complex HIS landscapes. The need for defragmentation of the healthcare domain's status quo drove and still drives multiple DHI projects of our research group. They all aim at design and development goals in distinct HIS landscapes and strive for their functional enhancements. Related design artifacts seek pathway-based care in inter-organizational settings, patient empowerment, inter-sectoral collaborations, and data-centered value propositions. But working on such defragmenting DHI and trying to integrate them into healthcare practice let us also experience the challenging task of DHI diffusion. Thus, an analytical investigation is motivated to explore the unique characteristics of such defragmenting DHI, their design, and their development. This problematization also includes exploring why the diffusion of such DHI remains challenging. Different meta-analyses of HISR confirm the need for scientific investigation in that regard. Ho et al. (2019) highlight research gaps on how inter-professional collaborations should be ensured and promoted by future DHI. Baird et al. (2020) emphasize this call and request more research on HIT that becomes increasingly more inclusive of additional stakeholders, including patients, outside of traditional health provider settings. Considering ongoing technological progress in data-centered value creation, Haried et al. (2019) postulate research opportunities for ISR to contribute to the growing trend of data-driven healthcare and demand interdisciplinary, design- and theory-oriented exploration. In this context, Davidson et al. (2018) highlight research opportunities regarding the integration of health data across multiple sources in their review. But releasing promising potentials of AI applications and other data-intensive approaches in HIS landscapes requires whether an already interoperable HIS ecosystem providing access to the relevant data sources or related DHI projects aiming at implementing such approaches have to elaborate appropriate defragmentation by themselves. They also conclude that the DHI's persistently insufficient diffusion rate requires further research on DHI adoption and diffusion.

Research activities motivated by this problematization Thread A are further intended to indicate directions for subsequent investigations on possible conceptual solutions toward defragmented, interoperable HIS landscapes.

Thread B – Increasing relevance and potential of socio-technical interoperability as an aid for structuring and orientation in DHI management. The relevance and role of interoperability change due to the unique characteristics of Digital (Health) Innovations and the ongoing demand for defragmentation in HIS landscapes. Rising streams of inter-organizational care, inter-sectoral collaborations, and data-centricity challenge DH innovators to ensure a DHI's capability to integrate seamlessly into complex target environments. At the same time, HISR, practice, and legal progress commonly prioritize interoperability as a goal property to overcome the perpetual fragmentation of healthcare systems. Thus, the concept of interoperability might be a holistic construct and guide future DHI projects. But previous conceptualizations either prioritize a technical scope or focus on socio-technical interoperability between organizations. In doing so, the potential to draw on a holistic understanding to support innovators in increasing the diffusion probability of DHI remains untapped. This background and the research results related to Thread A motivated further investigations addressing this conceptual gap. There is a need to clarify how the indicated paradigm change of interoperability in DHI can be beneficially promoted and underpinned by sound scientific exploration. Interoperability might no longer be seen as a technical requirement only. It becomes a predominant ability that all involved actors of HIS strive for. Thus, it might be used as a conceptual construct that could evolve into a managerial means for DHI management and diffusion improvement. But at the time of starting the research activities bundled in this thesis, this conceptualization need had not been pursued extensively by HISR. Albeit, the demand for conceptual revision addressing structure, extent, scope, ensuring mechanisms, and potential strategies were highlighted by HISR literature. Samhan et al. (2018) identified in their meta-analysis potential for further research that explicitly investigates the interplay of HIT innovations, their diffusion, and HIT interoperability to improve multiple collaboration scenarios in healthcare. Gersch and Wessel (2019) state promising research fields of "Wirtschaftsinformatik" in the context of HIT and emphasize conceptual and design-oriented investigations on interoperability for improving inter-sectoral alliances in modern healthcare. Finally and as introduced earlier, Hodapp and Hanelt (2022) recently postulated an agenda for ISR and recommended investigations addressing remaining conceptual and scoping issues. Here, the authors request, among others, to utilize socio-technological perspectives that account for both the role of digital technology and the corresponding organizational interactions as well as to theorize interoperability mechanisms and aspects that are universal and valid for multiple contexts.

2 Research Design

Current movements in the DH domain and indications for a changing relevance and role of interoperability are presented in the previous chapter. While these explanations might answer ”why” this thesis focus on interoperability for modern DHI, a swift to a top-down description is proposed in this chapter to introduce the research design. It provides information on ”how” this work contributes to the scientific discourse and presents all relevant parameters of the research process to make results transparent, interpretable, and comparable (Becker et al., 2003). Typically, a research design presentation describes three main parameters - the researcher’s position regarding the philosophy of science, the research objectives pursued, and the research methods used (Becker et al., 2003). In this thesis, a complementary description of the researcher’s position regarding the philosophy of economics is additionally provided.

2.1 Philosophy of Science

Three aspects fundamentally describe a researcher’s basic position in terms of the philosophy of science: their ontological position, their epistemological position, and their determination of the concept of truth (Becker et al., 2004, 2003; Braun and Esswein, 2006). The ontological position discloses how reality is assumed to exist beyond the realms of cognition and imagination of the individual subject (Becker et al., 2003). The epistemological question concerns the relationship of an object of cognition to the cognition obtained by a subject (Niehaves, 2005). The concept of truth describes how ”true” cognition is achieved (Niehaves, 2005).

This thesis is written from a moderate constructivist perspective. The author takes an open ontological position, whereby the existence of a ”real” world independent of human cognition is neither negated nor assumed. He further defines the cognition of an objective to be subjective dependent (epistemological question) and follows the consensus theory of truth, assuming that a statement is true for a group of people if the group accepts it to be true (Becker et al., 2004, 2003; Niehaves, 2005).

2.2 Research Objectives

Addressing the two threads of action explained in subsection 1.2, this dissertation’s overall research objective is summarized as *unifying the understanding of socio-technical interoperability and providing guidance for the management of complex DHI*. This overarching aim is divided into two subordinate objectives (RO) that structure this thesis. Each of the subordinate research objectives addresses one of the motivational threads. To achieve the objectives, corresponding research questions (RQ) have been specified as shown in Table 1.

Table 1: Research objectives and questions of doctoral thesis.

<table>
<tr><td colspan="2">Overall research objective: to unify the understanding of socio-technical interoperability and to provide guidance for the management of complex Digital Health Innovations</td></tr>
<tr><td colspan="2">Thread A: Challenge of design, development, and implementation of defragmenting DHI in HIS landscapes (pathway-based care, patient empowerment, inter-sectoral collaboration, and data-centered value propositions)</td></tr>
<tr><td rowspan="4">RO1
Understanding DHI in complex HIS landscapes</td><td>RQ1.1 – State of the art. What are the objectives pursued by current DHI projects of research and practice on pathway-supporting HIS?</td></tr>
<tr><td>RQ1.2 – Systematization. How can data-centered approaches, especially artificial intelligence techniques, enrich pathway-supporting HIS to improve individual care and learnings on meso- or macro-level?</td></tr>
<tr><td>RQ1.3 – Proposal of a HIS architecture as a reference. How shall HIS landscapes be designed to suit pathway-based care, patient empowerment, and data-centered value propositions?</td></tr>
<tr><td>RQ1.4 – Learnings from research projects. How can objectives of science and development simultaneously be pursued by current DHI projects?</td></tr>
<tr><td colspan="2">Thread B: Increasing relevance and potential of socio-technical interoperability as an aid for structuring and orientation in DHI management</td></tr>
<tr><td rowspan="4">RO2
Conceptualization and contextualization of socio-technical interoperability to support DHI management</td><td>RQ2.1 – State of the art. How does knowledge about Digital Health diffusion enrich a socio-technical understanding of interoperability?</td></tr>
<tr><td>RQ2.2 – Learnings from research projects. How do Hospital IS affect efforts of ensuring socio-technical interoperability in DHI projects?</td></tr>
<tr><td>RQ2.3 – Framework design. What are the relevant elements shaping a socio-technical conceptualization of interoperability from a Digital Health innovator's perspective and how shall existing interoperability frameworks be adapted?</td></tr>
<tr><td>RQ2.4 – Demonstration and validation of framework. How can a novel conceptualization of socio-technical interoperability beneficially be applied in future DHI projects of research and practice?</td></tr>
</table>

With the first research objective (RO1), understanding the challenge of design, development, and implementation of DHI in complex HIS landscapes that promote defragmentation of the healthcare system's status quo is aimed at. In this context, DHI intended for continuity of inter-organizational care, patient integration, inter-sectoral collaboration, or new data-centered value propositions are of particular interest. This objective is pursued by four research questions that explore literature-based the interdisciplinary field of objectives related to such DHI (RQ1.1) including new data-centered opportunities for value proposition (RQ1.2), derive architectural implications for realizing defragmented HIS landscapes (RQ1.3), and investigate how science- and practice-related objectives might by harmonized to promote a DHI process' success (RQ1.4).

Those research activities were initially motivated by the vision to elaborate design principles ensuring DHI's integration. But problematization results indicated limited validity of intended means-purpose relationships due to a high degree of context sensitivity of each DHI project. However, the same results also emphasized ”interoperability” as central property and indicated its suitability as a guiding socio-technical principle for the management of next-generation DHI.

Building on this, the second research objective (RO2) aims to conceptualize and contextualize socio-technical interoperability to support DHI management. In this regard, aspects crucial to DHI's diffusion and adoption by the healthcare practice were investigated based on literature and observations within ongoing research and development projects (RQ2.1, RQ2.2). Findings also had to be reflected against established interoperability concepts and indicated the need for a conceptual revision. Thus, another research question asks for the design of a new interoperability framework aiming at DHI support and an increase in DHI's diffusion probability in complex target environments (RQ2.3). A final research question addresses the validation and evaluation of the design artifact by demonstration and involvement of expert opinions (RQ2.4).

According to the classification framework for research objectives in the field of Wirtschaftsinformatik provided by Becker et al. (2003), this work's research objectives relate to different classes (see Figure 3). However, the sequential pursuit of both objectives followed a logical research flow, so they commonly constitute this thesis's overall contribution. The research journey started with a descriptive objective aiming at a sound understanding of DHI in complex HIS landscapes with a functional-driven focus, especially on current defragmenting DHI objectives (RO1). Investigating the characteristics and design of such DHI artifacts as well as their intended target environments (current and future HIS landscapes), related research activities revealed the increasing relevance of interoperability for a successful DHI's development and

	Descriptive objective	Design objective
Methodical focus	Understanding methods and techniques for IS design	Developing methods and techniques for IS design **Conceptualization and contextualization of holistic interoperability for DHI (RO2)**
Content- and functional-driven focus	Understanding business information systems and their field of application **Understanding DHI in complex HIS landscapes (RO1)**	Provision of IS reference models for distinct companies or industries

Figure 3: Classification of the research objectives according to Becker et al. (2003).

diffusion into practice. They indicated its potential as a guiding principle for DHI management. Consequently, the second research objective of a holistic conceptualization and contextualization of interoperability for the stated purpose (RO2) map as a design objective with a methodical focus.

2.3 Philosophy of Economics

The stated research objectives, their context, and intended contributions promote the mediation between a micro-perspective of DH innovators who strive to develop, implement, and operate novel DH artifacts and a macro-perspective of an advantageous, seamless interwoven healthcare domain designed for best healthcare delivery to the society. With the multitude of motivational influences in mind (see section 1.1), this work steps over the boundaries of traditional economic schools that defines the limited nature of societal resources (time, competencies, knowledge, technology etc.) as the central economic problem. Besides this *scarcity* of resources, the *uncertainty* of HIS landscapes, the *fallibility* of socio-technological knowledge of HISR, and the resulting dynamical *change* of the healthcare domain due to progress in medicine, public health, technology, and management research are also a key challenge for the healthcare economy.

Underlining the scientific-philosophical position in section 2.1, a brief statement on the economic perspectives which influenced this thesis is given here. In particular, the fundamentals of Complexity Economics (Arthur, 2021, 2015; Schasfoort, 2017) and Evolutionary Economics (Dopfer, 2007; Herrmann-Pillath, 2002) inspired the way of thinking about how the concept of "interoperability" might bridge micro-, meso-, and macro perspectives toward future DH economy. Both philosophies are built upon common ground and are somewhat associated with each other (Meyerhoff and Brökel, 2016). They define scarcity of resources, uncertainty, and change as the central challenges for research and practice. Appendix E provides a more detailed explanation of how foundations, epistemological thoughts, and axiology relate to the author's view on the problem space of fragmented but changing HIS landscapes as a part of current and future healthcare systems.

In doing so, this thesis aligns with other IS and HIS theory contributions. For instance, El Sawy et al. (2010) postulate a need for an adjusted paradigmatic lens in ISR for handling complexity and turbulent ecodynamics in the IS world. Other authors seek for biological analogies and investigate how IS artifacts emerge and evolute in digital ecosystems (Nischak et al., 2017; Schlieter et al., 2019). Agarwal and Tiwana (2015) refer explicitly to the complexity and evolutionary economics in their discussion of IS's evolvability from a macro perspective and emphasize the consideration of evolutionary characteristics in ISR . Selected examples including the healthcare domain underpin their generic thoughts. The authors retrospectively certify in this case an evolutionary process that did not result in synergistically interwoven HIS due to a lack of orientation on interoperability. In this context, the theoretical concept of path dependency might suit both descriptive and prescriptive objectives in HISR, e.g., to evaluate reasons for the insufficient status quo of interoperability, to provide prognoses of standardization processes, or to promote awareness of unintended paths to lock-in effects (Auschra and Gersch, 2022; Stegemann and Gersch, 2019).

2.4 Design Science Research Approach

Following the position regarding the philosophy of science (see section 2.1) and the formulated design-oriented research objectives (see section 2.2), the design science research (DSR) paradigm is applied to the work of this thesis. It is characterized by the creation of innovative design artifacts, i.e., constructs, methods, models, or instantiations (March and Smith, 1995) to answer questions contributing to solving real-world problems (Hevner et al., 2004; Peffers et al., 2006).

In this regard, the main design artifact of the DSR work in this thesis is a conceptualization and contextualization of interoperability as a guiding construct for DHI management - the Digital Health Innovation Interoperability Framework (DHIIF). This central design artifact is intended to moderate interoperability between the micro perspective of DH innovators (design, realization, and diffusion of DHI) and the macro perspective of complex target environments (socio-technical HIS landscapes).

According to (Hevner, 2007), DSR is constituted by three closely related activity cycles: The design cycle is an iteration of designing and evaluating the intended artifact, and the relevance cycle embedding the contextual environment into the design process for collecting requirements and testing the artifact in the environmental setting, and the rigor cycle embedding the relevant knowledge base into the process of artifact design in terms of scientific theories and methods as well as domain experiences and expertise and adding new knowledge generated with the research. Figure 4 presents the constituent aspects and interrelations of this thesis' DSR cycles.

This thesis belongs to the DSR genre (Peffers et al., 2018) of design-oriented information systems (DOIS) research, describing the German discipline of "gestaltungsorientierte Wirtschaftsinformatik" (Österle et al., 2011; Winter, 2008). According to Österle et al. (2011), IS are the research object of this genre. They are socio-technical systems comprising three object types, which are human task bearers (people), technical task bearers (information and communication technologies), and organizational concepts (functions, structures, processes) as well as their interrelations (Österle et al., 2011). The intended design artifact strongly relates to this fundamental position due to its motivation of managing the socio-technical complexity of current and future HIS landscapes.

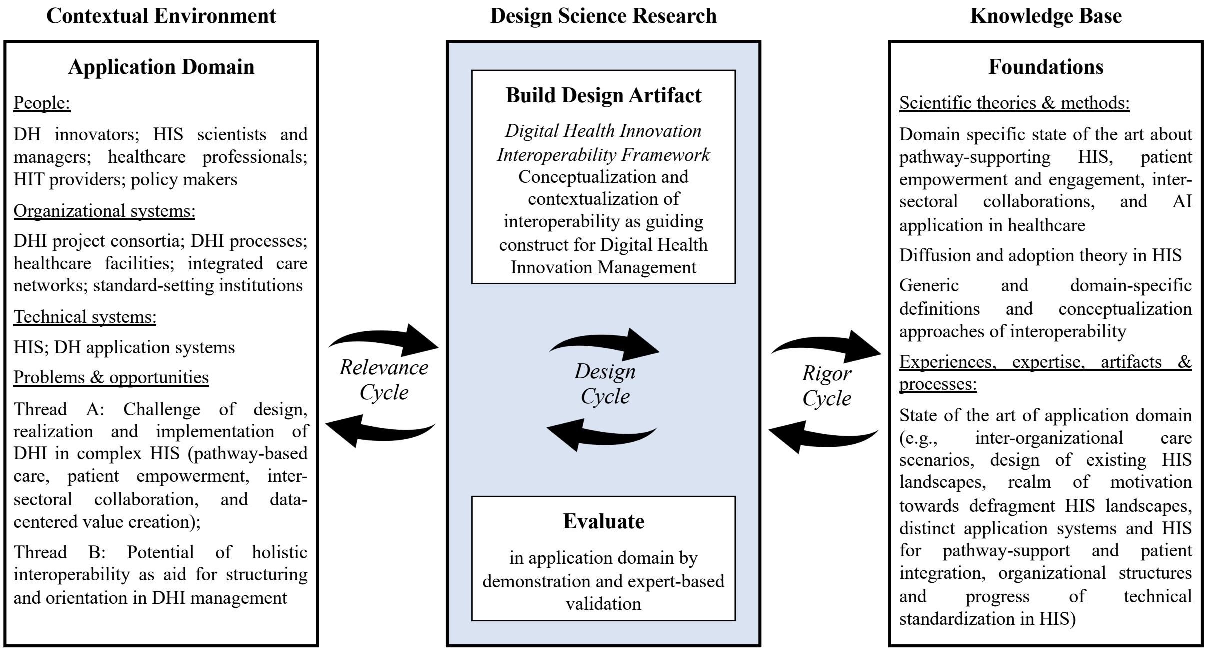

Figure 4: Design science research cycles according to Hevner (2007) applied to this work's field of research.

DOIS research generally aims at developing and providing design and operation principles of IS as well as innovative concepts with utility for practice as key criteria. The artifacts resulting from DOIS research should comply with the four basic principles of abstraction, originality, justification, and benefit (Österle et al., 2011; Peffers et al., 2018). These principles imply the following requirements for this work's design artifact, i.e. the DHIIF.

- **Abstraction** (i.e., the artifact applies to a problem class): The DHIIF needs to be generally applicable to DHI in current and future HIS landscapes.
- **Originality** (i.e., the artifact substantially contributes to the knowledge base): The DHIIF must add to the IS knowledge base, i.e., to the comprehension of the socio-technical realm of interoperability from a DH innovator's perspective and related mechanisms for ensuring interoperability appropriately.
- **Justification** (i.e., the artifact is justified and allows validation): The DHIIF's design must be justified using deductive and/or inductive reasoning, i.e., considerations of prior theory on DHI diffusion and interoperability in the DH domain as well as deriving requirements from the domain.
- **Benefit** (i.e., the artifact is beneficial for the stakeholder groups): Validation of the DHIIF must show if it yields support for DHI management in DH practice and provides a valuable and sound conceptualization for HISR.

There are several approaches to specify and structure a DSR process (e.g., Offermann et al. (2009); Peffers et al. (2007)). However, there is neither an indisputable way to conduct DSR research nor a final DSR method set. Instead, an individual configuration of multiple research methods can be used to run the design, relevance, and rigor cycles (Vaishnavi and Kuechler, 2021; vom Brocke et al., 2020). The four basic DOIS research phases described by Österle et al. (2011) – analysis, design, evaluation, and diffusion – are used to frame this thesis which are also inherent in the DSR research processes suggested by Offermann et al. (2009) and Peffers et al. (2007). The description of this thesis' research process and the methods used in each phase are depicted in Figure 5.

	Analysis	Design	Evaluation	Diffusion
General phase description	Problem identification and objective specification; State of the art of problem solving approaches	Justifiable creation of the artifact (iteratively or in sub-solutions)	Validation of artifact against objectives specified; use artifact to solve problem in suitable context	Diffusion of results among the target groups from science and practice
Thesis-related phase description	Problem-centered research entry; state-of-the-art analysis of diffusion barriers; requirements analysis of HIS for modern care scenarios (inter-organizational care, patient integration, inter-sectoral collaboration, pathway-centeredness, data-centered value propositions)	Conceptualization of socio-technical interoperability for DHI processes; creation of DHI process management support (DHIIF, PathwAI framework; reference architecture approach)	Validation of conceptualization regarding socio-technical interoperability and its utility to support DHI processes (suitability, completeness, adaption of ReEIF, ensuring strategies); demonstration and justification of DHIIF	Communication of problem and solution approaches including design aids for complex DHI, paradigm change of interoperability, and DHIIF as management aid at IS conferences, expert forums (interopforum, GI FGDH), and in multiple research and development projects
Research methods used	Literature reviews (scoping review, systematic literature review, review-of-reviews); qualitative content analyses; multi case study incl. qualitative requirements analysis; patient survey	Argumentative deduction and induction (user- and theory-based); conceptual modelling; multi case study incl. qualitative conceptualization; interview study	Demonstration of conceptual findings for DHI project management and evaluation; expert review by interview study and online survey	Scientific papers; presentations at scientific conferences and expert groups; university seminars; exploitation of results in project work

Figure 5: Research phases and methods used (based on Offermann et al. (2009); Österle et al. (2011); Peffers et al. (2007)).

3 Genesis of the Doctoral Thesis

This doctoral thesis results from a cumulative research project implementing the research design described in chapter 2. It comprises nine research articles (papers P1 to P9) each addressing one of the two stated research objectives by answering particular research questions. In that way, all articles present independent output of different research activities but also commonly contribute to this doctoral thesis's overall aim. The general structure, thematic interrelations, and logical research flow between the different articles are described in section 3.1. Each paper is outlined in the corresponding subsections 3.2 and 3.3. Their context, applied methods, results, and key contributions to this thesis are highlighted here. A final conclusion of their synergetic contributions to research and practice is presented separately in section 4.

3.1 Overall Structure and Context

All nine research papers (P1 to P9) commonly contribute to this doctoral thesis's overall research objective and provide answers to the different research questions raised in subsection 2.2. These papers represent outputs of different research activities related to different stages of the overarching DSR approach (see subsection 2.4). They further document how the corresponding research methods apply the DSR approach in distinct research activities. Figure 6 illustrates the research articles' overall structure, context, positioning, and interrelation along the DSR stages.

The analyzing and designing research activities presented within articles P1 to P4 commonly address RO1 and therefore seek to related answers on how DHI of the current and next generation can support the defragmentation process of the status quo HIS landscape. In P1 (subsection 3.2.1), literature-based analysis explored current streams of investigation related to pathway-supporting systems and states defragmenting purposes, e.g., the support continuity in inter-organizational care, the enhancement of new data-centered value propositions, and synergies for inter-disciplinary collaboration between healthcare management and healthcare delivery or healthcare practice and science. In P2 (subsection 3.2.2), we derived architectural implications for realizing such objectives using interoperable HIS landscapes designed especially for inter-organizational care settings seeking intensified patient engagement. Motivated by the rise of AI applications in healthcare, we conducted a literature-based in-depth analysis on how AI can improve pathway-supporting HIS in P3 (subection 3.2.3). We explored a differentiated set of pathway-related purposes for AI application and derived a conceptual framework to assist DHI design processes. Due to their shared foci, the articles P1 to P3 are strongly interconnected, even though their contributions do not follow a strict logical flow. In more detail, P1 identified the practical and scientific potential of fostering data-centered value propositions in synergy with pathway-supporting HIS. P3 investigates such synergies more comprehensively and P2 provide an architectural approach for HIS that might ensure them. However, the genesis of these contributions does not follow a sequential order. Nevertheless, they commonly help to clarify how current and future DHI follow defragmenting purposes by applying different research scopes. P4 (subsection 3.2.4) also addresses this analytical task. But in contrast to P1 to P3, it concentrates on the collaboration of scientific research and practice-oriented development while planning and conducting DHI projects.

The role of ”interoperability” was recurrently discussed within P1 to P4. It was considered an essential property for both the development of single DHI and the design of synergistic HIS landscapes. This work solidified the assumption that interoperability is more than a technical property but can be understood as a bridge between micro and macro perspectives. In consequence, further research addressed whether and how the concept of ”interoperability” can be elevated to a leitmotif of the design of DHI and its development processes.

With this adjustment of the research focus, five additional contributions were dedicated to the second research objective (RO2). In P5 (subsection 3.3.1), diffusion barriers of DHI were literature-based collected and reflected along an established interoperability framework (ReEIF). The ReEIF was also used in P6 (subsection 3.3.2) for structuring barriers and enablers of DHI collected in three research and development projects. The results underpinned the suitability of the ReEIF as a starting point for conceptualizing interoperability as a guiding principle for DHI. P7 (subsection 3.3.3) re-contextualized the ReEIF with a comprehensive literature review and derived a first draft of the intended design artifact. The critiques and limitations of these three contributions motivated an expert-based evaluation and a resulting refinement of the design artifact so that P8 presents the DHIIF as the central contribution of this dissertation (subsection 3.3.4). In P9 (subsection 3.3.5) the DHIIF is evaluated by an online survey and its applicability is demonstrated in the context of a current research project.

Within the past years, several channels and opportunities have been used to communicate research results to the professional audience (diffusion of resesrch results). In particular, the published research papers and related conference presentations should be mentioned here. A list of all publications and presentations can be found in the appendices A and B. Furthermore, results were directly applied in research projects and thus implicitly evaluated. At this point, I would like to gratefully emphasize the consortial achievements of the EFRE-funded innovation projects in which I was able to participate actively. These projects developed, among others, a platform-based integrated stroke aftercare in Eastern Saxony (INAN-SOS), a patient pathway-oriented healthcare portal for multiple sclerosis patients (IBMS), a digitally-enabled approach to inter-organizational care in psychotraumatology (Tele-NePS), and a tool for interoperability assessment of ongoing DH projects (HGS). In addition, the main contributions of this thesis could be communicated to further expert networks, e.g., by presentations and discussions within the special interest group Digital Health of the German Informatics Society (Gesellschaft für

Informatik) as well as in the Interoperability Forum, a voluntary association of key players to increase the interoperability of the German healthcare system (e.g., HL7 Deutschland e.V., gematik GmbH und IHE Deutschland).

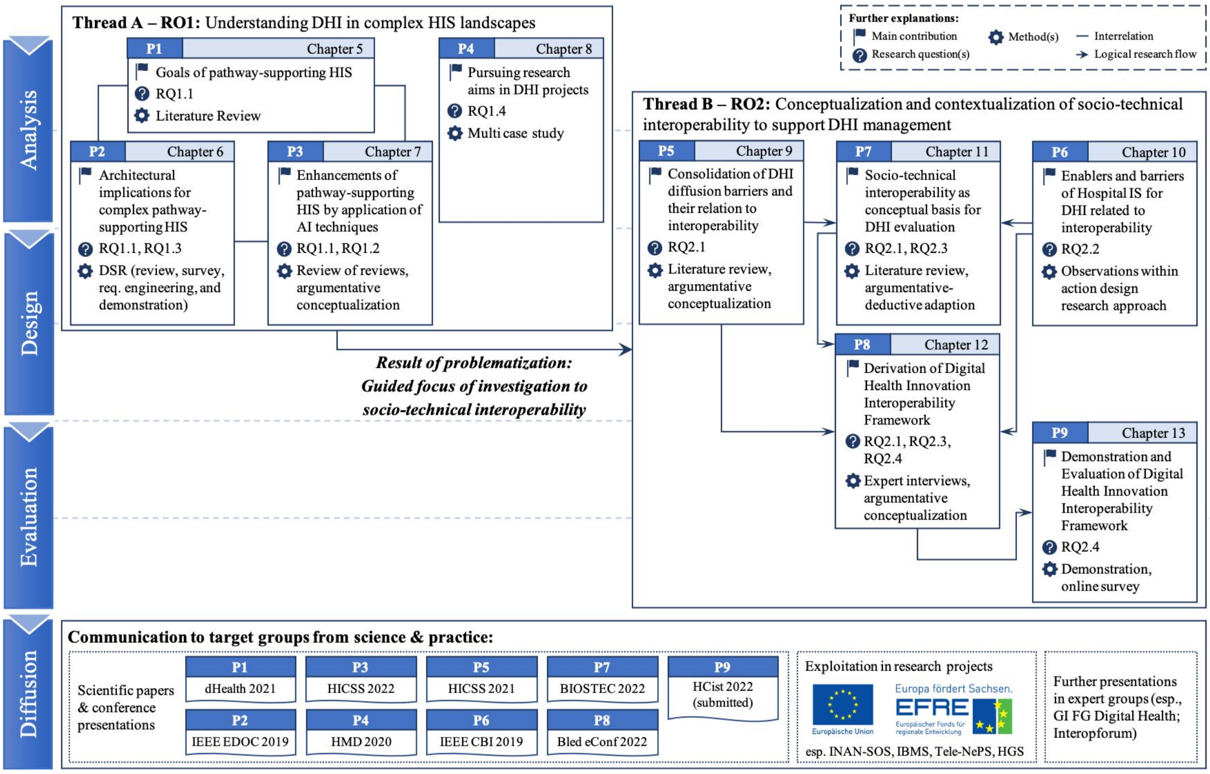

Figure 6: Structure of contributions building the doctoral thesis aligned to the research phases.

Finally, I would like to refer to three other papers published with my participation, which are not part of this cumulative thesis, but are closely related to the overall picture presented. At the beginning of my academic career, I explicitly dealt with the functional design of patient portals. I thus raised my awareness of DH solutions to strengthen patient integration in their treatment episodes (Scheplitz et al., 2018). On this basis, we developed an indication-sensitive patient portal for multiple sclerosis care in Saxony, strengthening the continuity of inter-organizational treatment settings (Voigt et al., 2020). Such project-specific contributions are particularly relevant for future translation tasks of gathered knowledge into healthcare practice. Socio-cultural aspects are also stated in the discourse on barriers and success factors of DHI projects within the papers mentioned above. Because precise statements about such influences require thorough incorporation of adequate methods and theories of social sciences, which are beyond the author's core competencies, this paper does not offer a detailed discourse in this regard. Nevertheless, indications for national-cultural conditions could be collected in a supplementary contribution (Otto et al., 2022).

3.2 Defragmenting DHI for Pathway-based Care, Patient Empowerment, Inter-sectoral Collaboration, and Data-centered Value Creation

3.2.1 Outline of P1 – Pathway-supporting Health Information Systems: A Review

Context and Method

Care pathways and supporting HIS have been permeating HISR over the years. Interdisciplinary goals increasingly extend traditional objectives of workflow assistance from technology, medicine, management, and public health research. In a systematic literature review, this integrating character has been investigated (Scheplitz, 2021). It examined the interdisciplinary mesh of objectives associated with care pathways and pathway-supporting HIS in the HISR literature. It uncovered six thematic themes to support design and development processes as it describes the solution space of future pathway-supporting HIS addressing requirements stated by multiple stakeholders.

Results

This review identified 47 articles from highly ranked literature databases discussing care pathways or pathway-supporting HIS. Through their interpretation, six themes were derived representing the range of interdisciplinary goals with and for pathway-supporting HIS. Table 2 refarch shows all themes and sub-topics to give an overview of pathway-related HISR of the last decade. The following additions highlight selected findings or implications for future design and implementation activities of pathway-supporting HIS.

I. *Design, development, and implementation of pathway-supporting HIS:* Articles of this theme present generic approaches or descriptions of distinct pathway-supporting HIS and application systems for specific care scenarios. The traditional workflow support of clinical processes is increasingly complemented by articles that present solutions for more complex, inter-organizational, and patient-integrating care scenarios. Future work on this theme should concisely characterize the care scenario and parameterize targeted improvements to care-related goals or further outcomes to increase reusability.

II. *Evaluation and assessment of pathway-supporting HIS:* Articles of this theme investigate the effects of pathway-supporting HIS. Increasingly complex care scenarios require future evaluative papers to consider all involved stakeholders more comprehensive (e.g., multidisciplinary care teams, patients, expanded health care market) and to discuss competing or synergistic effects and measurable outcomes.

III. *Modeling and modeling languages of care pathways:* Research with a focus on pathway modeling, modeling languages, and tools discusses less the design and realization of application systems but addresses the underlying pathway models and their genesis. The established knowledge base provides already valuable guidance. However, the scope change to inter-organizational, highly digitized care scenarios requires additional work to offer appropriate techniques for precise, comprehensive, and consistent pathway models.

IV. *Data-driven pathway models and integration of data-based prediction models:* Recent advances in data science, machine learning, and related disciplines drive articles on this young theme. It includes articles that discuss the data-based derivation of care pathways from existing data, e.g., of EHR. Such retrospective pathway analyses provide the opportunity to compare originally defined care plans with de facto care pathways and to investigate deviations. Consequently, this knowledge might be used to optimize individual care pathways or general pathway templates prospectively or improve medical guidelines (e.g., for care quality or efficiency). On the other hand, this theme also includes discussions of how pathway-supporting HIS can provide the data basis for data-driven medical decision support systems or management-oriented predictive models. Both sub-themes - pathway-supporting HIS as a source and a sink of data-driven processing of health information - like to merge and are currently of increasing interest.

V. *Conceptual integration of the management perspective:* Traditional workflow assistance fosters goals directly related to care processes, such as accelerated process flow or lower error rates. Articles of this fifth theme investigate how pathway-supporting HIS can support additional short-, medium- and long-term healthcare management tasks on micro-, meso- or macro-level (e.g., quality management, resource management, health program management). Future work shall explore how pathway-supporting HIS need to be designed to satisfy this information demand and to offer management decision support.

VI. *Care pathways as a means for HISR:* Pathway-supporting HIS can be a starting point and data source for diverse research questions. Future design and implementation activities should consider the access to and scientific usability of the processed data and integrate validation and anonymization mechanisms in particular.

Contribution to Doctoral Thesis

This article opens the problematization efforts related to the initial research objective aiming at a sound understanding of DHI in complex HIS landscapes (RO1). In particular, it provides answers for RQ1.1 that asks for an overview of objectives that are pursued by current DHI projects of research and practice on pathway-supporting HIS. Here, the six identified themes of recent

Table 2: Analytical results of P1 - themes on pathway-supporting HIS

Theme (Number of papers that led to theme): Sub-topics
I. Design, development and implementation of pathway-supporting HIS (n=13):
- Development and implementation of clinical pathway for specific healthcare scenarios
- Generic conceptualizations and design recommendations
II. Evaluation and assessment of pathway-supporting HIS (n=16):
- Studies on effectiveness, efficiency and user experience
- Usage analyses for coordination and communication
- Maturity model for care pathways and its implementation in HIS
III. Modeling and modeling languages of care pathways (n=8):
- Development of process-oriented modeling languages for care pathways
- Conceptualization and modeling approaches
- Modeling tools for care pathways
- Examples of care pathway modeling (process and final pathways)
IV. Data-driven pathway models and integration of data-based prediction models (n=7):
- Modeling methods or tools for care pathways from electronic health records
- Development of data-based prediction models (Data & Process Mining, Machine Learning, Deep Learning) for medical decision support
- Data-based analysis and decision models from data of pathway-supporting HIS for healthcare and hospital management
V. Conceptual integration of the management perspective (n=5):
- Intersection analysis of Information Systems, Operational Research and Industrial Engineering to solve problems related to care pathways
- Method conception for the embedding of quality management in care pathways
- Path-based data analysis for tactical and strategic hospital management
- Conceptualization and modeling approaches for aligning evidence-based Clinical Practice Guidelines and Clinical Pathways
VI. Care pathways as a means for HISR (n=7):
- Analysis of the Status Quo of the Digital Transformation
- Analysis of technology support across care pathways
- Analysis of key areas via patient flow pathway mapping
- Studies on personalization of HIS services

literature represent clusters of objectives related to pathway-supporting HIS. The themes I - III commonly confirm the inherent goal of process support that increasingly focuses on complex inter-organizational and patient-integrating care scenarios. Theme IV indicates the interplay of pathway-supporting HIS and ongoing progress in the field of data-centered value propositions ensured by novel mechanisms of AI. Due to its topicality and relevance, this contextual interface is investigated more in detail in P3 of this doctoral thesis (see subsection 3.2.3). Theme V points to objectives related to the effective and efficient organization of healthcare delivery. Especially opportunities for resource and quality management as well as design and realization of health programs are highlighted by this theme. Finally, theme VI indicates the potential for inter-sectoral collaborations between healthcare practice and interdisciplinary research due to the provision of valuable data gathered by pathway-supporting HIS. In consequence, this review describes the realm and variety of objectives related to current DHI within pathway-supporting

HIS. Technological advances in data science and related disciplines indicate an enhanced potential for both personalized care and learning systems on a macro level for management and medicine.

3.2.2 Outline of P2 – A Reference Architecture Approach for Pathway-based Patient Integration

Context and Method

In a past research project, we designed and implemented a patient portal for the treatment of Multiple Sclerosis (MS) patients. One of the main motivations was to enrich an existing information system landscape to, on the one hand, support the inter-organizational care setting of this ”disease of a thousand faces” and, on the other hand, actively involve patients who are often young at the time of initial diagnosis (between 20-40 years) in the diagnosis and treatment processes. The active integration of a patient into his/her care process offers great potential for improving care quality. In this regard, patient portals are frequently referenced for enabling patient empowerment and engagement. At the time of this research, existing solutions primarily focused on access to electronic health records (EHR) but did not aim for the integration of cross-institutional information about the course of treatment itself (the patient pathway). In this paper, we presented results of our design process toward a pathway-supporting, patient-integrating HIS landscape (Benedict et al., 2019). We show how high-level requirements have been captured from both a user's and a theory perspective. Therefore, a large-scale patient survey was conducted within a general DSR approach. They were transformed into appropriate modules and components that were further used to propose a reference architecture. Its applicability is demonstratively shown by the development of a MS patient portal.

Results

With this research, we were able to raise seven central user requirements from both the patient's and a care provider's perspective related to treatment planning, organization, and monitoring. As a next step, we developed seven related functional requirements of the intended HIS landscape. On that basis, modules in the sense of architectural building blocks were derived and combined into a reference architecture approach (see Figure 7). The original article presents comprehensively the architectural design process. Here, only a brief description of functional requirements, modules (see Table 3), interfaces, and their interplay is given to provide insights into a HIS architecture that supports both patient integration and inter-organizational care along a care pathway. The following list of specified functional requirements describes those elements that are necessary for realizing patient pathways within patient portals.

F1 Task and schedule control should be actively carried out. Appointments and tasks should be actively communicated to involved systems.

F2 A pathway-supporting, patient-integrating HIS should be capable of informing involved applications about changes of a patient's status, treatment plan, a particular treatment, or specific values.

F3 By using appropriate tooling (e.g., modeling tools), pathway templates should be created and managed comfortably as well as provided to involved systems.

F4 Pathway templates should be integrated into the case documentation of the pathway-supporting, patient-integrating HIS and need to be instantiable individually

F5 Patient pathways should be visible and editable for authorized actors in the context of a patient-specific case. The modification of the planned patient-specific pathway should be possible at any time whereby the possibility to justify modifications is essential.

F6 Evaluation and monitoring functionalities should be carried out centrally for every stakeholder. Alternatively, existing process mining tools should be integrable.

F7 Instances of pathways should continuously be adapted to the documentation situation of the involved clinical application system and other documentation systems.

The range of patient portals' functions should reflect a patient's disease-specific informative needs. Therefore, the configuration or instantiation of a patient portal may vary by selection and specific realization of functions. Thus, the above-stated list of functional requirements as well as the proposed modules should not be seen as a completed set due to the possibility that other treatment contexts can require additional modules. Instead, this composition offers a valuable entry point for design activities of DHI project with comparable objectives.

Eight architectural modules divided into three classes were derived for realizing these functional requirements: Kernel modules, specific pathway modules, and pathway-associated modules. Kernel modules include the basic configuration as well as central functionalities and interfaces. Functionalities of specific pathway and pathway-associated modules depend on Kernel modules (e.g., rights management). The specific pathway modules are responsible for functionalities for the representation and execution of particular pathway instances. In contrast, pathway-associated modules describe subject-specific functionalities related to a pathway. For example, within the pathway-associated module ”Documentation”, a patient can let the portal display all documents linked to the pathway step ”Anamnesis”. Furthermore, appointments or linked medications are available throughout the modules ”Encounter” and ”Medication”.

Figure 7 shows the proposed reference architecture which sums up the roles of particular modules and the interfaces between them. Therefore, the architecture approach proposed by

Table 3: Modules of a pathway-supporting, patient-integrating HIS landscape

Module	*Description*
Infrastructure/Kernel Modules	
Kernel	This module implements fundamental functionalities and configurations (authentication, identity-, demographic data- and software interface-management as well as metadata configuration).
Specific Pathway Modules	
Care Plan Module	This module implements that kind of pathway functionalities that can be influenced by patient engagement.
Self-Tracking Module	This module implements health status monitoring.
Pathway-associated modules	
Encounter Module	This module implements functionalities for the management of appointments and other medical or nursing interventions.
Documentation Module	This module implements access functionalities to electronic health records and other medical documentation as well as providing documentation capabilities for the patient.
Assessment Module	This module implements screening and questionnaire functionalities.
Education Module	This module implements the patient specific therapy support functionalities (exercise instruction, explanatory materials, etc.).
Medication Module	This module implements medication-related management and monitoring functionalities.

Schlieter et al. (2017) has been taken up and extended by communication relations between backend services and the patient portal. The Patient-oriented Pathway Repository has the responsibility to persist pathway instances. Pathway templates are stored in the template repository. Professional control – the use of pathways by the care provider – is ensured by the Professional Pathways-Service. This component includes all components of pathway instantiation, modification, and analysis as well as components of data integration. In addition, it enables active pathway changes, automatisms, and manipulations done by the care provider responsible for pathway execution. The component Patient Pathways Service serves the execution of pathways from a patient's point of view. It realizes pathway-related functions for the patient and ensures access to pathway information. Also, it offers functionalities that allow direct patient involvement in the treatment process by modifying pathway instances. In this way, questionnaires that must be completed by the patient in dependency on the treatment progress could be integrated. The component Clinical and Professional Application Systems represents existing clinical IT systems for documentation and management. These systems are particularly relevant as they provide information or functions for pathway planning, execution, or monitoring.

Parallel to identifying and specifying relevant building blocks, we also defined different bidirectional interface types connecting the presented components. The original research article describes these interface types, the information transmitted, and access modalities in more detail. We focused on internal interfaces required to ensure the synergies of pathway support and

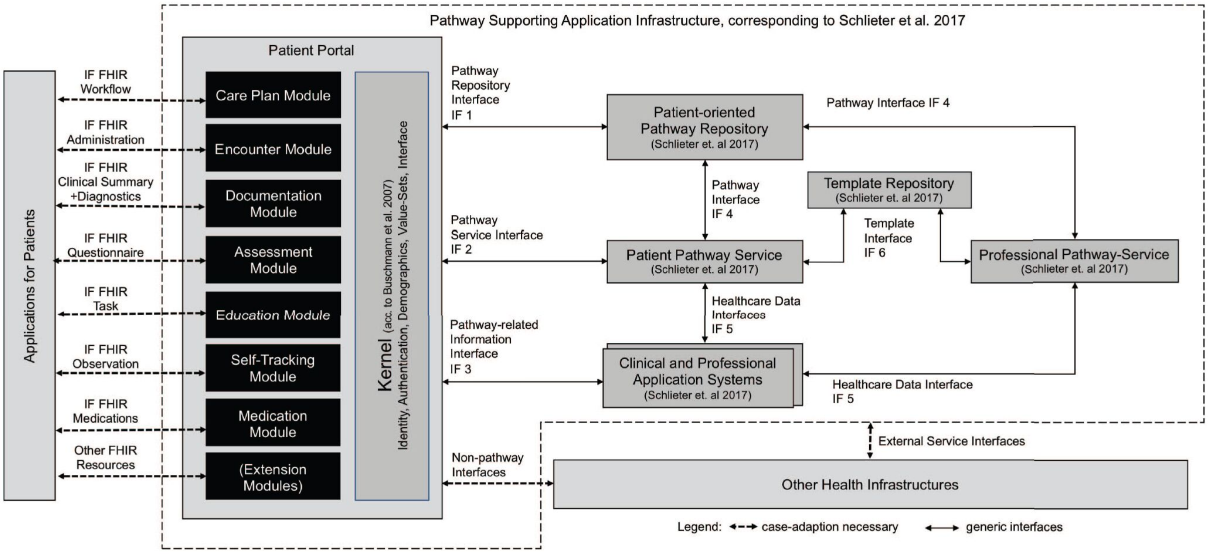

Figure 7: Reference architecture approach for a pathway-based, patient-integrating HIS landscape.

patient integration via a patient portal. We also highlighted open and interoperable interfaces to external devices (e.g., blood pressure monitors) and applications (e.g., health apps). These interfaces serve as case-dependent integration points because external services may be used in various contexts. For patient portal interfaces, the proposed reference architecture points explicitly to the Fast Healthcare Interoperability Resources standards (FHIR) for orientation purposes. Generally, interfaces have to be adapted to the specific disease and the particular scenario so that other standards or formats can be used.

Contribution to Doctoral Thesis

Article P2 addresses the realization of pathway-supporting, patient-integrating HIS landscapes from an architectural point of view. A reference architecture approach has been developed based on a catalog of requirements. It specifies typical system components, roles, and communication relations. Also, a proof-of-concept is proposed by its utilization for the specific case of MS treatment within the full article as an evaluating research step. In addition, it shows the applicability and instantiation of the generic architecture concept.

This article contributes to the first research objective (RO1) which aims to investigate the design, development, and implementation of DHI in complex HIS landscapes. It implicitly confirms the goals of more vital patient involvement and the support of inter-organizational care processes, which are to be pursued by current and future DHI (RQ1.1). It takes an architectural perspective and explores how complex HIS landscapes should be designed to achieve those healthcare goals (RQ1.3). Here, a HIS architecture is proposed that ensures objectives investigated in P1 (see subsection 3.2.1) and P3 (see subsection 3.2.3), especially 1) supporting inter-organizational care settings along uniform care pathways, 2) fostering a proactive integration of patients into their care process, and 3) ensuring a HIS environment that facilitates data-centered value propositions of further DHI by the use of standardized interfaces. Regarding the latter aspect, indications for an increasing relevance of interoperability were observed – here mostly in its technical interpretation – which guided subsequent research activities toward an in-depth investigation on interoperability for DHI (RO2).

It has to be mentioned that this article focuses on the functional-technological realization of a pathway-oriented patient portal. Further systems interactions, e.g., for administration or finance purposes, generate a variety of additional boundaries but are not addressed in this work. Also, aspects regarding data security are not explicitly considered in this approach but do influence a distinct realization on the architectural level. Therefore, the proposed reference architecture serves as a limited design aid but offers a practical approach to accomplish the transformation process to pathway-centered patient integration.

3.2.3 Outline of P3 – PathwAI Systems in Healthcare: A Framework for Coupling AI and Pathway-based HIS

Context and Method

In prior research and development projects, we investigated how HIS enable the planning, execution, and improvement of standardized care pathways to enhance continuity and defragmentation of inter-organizational care scenarios. We indicated that such pathway-based HIS support the adaptivity of individual healthcare processes and learnings about the efficacity and efficiency of pathway models and their application in distinct care scenarios. Knowing that adaptive behavior and learning effects are taken to a new level by advances in AI, we were motivated to investigate how these novel data-centered techniques could enrich pathway-based HIS (Scheplitz et al., 2022). At the time of this article's origin, design support to unlock synergies from coupling pathway-based HIS with AI was lacking. Thus, we conducted an umbrella review to identify applied purposes of AI in healthcare related to pathway-based HIS and derived a PathwAI Framework as design support for future research and development activities.

Results

As an interim result, we developed an analysis concept that describes the bandwidth of possibilities to integrate AI in pathway-based HIS (see Figure 8). It allowed us to structure our findings deductively and comprises the following elements:

- *Pathway Template:* Model of a care process; Represents standardized process knowledge; Differentiation by views on medical care, coordination of professional care delivery and business as well as administration; Different reference levels describe intra-organizational (micro), cross-institutional (meso), and national or international (macro) levels.

- *Pathway Instance:* Application of the pathway model for a patient; process execution on all views (care, professional coordination, business and administration); pathway systems as application systems to apply, execute and store pathway instances.
- *Cohorts of Pathway Instances:* Selected set of pathway instances; Cohort building by, e.g., indication, symptom, treatment, demographics, time period, etc.
- *Data Sources:* Multimodal set of structured and unstructured data; a variety of HIS, application systems, and devices including, e.g., EHR systems, clinical information systems, health information databases, med-tech devices, and the patient's IT in their home environment.
- *AI:* interpreted as a black box of algorithms and techniques to generate knowledge from different data in an automated way for defined purposes.

Two questions led the investigation with a simplified understanding of AI as a black box. First, for which particular purposes is AI attempted. And second, what data is needed as input for these purposes. We assumed that AI might be coupled with pathway-based HIS to fulfill one or more of the proposed six top-level purposes (P.1-P.6, see Figure 8). These top-level purposes were analyzed more in detail by this study. Thus, we examined how AI supports ongoing care (P.1-P.3) and general learning effects at the micro, meso, or macro level (P.4-P.6).

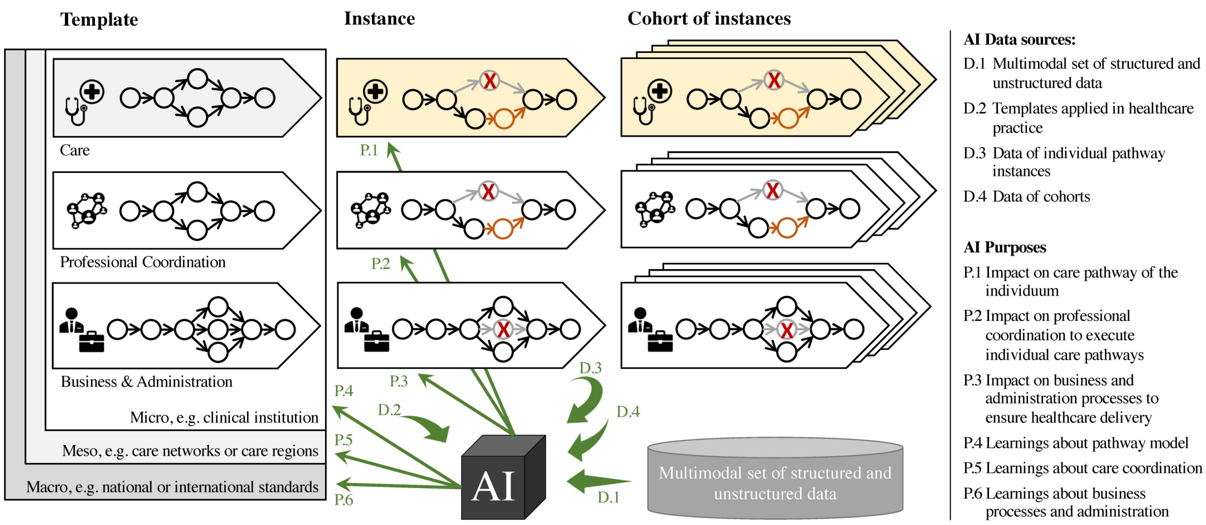

Figure 8: Analysis concept for investigating the application of AI in pathway-based HIS landscapes.

We further assumed that AI could use four general types of data input (D.1-D.4) but highlighted that this distinction should not be understood as physically delineable data repositories. Instead, data structures of pathway-based HIS should be delineated from the set of other data sources. Consequently, we focused only on abstract indications of data exchange relations between AI components and pathway-based HIS that might be part of future in-depth analyses.

With this conceptual entry point, we analyzed previous reviews on AI application in healthcare with an explicit relation to care pathways. Previous studies already provide a large base of approaches to realize personalized care pathways and improve coordination and business operations. Furthermore, potentials for designing learning health systems at micro, meso, and macro levels are formulated, but there is still significant opportunity for future research and design. Pathway-based HIS in this context can provide interpretable and interoperable data input and be conceptual and operational receivers of artificially generated knowledge. Finally, we described and systematized the identified purposes and interdependencies in the PathwAI Framework (see Figure 9 and Table 4). It offers a structured view of the bandwidth of possible data-driven improvements and, thus, guidance for interdisciplinary DHI teams of clinicians, technologists, and health systems managers. Future research shall further focus on the symbiosis of AI within pathway-based HIS to ensure adaptive, multi-level learning and high-performance HIS as current literature lacks in evidence for that scope.

Contribution to Doctoral Thesis

This review article offers a high-level overview of how HIS can be improved by ensuring synergies of pathway-based HIS and the application of AI within such HIS landscapes. The descriptive analysis results were transformed into the proposal of a systematization aid for future DHI projects – the PathwAI Framework. It offers support for the conceptualization of distinct DHI objectives (RQ1.1) that strive for the integration of AI applications. Regarding the complexity and broad realm of opportunities in the interplay of pathway-supporting HIS and AI techniques, this paper's contributions increase the understanding of data-centered value propositions of DHI in complex HIS landscapes by providing a systematization aid (RQ1.2, RO1) for future DHI design and development efforts. Even though this article does not discuss technical systems interactions in particular it indicates the relevance of interoperability by highlighting data input-output relations of multiple sub-systems required to ensure the identified purposes.

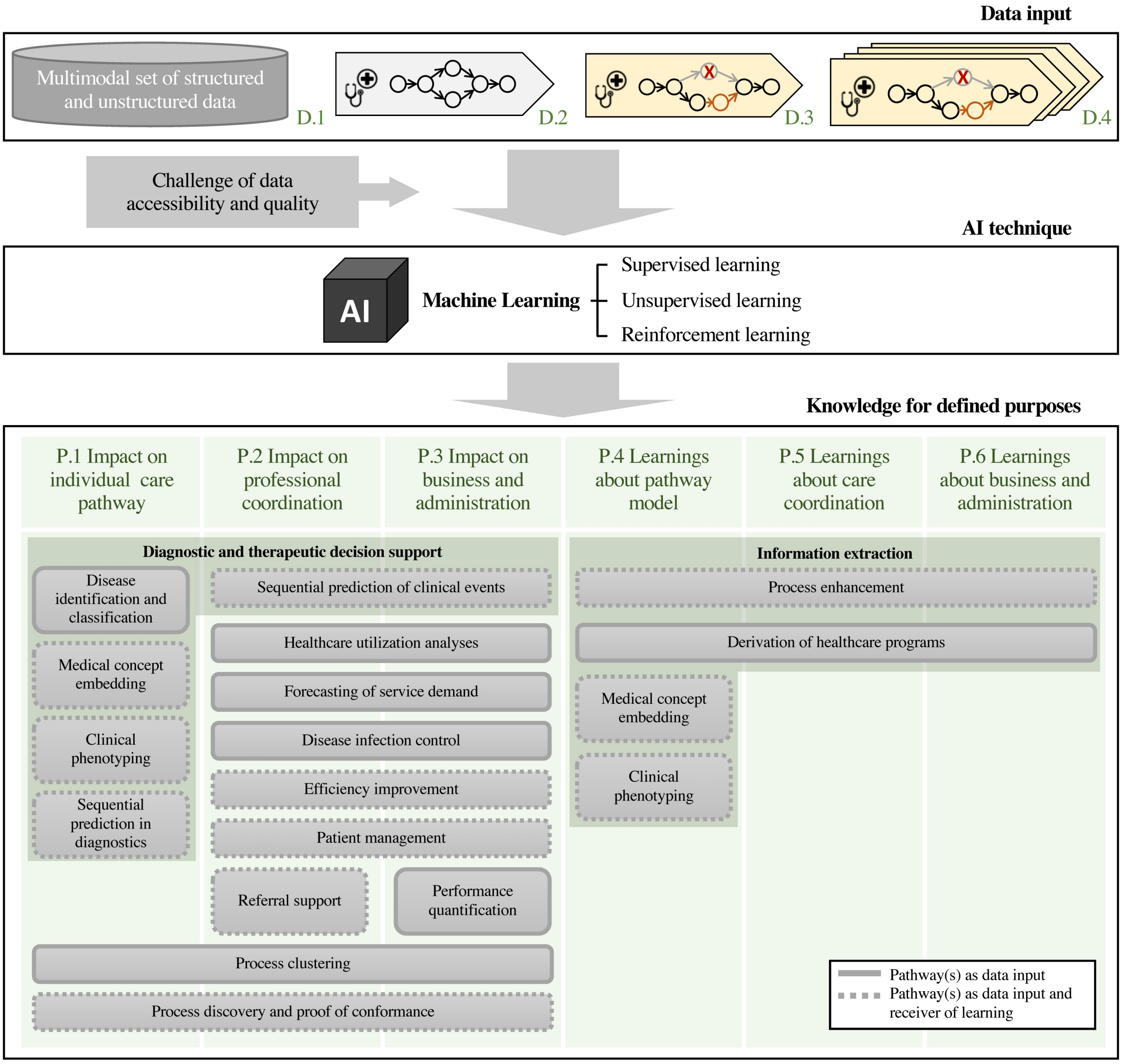

Figure 9: PathwAI Framework systematizing purposes of AI application in pathway-based HIS landscapes.

Table 4: Findings of umbrella review - purposes of AI application in relation to pathway-based HIS.

	Description	Purpose group
Diagnostic and therapeutic decision support	AI provided information to inform diagnosis and treatment decisions. Diagnostic applications typically seek for onset or probability that a patient has a particular condition or recommend diagnosis categories. Diagnostic decision support is used to describe and/or predict various conditions or events. Therapeutic decision support includes any management or care provided (or absence of unnecessary actions) to a patient with specific health condition(s) or symptom(s). Therapeutic applications result typically from diagnostic decision support. They are often used to predict or define a personalized treatment, e.g., medication or treatment plans, for improvements in quality outcomes or efficiency.	P.1, P.2, P.3
⌊ Disease identification and classification	AI used to screen and detect whether specific diseases can be confirmed. Different types of Classifications are applicable: disease specific (categorical or multi-label) or disease non-specific (normal, preictal or seizure subject).	P.1
⌊ Medical concept embedding	AI used to derive abstract representation of clinical concepts based on analysis of real cohorts. It aggregates medical concepts that occur frequently together. Concept embedding is often an intermediate, descriptive step for building a predictive model of previous and next steps from a certain position in the pathway for better performance.	P.1, P.4
⌊ Clinical phenotyping	AI used to discover phenotypes via feature representation and investigates association of pathway instance to different phenotypes. First, phenotypes are extracted as new knowledge out of cohorts of instances, e.g. by prevalence of a condition or patterns of patient profiles. Second, single instances are matched with discovered phenotypes. Third, treatments might be personalized, e.g. by pathway instance adaptions. Clinical phenotyping is considered as a type of concept embedding.	P.1, P.4
⌊ Sequential prediction in diagnostics	AI predicts future diagnoses based on past longitudinal event sequences (patient's history), e.g. onset of new disease condition, risk of in-hospital mortality, discharge diagnoses. Differentiation of static (categorical or numeric) or temporal (time stamp or range included in prediction)	P.1
⌊ Sequential prediction of clinical events	AI predicts future clinical events based on past longitudinal event sequences (patient's history), e.g., unplanned hospital admission/ readmission, length of stay. Differentiation of static (categorical or numeric) or temporal (time stamp or range included in prediction)	P.2, P.3
Process clustering	AI identifies groups of similar business processes or care pathways based on analysis of a cohort of instances.	P.1, P.2, P.3
Process discovery and proof of conformance	AI used to derive retrospectively or ad hoc business process or care pathway instance based on analysis of a single or a cohort of instances. Often follows a check on how a business process or care pathway instance align with the underlying template.	P.1, P.2, P.3
Referral support	AI provided information to support decisions about referring patients to specialist services or AI assisted with technical aspects of the referral process.	P.2
Health care utilization analyses	AI provided information about interactions with or processes within health care systems, for example frequency or quantity of patient visits.	P.2, P.3
Forecasting of service demand	AI used to predict demand of healthcare services on macro level	P.2, P.3
Disease or infection control	AI used to monitor and predict dynamic of diseases or infections on macro level	P.2, P.3
Efficiency improvement	AI used to predict service demand on micro level and improve resource utilization and allocation (decision support)	P.2, P.3
Patient management	AI used to adapt scheduling and forecasting based on patient conditions and behavior (decision support)	P.2, P.3
Performance quantification	AI used to quantify performance of medical service delivery	P.3
Information extraction	AI used to extract knowledge from structured or unstructured data	P.4, P.5, P.6
⌊ Process enhancement	AI used to extent pathway templates with information from event logs.	P.4, P.5, P.6
⌊ Derivation of healthcare programs	AI used to improve design of national healthcare programs (macro level)	P.4, P.5, P.6

3.2.4 Outline of P4 – Research in Digital Innovation Projects: Between Practicality and Scientific Relevance

Context and Method

The multiple research and development projects of our research group that I could participate in always aimed for a synergetic combination of a DHI's development and accompanying research. On the one hand, we fostered the development and integration of a distinct DHI providing one or more value propositions demanded by healthcare practice. On the other, we strove for the scientific exploration of how a distinct DHI shall be designed, which methods and techniques should be applied and how the DHI supports the transformation of its specific HIS landscape to a learning system. Explicit and implicit knowledge, as project results in addition to the innovation itself, can be critical for the organization and implementation of similar projects. But their communication and structured provision have been little addressed in science at that time of our investigation. Thus, we were motivated to investigate how healthcare practice and science objectives can be systematically pursued in harmony (Scheplitz et al., 2020). Therefore, this paper shows how knowledge from DHI projects can be better extracted and communicated. For this purpose, an existing approach to systematize design-oriented research projects, the Design Science Grid proposed by vom Brocke and Maedche (2019), is applied in three case studies. We identified seven different types of knowledge that can result from DHI projects. These knowledge types can serve as a starting point for classifying goals for future DHI projects.

Results

In this paper, we investigated which approaches of the current scientific discourse provides support for systematizing knowledge contributions in design-oriented DHI projects. For this purpose, the DSR Grid of vom Brocke and Maedche was first introduced and the role of descriptive and prescriptive knowledge within ISR was discussed. Since practice projects often lack to translate their innovation(s) and project results appropriately into generalizable prescriptive knowledge, this grid provides a good facilitation framework for analyzing and explicating knowledge within DHI projects. Within three case studies, we applied the Design Science Grid to illustrate how such a systematization can look. Thus, we demonstrated its usefulness for project systematization and the structurization of scientific objectives.

Based on the knowledge contributions collected in the case studies, we further derived a classification approach that distinguishes seven potential knowledge types of DHI projects. The individual knowledge contributions were classified concerning comparable properties and assigned to knowledge types. The knowledge types are thereby specializations of the key concepts of design science: concepts, models, methods, and instantiations (Drechsler and Hevner, 2018). The following list presents briefly all knowledge types elaborated and their essential characteristics. Due to inductive derivation, the comprehensiveness and validity are limited. Thus, the knowledge types presented are not a closed set. Rather, the paper shows how emergent knowledge can be systematized and offers a reference for knowledge characterization in DHI projects. Although the knowledge types are derived inductively, they can serve as a reference and legitimation for research goals.

- *Technical Architecture:* Description of technological components, their roles, and interrelations; Serves as a starting point for coordinating integration requirements and related tasks within a consortium; Can be used as a reference for similar projects, e.g., for discussing data security or distribution of functionality by different components.
- *Specification:* Detailed description of specific system component's design; Focus on a particular solution; Description can be either domain-driven (e.g., medical description of a stroke rehabilitation report) or technology-driven (e.g., FHIR profile for the exchange of questionnaires) whereby the boundaries are fluid; Potential artifacts for standardization processes via official bodies.
- *Digital Care Model:* Description of the central and logical modes of healthcare delivery based on the use of one or more digital technologies within a defined network of actors; Assumes an idealized and coordinated healthcare delivery for the patient; Emphasizing the use of digital technology for service delivery, summarize the service network and value propositions, and the core business processes.
- *Medical Domain Model:* Structural (e.g., semantic representations) or dynamic (e.g., patient pathways) description of a distinct care scenario or of a particular aspect of it; May serve as both a visual and a (semi-)formal representation of medical facts; Used by healthcare professionals to derive (digital) care models or by IT specialists to derive technological specifications.
- *Integration Model:* Methodical and structural description of interdisciplinary tasks and cooperation between DH actors to ensure required interplay of medical, technological, and organizational aspects for DHI artifact's integration into practice.
- *Design Principles:* Recommendations for the functional and technical design for either digital care models or medical technologies; Considerations of the organizational environment and stakeholders' interests.
- *Methods:* Formalization and generalization of methodological approaches used to develop and integrate novel DH artifacts into a reusable knowledge contribution;

Contribution to Doctoral Thesis

This paper is part of the problematization along RO1 to gain insights into the complex set of requirements of current DHI projects. It deepens the focus on inter-sectoral collaboration between science and healthcare practice within DHI project consortia. Complementing the papers P1-P3, which also highlight the research-enhancing potential of new DHI artifacts, this study focuses on the scientific knowledge gained within a DHI process. It answers research question RQ1.4 by arguing for using current design science approaches within DHI projects and provides support for characterizing scientific knowledge goals. Beyond evaluating a specific DHI artifact in the field (e.g., medical, economic, or organizational), seven knowledge types are described that can be explicitly pursued as scientific goals of HISR in parallel with development goals of a DHI project.

The more detailed discussion of the identified knowledge types influenced further research activities of this dissertation through two conclusions. First, all seven types underpin the need for a socio-technical position to harmonize DHI development and science objectives in complex environments. In doing so, they implicitly indicate the socio-technical spectrum of interoperability aspects contextualized and differentiated within the work on RO2. Further, the emerging awareness of the knowledge type integration model influenced the refinement of this thesis' research focus. Within the broad potential of possible research aims along different research projects, this work strives for knowledge and design goals that seek to improve the integration of DHI into complex HIS landscapes. Thus, P4 supported the focus of the overall research objective to investigate a socio-technical conceptualization of interoperability as a key property for the development and integration of DHI.

3.3 Socio-Technical Interoperability for DHI

3.3.1 Outline of P5 – Overcoming Diffusion Barriers of DHI: Conception of an Assessment Method

Context and Method

Motivated by the results of problematization activities related to RO1, the research focus shifted from defining the solution space of complex DHI in modern HIS landscapes to the determination of diffusion barriers of DHI. Despite DHI's relevance for the healthcare domain, their political and societal attention as well as the general support from health insurance companies, DHI still struggle on their way into healthcare practice. One central challenges is the multitude of diffusion barriers, which are either little known or difficult to handle in complexity from an innovator's perspective. They, therefore, pose a high risk for the DHI's translation into healthcare practice. This paper steps into this discourse with a design-oriented research approach (Hobeck et al., 2021). A systematic literature review enhanced by a qualitative content analysis identified DHI barriers that are further evolved to a concept for assessing barrier resilience. On that basis, a framework was developed to administer diffusion barriers to DHI in Germany systematically. The proposed framework aims to assess the likelihood of a successful implementation and indicates alignment with the concept of socio-technical interoperability in the DH domain.

Results

This paper discussed a central issue of DHI: even highly optimized DHI with strong problem-solving potential do not necessarily scale-up in the intended environment. A crucial factor is system-imposed barriers that must be considered to introduce innovations to end-users and unfold expected benefits for care provision. To tackle this issue, the first draft of an evaluation approach was developed by this research to determine the resilience of DHIs to diffusion barriers. This article contributes to diffusion and adoption research in healthcare. It offers insights into healthcare-specific diffusion barriers by integrating former literature and focusing distinctly on the German healthcare market. The resulting categorization (see Table 5) offers a frame for further investigations. It also leads to the design of an easy-to-use approach for assessing the readiness of a DHI to spread successfully. The usefulness and functionality of DHI play only a secondary role in this approach. Sustainable value is rather added by shifting from functionality-focused thinking toward dissemination-centered considerations. Summarizing this paper's scientific relevance: it enriches existing knowledge about DHI diffusion into healthcare markets by a formative assessment method that allows determining how a DHI may take the hurdles of concrete diffusion barriers.

Table 5: Identified diffusion barriers of DHI structerized by categories and super-categories.

Super-categories	Categories
(1) Reimbursement and Financing	Remuneration conditions cross-sectoral; Remuneration conditions in the stationary sector; Reimbursement in the outpatient sector; Non-remuneration of cost savings; Infrastructure costs; High initial costs; Low willingness to pay on the second healthcare market
(2) Regulations and Guidelines	Health market approval conditions; Legal data protection regulations; Lack of standardised regulations: Liability risks; Ban on remote treatment
(3) Technical Barriers	Technical maintenance; Infrastructural barriers; Lack of security/reliability of medical data; Lack of technical interoperability/compatibility
(4) Proof of Effectiveness	Deficit in studies; Missing certification method; Lack of evidence of efficacy; Lack of evaluation methodology
(5) Proof of Efficiency	Lack of efficiency evidence; Duration of efficiency assessment
(6) User Acceptance	Knowledge and competence-related barriers; Insufficient relative advantage; Necessary process changes; Resistance of the practitioner to changes in established practices; Questions of trust towards the provider; Unsuitable organizational structure of the adopters; Stigmatization of the patient; Reading/spelling deficit of the patient; Conservative attitude of physicians towards innovations; Lack of technical affinity or knowledge among physicians and patients; Fear of job loss on the part of the physician

The proposed evaluation approach supports innovators and development teams struggling with the complexity of DHI diffusion into day-to-day healthcare. We enveloped the socio-technical realm of diffusions barriers that need to be considered particularly within DHI processes. We highlighted thereby the observation that our results align with a European consented concept of interoperability (the ReEIF, see subsection 1.1) in terms of both the basic socio-technical positioning and distinct categories. We found a strong relation of our results to the six interoperability levels of Legal and regulatory, Policy, Care Process, Information, Applications, abd IT-Infrastructure) that motivated further research direction.

Contribution to Doctoral Thesis

Article P5 opens the activities toward the second research objective (RO2). While previous papers P1 to P4 examined the characteristics of current DHIs in complex HIS landscapes and described connected goals of digitally-enabled healthcare, this and subsequent papers focus on the diffusion process of a DHI into a specific target environment. In this initial contribution, relevant literature on DH diffusion was analyzed and consolidated, indicating the thematic intersection with a socio-technical understanding of interoperability (RQ2.1). These findings justified further research activities, which became major contributions to this doctoral thesis. In this way, this paper motivated a more intensive exploration of the extent to which the concept of socio-technical interoperability can be underpinned by DH diffusion theory plus practical experience (see P7 and P8 in subsection 3.3.3 and 3.3.4). In this regard, P5 strengthened the transmission of the research focus to the question, how socio-technical interoperability can become a leading principle of DHI management.

3.3.2 Outline of P6 – The Critical Role of Hospital IS in DHI Projects

Context and Method

Societal demand and political support drive researchers and practitioners to work in numerous initiatives to create digital innovations in healthcare. Despite all support, the problem of unsuccessful or not-satisfying translation of project outputs into the healthcare reality remains. The challenge of a DHI's diffusion into practice could not only be gathered from literature but was also experienced by the author of this thesis in multiple design-oriented research projects. These projects had in common that they all aimed to achieve distinct DHI development goals to improve complex, inter-organizational care scenarios and, thus, offered a case study environment to investigate diffusion barriers. This environment enabled a close-to-practice investigation of a DHI's integration into evolved Hospital IS. We applied the Action Design Research (ADR) approach of Sein et al. (2011) to analyze the role of Hospital IS in DHI projects and provide, first, a detailed description of a context-specific framework for the formalization of learning in DHI projects and, second, a systematic consolidation of observed enablers and barriers (Scheplitz et al., 2019). Thereby, a management perspective was taken which was conceptually guided by socio-technical interoperability as an overall key factor for successful implementation.

Results

Two results of this article are highlighted in the context of this doctoral thesis. First, the ADR approach of this paper demonstrates the methodological use of socio-technical interoperability as a systematization aid for investigating critical diffusion aspects of DHI projects. Second, observed and formalized enablers and barriers of DHI regarding the diffusion of DHI into established HIS landscapes confirmed their socio-technical realm and contextual relation to the construct interoperability.

From the methodological standpoint, the construct of interoperability was successfully embedded into the overall ADR approach (Sein et al., 2011) of this article (see Figure 10). Within the fourth stage (Formalization of Learning), we used a conceptual matrix considering two dimensions. One dimension focuses on typical life cycle stages of DHI projects (scope: conceptualization, implementation; not part of investigation execution and termination). The other focuses on the different interoperability-specific views that can be applied to Hospital IS. We

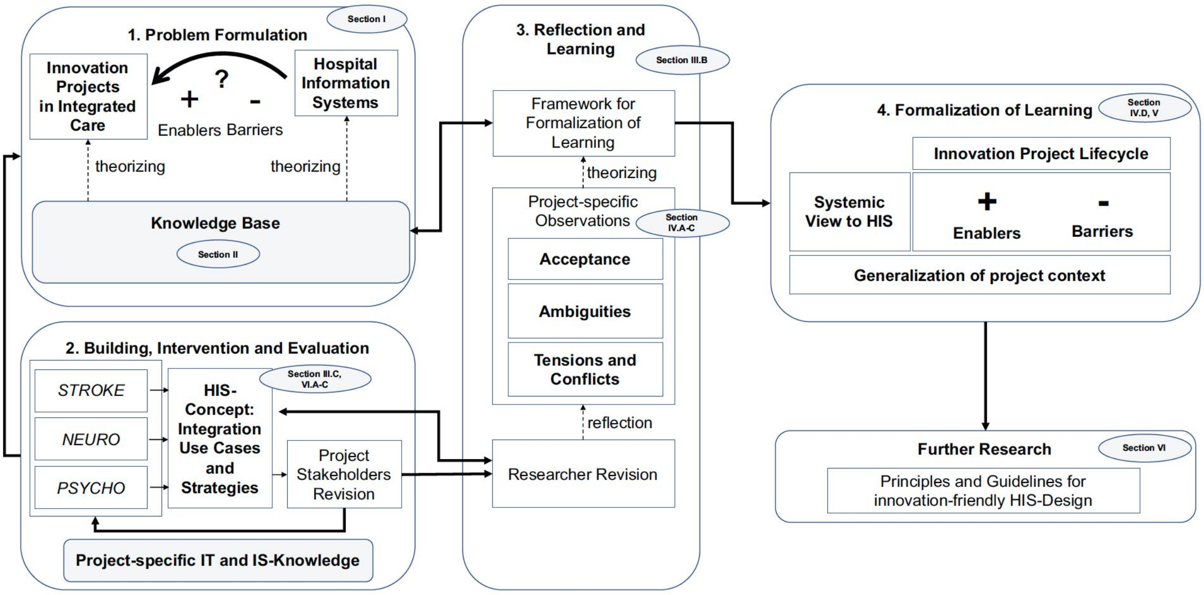

Figure 10: ADR approach for investigating diffusion barriers and enablers of DHI projects using the ReEIF as systematization aid.

selected the ReEIF as conceptual aid for systematizing our observations as it is considered a Europe-wide established framework and is accepted in the community (eHealth Network, 2015). On the other hand, it provides a granular view on healthcare interoperability by proposing six thematic layers: Legal and Regulatory, Policy, Care Process, Information, Application, and IT-Infrastructure.

We used the proposed ADR approach within three DHI projects that are briefly described in Table 6. A summary of the observations from these three DHI projects facilitates the identification of multiple possible barriers and enablers at various levels of interoperability (see Table 7). We were able to identify enablers as well as barriers on each interoperability level suggested by ReEIF. According to our understanding that Hospital IS and DHI are socio-technical constructs, the systematization via ReEIF helped to achieve different views on our DHI projects. This generally confirmed the suitability of the ReEIF as a socio-technical structuring aid for diffusion-critical aspects of DHI projects. However, the ReEIF did not suit some aspects of DHI project organization well without a technology relation. For instance, it was difficult to classify social observations, e.g., "insufficient collaboration with project partners". Additionally, a few observations, e.g., "insufficient technical documentation about existing systems", could not be allocated into the framework as they do not fit into one ReEIF level. The distinct enablers and barriers can also be named as relevant results, as they highlight specific diffusion aspects. However, this overview shall not be interpreted as a generally valid and completed list due to the methodological limitation of case study findings.

Table 6: Overview of DHI projects investigated by ADR approach.

Project	Project Description			
	Care innovation	*HIS artifact*	*Medical domain*	*Participants*
STROKE	Improving aftercare management by integrating general practitioners	Integration infrastructure for application systems of physicians	Stroke Aftercare	• 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, inter-organizational case record	Neurological Diseases	• 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	Inter-organizational case record, integrated professional tools, mobile apps for intraclinical assesment	Psycho-logical Care	• Medical experts from multiple hospitals • Provider of clinical documentation system • Provider of case record system • Information systems department of university hospital • Mobile app developers

Contribution to Doctoral Thesis

Hospital IS remain an essential hub for healthcare information processing even in inter-organizational care settings. DHI have to be integrated into these complex systems, consisting of different information processing actors and application systems. Based on an ADR approach, this article shows which barriers and enablers may occur with this task (RQ2.2). Thus, P6 contributes to diffusion theory by formalizing existing barriers and enablers from a practical setting. Additionally, we demonstrated and confirmed the practical and methodological use of a socio-technical conceptualization of interoperability to systematically investigate aspects critical to a DHI's diffusion. We indicated that the ReEIF generally suits these purposes but the identified vagueness also motivated further research in conceptualization and contextualization. These impressions led the logical flow of this doctoral thesis to the subsequent contributions P7 and P8 searching for conceptual improvements of this construct.

Table 7: Formalized enablers and barriers investigated by interoperability-based ADR approach.

Interoperability views (ReEIF)	DHI 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 DHI artifacts B: Missing interface strategies B: Divergent DHI 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

3.3.3 Outline of P7 – Ensuring Socio-technical Interoperability in DHI Projects: an Evaluation Approach

Context and Method

After investigating the challenge of a DHI's diffusion into healthcare practice by both theory-based and practice-oriented method sets, the motivation occurred to seek actionable management support for DH innovators. They inherently try to harmonize the realization of a distinct DHI's value proposition and the fulfillment of the complex web of requirements set by the target environment. It was also indicated in previous research activities of P5 and P6 (see subsections

3.3.1 and 3.3.2) that a socio-technical understanding of interoperability offers structurization to the latter task and becomes, therefore, a key property that DHI processes should strive for.

Nevertheless, management guidance based on a scientific conceptualization of interoperability remained to be discovered. Thus, this research paper aims to provide a DHI management aid explicitly reasoned by the overall aim of ensuring socio-technical interoperability from a DH innovator's point of view. It asks in detail how innovators can self-assess the progress of a DHI process holistically and tangibly to promote the later integration into complex HIS landscapes (Scheplitz, 2022). It proposes an evaluation approach that is conceptually based on the ReEIF. A systematic literature review enhanced by a qualitative content analysis approach derived concretizations of the six interoperability levels stated by the ReEIF. In detail, this article explored comprehensive descriptions of 181 potential parameters for a web-based self-assessment tool ("Interoptimeter"[2]).

Results

In this work, the idea of a self-assessment tool for DH innovators based on a holistic conceptualization of interoperability is initially elaborated. DHI processes might differ due to the artifact's specificity, the distinct target environment, and organizational circumstances but always pass typical stages (e.g., idea creation, conceptualization, development, and prototyping) and strive for a final integration into existing HIS landscapes. Evaluating the current progress with intended objectives is essential whether a DHI process is managed by using agile, sequential, or hybrid development models. Thus, innovators shall be supported in continuous or repeating evaluation activities to assess how the ongoing DHI process ensures the integration capability of their DHI artifact in a pilot environment or, later on, in healthcare practice.

To describe this integration capability, this paper proposes the construct of socio-technical interoperability as a representative key property (evaluation top criterion) and steps toward its conceptualization. A first systematization is provided via the ReEIF that defines six interoperability levels for the DH domain (evaluation sub-criteria). In consequence, this article presents an initial contextual concept of an evaluation tool (see Figure 11 intending to support DH innovators in assessing the integration capability of their DHI artifact (evaluation object). It should provide self-assessment questionnaires with appropriate items from different interoperability perspectives and present a structured report about how these perspectives are already addressed. The ReEIF might be used to systemize interoperability but does not provide a tangible operationalization. The presented research contributes to this need. It discovered literature-based actionable activities, tasks, or duties that might be included within a self-assessment.

The complete material run identified approximately 4500 markings. The markings showed

[2]Access to online tool via https://interoptimeter.webspace.tu-dresden.de/ or www.interoptimeter.de

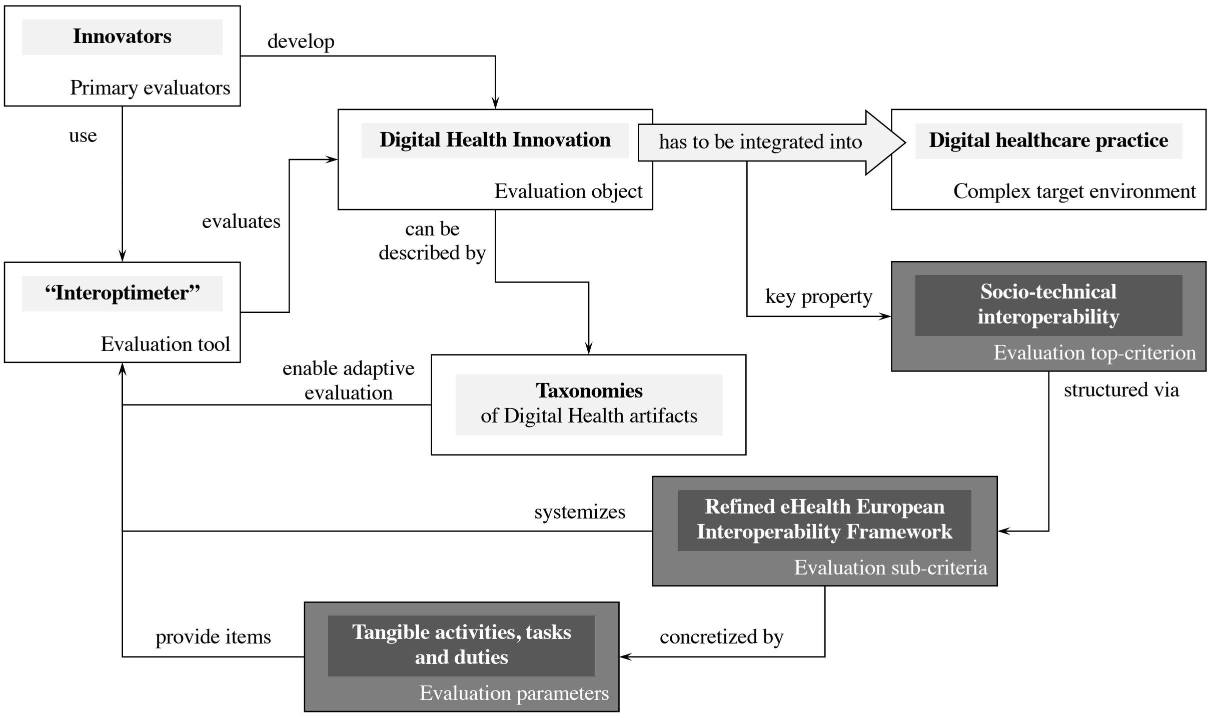

Figure 11: Research focus of P7 within the evaluation concept of the "Interoptimeter" tool.

differences in the degree of abstraction but could be subsumed into 122 descriptive aspects and 181 potential parameters. The extent of findings allows at this place only referencing their presentation within the original article (see section 11) and the complete compilation of explanations, list of descriptive aspects, and potential questionnaire items in Appendix F, G, and H. These detailed descriptions enrich the existing explanations of ReEIF (eHealth Network, 2015) and adopt them for the context of integration activities of DHI into healthcare practice.

In conclusion, the ReEIF generally suited the task of systematizing interoperability from a socio-technical HIS point of view. Nevertheless, some vagueness remained in the context of a DHI's diffusion into HIS landscapes of practice. In detail, two themes have been assigned within the ReEIF but do not perfectly match a level's intention: First, the differentiation of a process-centered and a user-centered view and, second, the access to required data. In subsequent research (see subsection 3.3.4), those themes have been investigated more in-depth and are here only noticed for comprehensiveness.

As the ReEIF is originally focused on interoperability between organizations, the use of a DHI by a defined user group is not appropriately represented. Findings regarding usability have been assigned to the Care Process level, as a DHI generally intends to support healthcare activities, or to the Application level, as data exchange within interconnected HIS components might be crucial for usability to ensure continuity of information flow. Considering the extent of the Care Process level presented in the paper, the distinguishment of user-centered topics ("Use of DHI") from process-centered topics is proposed. Other authors promote a similar separation of a DHI's usage and continuity of process landscapes in a target environment of connected HIS (Lau and Price, 2017a; van Mens et al., 2020).

Another critique relates to a vague allocation of required data for a DHI's functionality into the ReEIF levels. Especially in the light of data-centered value propositions by AI-based DHI, valid access to required data sources becomes a central topic for innovators. Thereby, data requirements rather combine all three technical ReEIF levels than perfectly fit into a single one. Even though the interplay of syntax and semantics (Information), technical system interfaces, and communication standards (Application) as well as appropriate connection to networks, server architectures, and databases is embedded in ReEIF, a sound conceptualization should emphasize this interplay explicitly.

Contribution to Doctoral Thesis

This article contributes to RO2 as it initiates the conceptualization and contextualization process of a socio-technical understanding of interoperability for the selected scope. The conducted research systematically analyzed relevant literature on DH diffusion and related contributions (RQ.2.1). It explored and consolidated detailed descriptions and potential parameters that allow the determination of different interoperability perspectives. In this regard, the ReEIF and its six interoperability levels generally suited the initial structurization and could be confirmed as starting point for the framework design (RQ2.3). This review and revision of the ReEIF represents a first design cycle as requested by the overall DSR approach (see subsection 2.4).

However, some vagueness of the ReEIF remained even though the explanations of each level could be updated. This paper motivates therefore an in-depth investigation of how aspects regarding the use of a DHI shall be distinguished from other levels and how the interplay of technical interoperability levels should be emphasized in a new framework (see subsection 3.3.4). Furthermore, this paper also promotes the application of the intended conceptualization artifact for managerial purposes. It presents the design of an interoperability-based self-assessment tool for DH innovators allowing them to evaluate the progress of distinct DHI projects aiming at a successful integration into complex HIS landscapes.

3.3.4 Outline of P8 – Holistic Interoperability from a DH Innovator‘s Perspective: An Interview Study

Context and Method

The previous literature-based investigation (see subsection 3.3.3) explored a first description of a socio-technical interoperability understanding in extent and structure in the context of DHI management. However, congruency between knowledge stated in literature and experience of practice shall not be taken for granted. Also, limitations and vagueness of the ReEIF as a conceptual basis have been identified which motivated an additional expert-based research step. This evaluation and design iteration of conceptualization and contextualization is part of the eighth research article presented here (Scheplitz and Neubauer, 2022). An expert study with 29 participants was conducted to explore whether and how the ReEIF suits DHI management from an innovator's perspective. For this purpose, a semi-formal interview guide[3] was derived for 1-on-1 interviews (Myers and Newman, 2007; Schultze and Avital, 2011) that have been recorded, paraphrased, and qualitatively analyzed. All analysis activities were oriented toward the recommendations of summarizing, qualitative content analysis (Mayring, 2014). It proved how relevant aspects regarding successful DHI diffusion are covered by the ReEIF and discussed strategies as well as activities for ensuring interoperability holistically. As a main result, the Digital Health Innovation Interoperability Framework (DHIIF) is proposed in this article that aims to support DHI practitioners in achieving more interoperability and improving the diffusion probability of their DHI.

Results

During the interviews, the participants described their experiences and provided advice on DHI management aiming at a successful diffusion of a DHI artifact into practice. They also reflected the ReEIF as a potential conceptual basis to support this challenge, expressed critique, and discussed how DH innovators could differentially ensure interoperability in a socio-technical manner. The general feedback on ReEIF as a conceptual basis was positive. However, with a view to comprehensiveness, some participants perceived the following uncovered topics:

- *Distinguishment of user-centered and process-centered issues.* The view of users and how they use a DHI is a prominent factor but is underrepresented if positioned within the Care Process level.
- *Highlighting the interplay of technical interoperability levels.* Some participants asked how the access to required data is covered within ReEIF. Here, they assume that the technical levels of ReEIF (Information, Application, IT-Infrastructure) address this in symbiosis but also doubt if innovators would recognize this interplay easily.
- *Highlighting the business perspective.* The definition of appropriate business models as a solid base for activities on the policy level should be presented more popular since those efforts should not be underestimated, especially for DHI with revolutionary value propositions.

[3]The complete interview guideline can be found in Appendix I

- *Considering cultural influences.* On a macro-level (e.g., the inertia of medico-legal conditions) and on a micro-level (e.g., managing interdisciplinary collaboration), cultural factors influence ensuring interoperability.
- *Understanding of DHI as a volatile process.* Enhance ReEIF in a way that offers implications on DHI process management since it currently does not provide a processual perspective, especially when perceiving a DHI as a dynamic process.

Asking the participants which ReEIF level requires the most attention, they often tried to balance related efforts and relevance. No clear preference regarding the latter was formulated as unawareness of each level could lead to a failure of a whole DHI project. However, a majority of 20 experts mentioned that activities related to the care process level should gain the most attention in a DHI project. They reasoned it by i) the high need for communication and analysis resources and ii) a dominating impact of this level. Within the full article (Scheplitz and Neubauer, 2022), we present results about more specific aspects of interoperability that are crucial for DHI diffusion from the interviewees' point of view. Here, I would like to emphasize only two findings that influenced the design of the DHIIF in particular and refer to the original article for a comprehensive presentation (see section 12) First, more than half of the interviewees mentioned user-centeredness as a maxim and expressed its positive influence on usability and utility (Care Process level). They also highlighted positive follow-on effects on all interoperability levels by a resulting commitment of users and stakeholders. Second, an in-depth understanding of main care processes and accompanying processes of coordination, administration, and business management was frequently stated. The required awareness of intended and unintended effects of a DHI's integration, especially on the accompanying processes, is difficult to explore beforehand. In this context, multiple observations of daily practice with and without a DHI as a prototypical or final artifact become highly relevant.

In the following research step, we reflected our findings against domain-specific diffusion theory (Greenhalgh et al., 2017; Lau and Price, 2017a; van Mens et al., 2020) and proposed the DHIIF. The DHIIF's center adapts the ReEIF to describe interoperability as a holistic key property for the successful diffusion of a DHI artifact into a specific target environment. It thematically differentiates seven interoperability levels that comprise the socio-technical realm of relevant topics (see Figure 12). Looking through a technical lens, the DHIIF underlines the symbiotic interrelation of Information, Application, and IT-Infrastructure level to fulfill requirements of data exchange that become even more relevant in the light of rising data-centered DHI and AI applications. It further distinguishes interoperability from a user-centered and a process-centered perspective. Within the latter, the DHIIF explicitly emphasizes the interrelation of main care processes focused by a DHI and accompanying process of coordination, organization, and business management. Even though the user-centered and process-centered

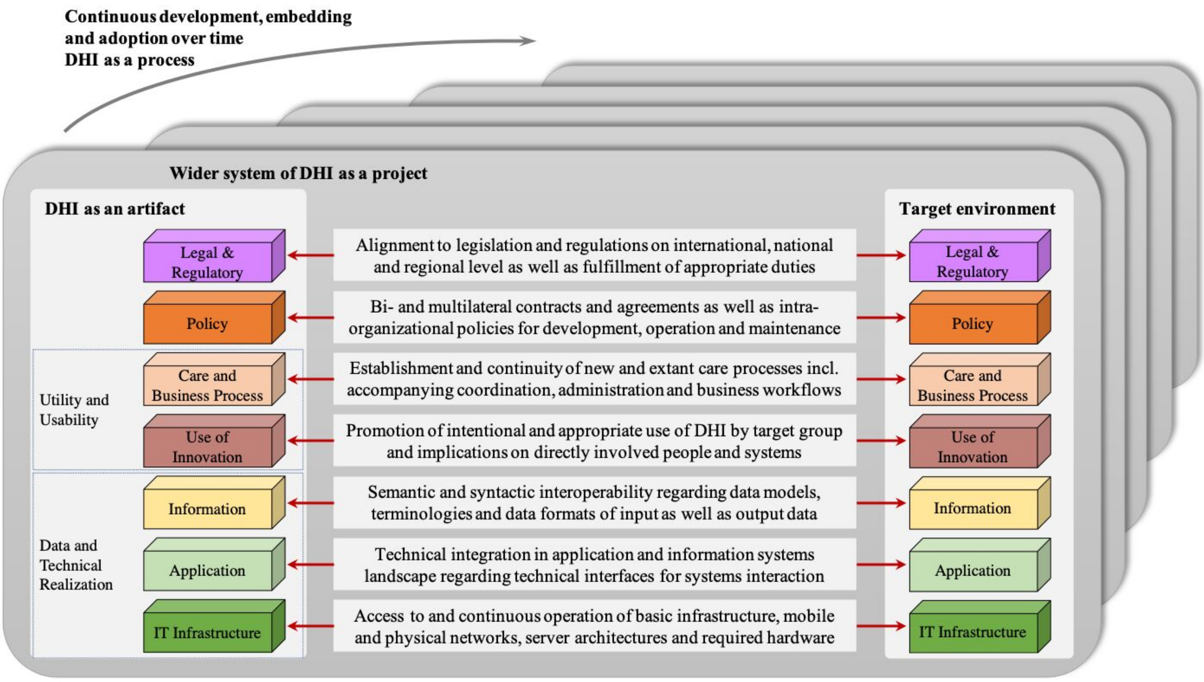

Figure 12: Digital Health Innovation Interoperability Framework.

perspectives are interwoven and commonly determine a DHI's utility and usability, innovators should concentrate on both levels separately. The DHIIF also considers factors and circumstances influencing how interoperability can be ensured on each level. Thereby, the DHIIF aligns with adoption theory highlighted in the NASSS framework (Greenhalgh et al., 2017), which describes the influence of the wider system of a DHI project (e.g., its organizational background, conditions of the specific target environment, cultural influences) and longitudinal dynamics that reason changes in interoperability strategies or ensuring mechanisms.

All interviewees agreed that ensuring interoperability is a task that innovators are responsible for, even though systemic issues, e.g., legal acts for mandatory use of IT standards, are related to public institutions or official committees. Innovators always have an influence but the way how they force it differs. This expert-based and previous literature-based investigations consolidated numerous activities or aspects within the responsibility of DH innovators in this regard. But overall, two general strategies for ensuring interoperability have been identified: I. via a proactive influence on the target environment to change the status quo or II. via a reactive influence by compatibility with the target environment. These strategies should be seen as ends of a continuum rather than a binary differentiation. The participants stated tendencies of advantageousness for each DHIIF level (see Figure 13) but innovators mostly have to balance these strategies for the specific DHI project. Consequently, these strategy types unfold a continuum allowing innovators to define their strategies and activities for a specific DHI process.

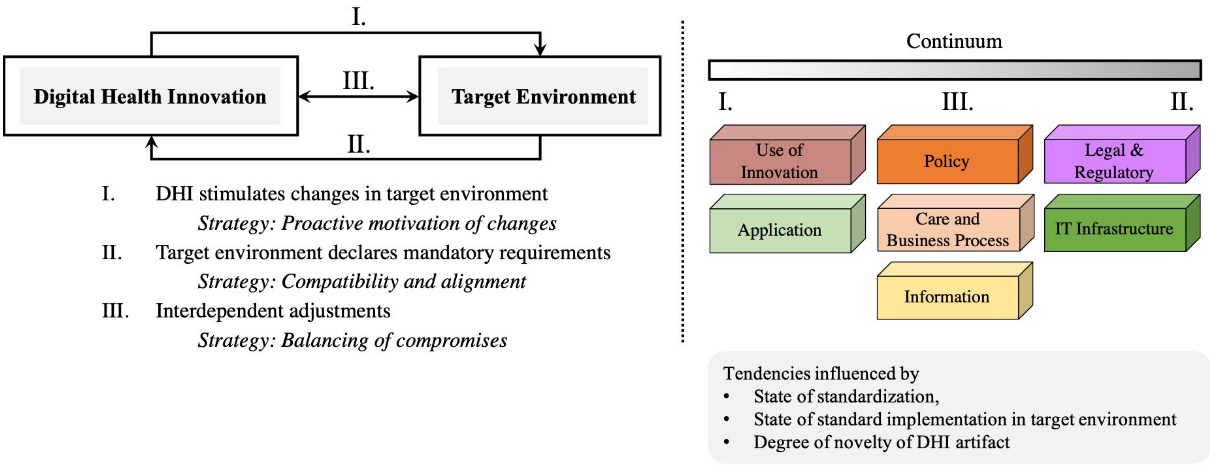

Figure 13: Dominance in interoperability and indications on ensuring strategies.

Contribution to Doctoral Thesis

This expert study has taken an essential step toward more guidance on DHI management strictly focused on socio-technical interoperability. This article gathered knowledge from domain-specific diffusion theory (RQ2.1) and experienced practitioners evaluating the ReEIF as a theoretical entry point for conceptualization and contextualization (RQ2.4). Within this research, the DHIIF is proposed that provides structurization and strategic implications for ensuring interoperability and increasing diffusion probability (RQ2.3). Thus, this article contributes to the objective of conceptualizing interoperability (RO2) in multiple ways. Also, the consideration of evaluating critique on the ReEIF gathered by previous research articles P5 and P7 (see subsection 3.3.1 and 3.3.3) and the subsequent derivation of the DHIIF represents a second and essential design cycle as requested by the overall DSR approach (see subsection 2.4). As methodologically proposed there, the following subsection 3.3.5 of P9 presents results of the subsequent evaluation cycle.

3.3.5 Outline of P9 – Demonstration and Evaluation of the Digital Health Innovation Interoperability Framework

Context and Method

This final research paper (see section 13) builds upon the results of conceptualization and contextualization of a socio-technical understanding of interoperability for the context of DHI from prior research (see subsections 3.3.3 and 3.3.4). It first presents a demonstration of using the DHIIF within an ongoing DHI project on Digital Phenotyping for MS care for structuring and determining interoperability strategies. Second and complementary, a small-scale expert survey was conducted to evaluate the DHIIF's utility for DH practice and science (ex-post assessment).

Twelve DH experts participated and critically assessed the DHIIF's suitability by use cases and target group as well as its utility to address current research themes on interoperability.

Results

In a current research project, we used the DHIIF to structure interoperability efforts and ensure strategies to improve the integration capability. The project's main goal is to develop a Digital Phenotyping application for improving precision medicine for multiple sclerosis (MS) care. Simplified, multimodal datasets from professional information systems and patient-side applications shall be processed using machine learning techniques to digitally represent clinical biomarkers, enrich them with further progress and usage data, and thus gain insights into individual treatment and coping strategies. Through a technological lens, this DHI shall be embedded in a HIS landscape composed of a hospital information system, a professional application system for MS, a pathway system for planning and conducting integrated care pathways, a patient portal, and mobile devices at the patient's side.

For an initial structurization of required efforts, we applied the framework of mechanism for ensuring interoperability of Hodapp and Hanelt (2022) using the DHIIF which opened the potential range of interoperability-related tasks (see Figure 14). In group sessions of the project consortia (DH innovator), we explicitly reflected on each cluster, identified related aspects ("What"), and discussed strategies and tasks to address them ("How"). We thereby followed six refinement steps: 1. Differentiate clusters by relevance for distinct DHI; 2. Identify subtopics within priority clusters; 3. Clarify the general state of standardization for each cluster; 4. Clarify the standard implementation state in each cluster's target environment; 5. Reflect DHI's novelty for each cluster; and 6. Determine ensuring strategy for each cluster. This procedure systematically clarified how interoperability would be addressed holistically within our ongoing DHI project. We could identify relevant tasks and determine ensuring strategies differentially on each DHIIF level (see Figure 15, right and Table 8). Furthermore, this DHIIF-based structurization supported our internal communication regarding establishing a consented understanding of detailed interoperability goals. Despite our observed advantages, this individual approach shall be interpreted as an exemplary demonstration of applying the DHIIF. It motivates the use of the DHIIF for other distinct DHI projects in similar ways but underlines the need for revision and adaptation.

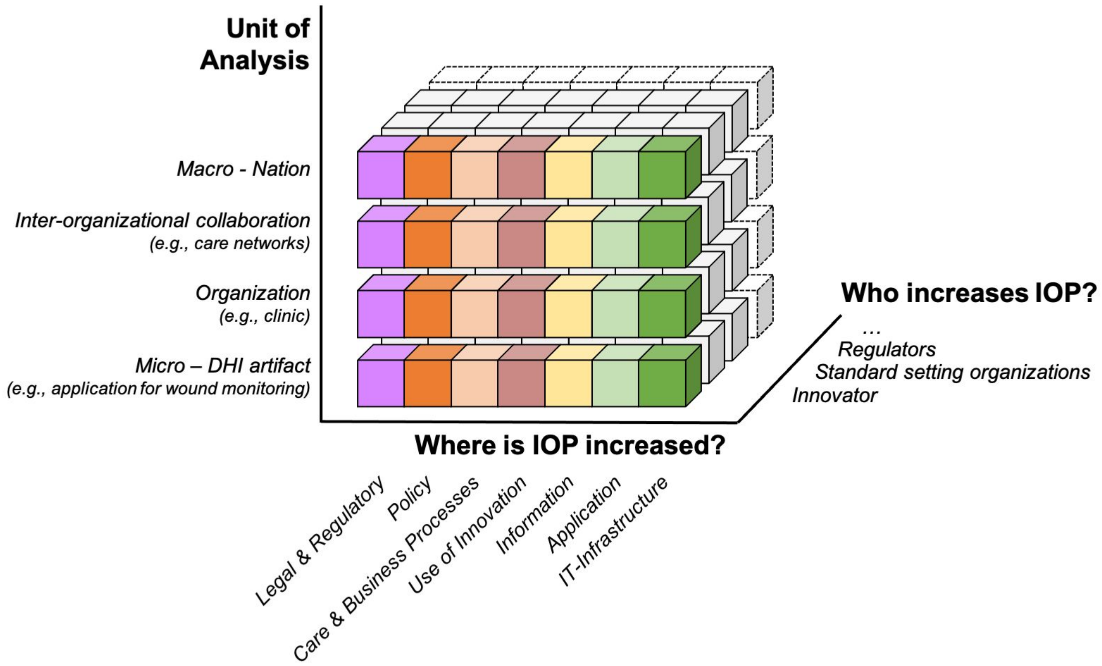

Figure 14: Framework of mechanism for ensuring interoperability by Hodapp and Hanelt (2022), applied by using DHIIF.

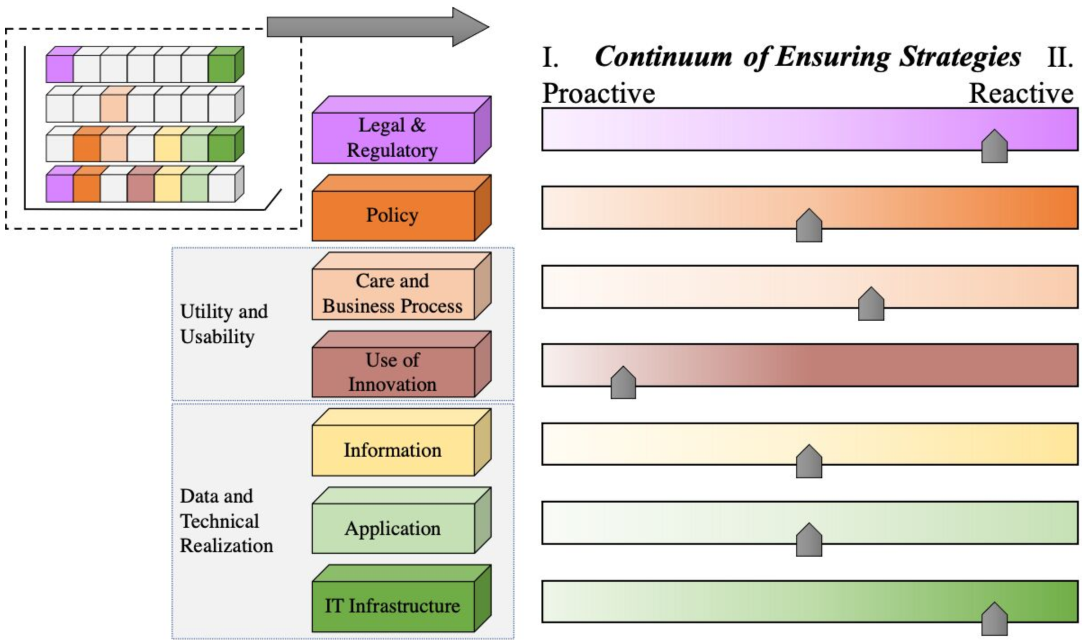

Figure 15: Using DHIIF to define central fields of action and differnentiated strategies for ensuring interoperability in a distinct DHI project.

Table 8: Defined strategies for ensuring interoperability in a distinct DHI project using DHIIF.

DHIIF Level	Strategy I – Proactive motivation of change (end of continuum)	Determined strategy for distinct DHI project (Digital Phenotyping MS)	Strategy II – Reactive alignment and compatibility (end of continuum)
Legal & Regulatory	Identification, negotiation and resolving of legal or regulatory conflicts; Involvement in political decision making and lobbying	Macro: Compatibility dominated (e.g., ethical approval, data privacy and security laws, duties of medical device certification process); Micro: Proactive negotiation of specific patient-related, data-centered value proposition	Identification of and alignment with appropriate laws and regulations; Fulfillment of duties and potential DHI redesign;
Policy	Definition of revolutionary business model and bi- or multilateral negotiations as well as contracting with small room for compromises	Low priority – Organization & Micro: Balanced strategy regarding preparations and negotiations of business model, terms of conditions and business collaborations with compatibility to hospital policies	Embedding in or enhancement of existing policy structures; Alignment with established and standardized remuneration models; Passive policy negotiations
Care & Business Processes	Reconfiguration of existing or definition and implementation of new processes (care, administration, business, coordination) due to DHI's integration in specific setting	(Inter-)Organizational: Balanced strategy where high level care processes and routines are improved by pathway adaption via machine learning techniques and phenotyping	Identification of and alignment with existing care processes and accompanying procedures; prioritizing continuity of status quo and avoiding processual changes
Use of DHI	Realization of new human-technology-interaction scenarios and promotion of intentional and appropriate use by target users	Low priority – Micro: Result representation via existing professional systems and patient portal; Application of explainable AI guides	Design and realization of human-technology-interaction scenarios that are well known by target users
Information	Reuse of standards (data models, formats, terminologies); Definition and application of specifications; Standardization activities	Organization & Micro: Balanced strategy with compatibility to (prospectively) implemented information standards (HL7/MII) in hospital information system and proactive inquiry of sufficient standard implementation in MS system	Identification and reuse of as well as alignment with data models, terminologies and formats applied in target environment
Application	Reuse of communication standards and protocols; Definition and application of new specifications; Standardization activities	Organization & Micro: Balanced strategy with compatibility to (prospectively) implemented communication standards (HL7/MII) in hospital information system and proactive inquiry of sufficient standard implementation in MS system	Identification of and compatibility to technical interface definitions and communication standards applied in target environment
IT-Infrastructure	Identification, negotiation and resolving of infrastructural conflicts (e.g., lack of accessibility or hindering requirements)	Organization & Macro: Compatibility dominated (IT infrastructure of university hospital, nationwide telematic infrastructure and connectivity to research data infrastructure)	Embedding in existing infrastructures; Adjustments of DHI due to given restrictions (opportunities and requirements)

Regarding the results of the small-scale online survey, the participants generally confirmed the DHIIF's design and extent. All experts agreed (n=6) or strongly agreed (n=6) with the holistic conceptualization approach. However, the participants assessed the DHIIF's usefulness differentially regarding intended use cases of DHI practice, potential target groups, and its contribution to current research questions about interoperability in the era of DHI (see Table 9). In the experts' opinion, the DHIIF suits best for describing and structuring interoperability and for providing orientation for DHI project and process management. The participants also underlined that the DHIIF offers valuable support, especially for academia, business professionals responsible for DHI management, domain-specific associations, and standard-setting organizations. In line with the utility for research-related scenarios, the participants see the DHIIF as a valuable contribution to the scientific discourse, especially about the co-evolution of interoperability and strategic rationales in DHI, the determination of a theoretical foundation for studying interoperability in DHI, and its influence on domain issues due to fragmentation.

In additional qualitative feedback, a few participants underlined the DHIIF's benefits of a comprehensive, structured explanation including the consideration of dynamics in adaption and continuous, evolutionary improvement. Here, these persons also criticized the DHIIF's theoretical, complex, and generic nature, so its use for distinct DHI projects might be challenging. Further stakeholder-oriented material, e.g., application guidelines or manuals, was recommended to address the gap between a generic validity of a framework and its utilization in DHI practice. Such material shall also discuss the interrelations of DHIIF components in more detail.

To sum up, this survey confirmed the DHIIF's contribution on both the scientific and the DHI practice side. While the latter requires more nuanced and actionable material, HIS research might directly profit from the proposed socio-technical understanding of interoperability to investigate its impact on increasing success rates of DHI projects and how ensuring mechanisms cause advantages from multiple perspectives.

Table 9: Results of a DHIIF's small-scale evaluation via an online survey; * at least one participant did not assess the item.

Category (Scale)	Assessment task / question	Results Avg. [Distribution]
Usefulness for specific use cases	The DHIIF is useful to …	
(5-level Likert; from	… structure interoperability for DHI.	4,42 [0,0,2,3,7]
"do not agree" – 1 to	… describe the realm of interoperability.	4,42 [0,0,1,5,6]
"fully agree" – 5)	… reduce complexity for DHI support.	3,42 [0,3,4,2,3]
	… support the conduction of DHI projects.	4,42 [0,1,2,5,5]
	… manage DHI processes.	4,08 [0,0,3,5,4]
	… reduce failure rate of DHI projects.	3,58 [0,2,3,5,2]
Usefulness for target groups	The DHIIF usefully supports …	
(5-level Likert; from	… medical professionals.	3,42 [0,3,2,6,1]
"do not agree" – 1 to	… clinical and care management.	3,58 [0,2,3,5,2]
"fully agree" – 5)	… economy, esp. medical technology and health IT.	4,08 [0,1,2,4,5]
	… innovation hubs, incubators, and project management.	4,25 [0,1,0,6,5]
	… associations and standard-setting organizations.	4,08 [0,0,3,5,4]
	… public health.	3,36 [0,1,5,5,0]*
	… insurance and other payors.	2,92 [0,3,7,2,0]
	… legal and regulatory.	3,58 [0,2,3,5,2]
	… science.	4,67 [0,0,1,2,9]
Contribution to research questions	How does the DHIIF contribute to current research questions [9] of	
(3-level Likert;	… how does interoperability co-evolve with strategic rationales in DHI?	4,67 [0,2,10]
"not all" – 1;	… how can interoperability counteract increasing fragmentation?	4,27 [0,4,7]*
"slightly" – 3;	… how does interoperability holistically influence digital business ecosystems underlying DHI?	4,09 [0,5,6]*
"very" – 5)	… how can we foster interoperability and DHI while mitigating potential negative effects?	3,00 [2,7,2]*
	… what is the appropriate theoretical foundation for studying interoperability in DHI?	4,40 [0,3,7]*

Contribution to Doctoral Thesis

This work contributes to conceptualizing and contextualizing interoperability for DHI (RO2). It reflects the proposed DHIIF, demonstrates its application for structuring and orientation in modern DHI projects, and presents confirming results of a small-scale evaluation conducted via an online survey (RQ2.4). Besides the potential for future enrichments of DHIIF to increase suitability for different target groups, the DHIIF provides a valuable conceptual fundament for science and DHI practice.

In previous analyses and design stages, the DHIIF was developed based on both literature- and expert-based methods (see subsections 3.3.3 and 3.3.4) to support structuring and guidance for future DHI projects. This paper contributes mainly to evaluation stages (Österle et al., 2011; Sonnenberg and vom Brocke, 2012; Venable et al., 2012) within the overarching DSR approach presented in subsection 2.4.

4 Conclusion

The conducted research first describes an in-depth investigation into characteristics and challenges of modern DHI that strives for defragmentation within complex HIS landscapes esp. regarding inter-organizational care scenarios, patient integration, inter-sectoral collaboration of science and healthcare practice, and novel data-centered value propositions for the healthcare domain (see RO1). Secondly, this thesis claims for an increased relevance of interoperability for DHI management and recommends understanding interoperability as a guiding principle for distinct DHI projects in managing DHI and their environments. In this context, a new socio-technical conceptualization and contextualization of interoperability – the Digital Health Innovation Interoperability Framework – is provided to support HISR and HIS development (RO2). The main contributions of this doctoral thesis to research and practice regarding these two threads are described in subsection 4.1. Subsection 4.2 concludes the work with a critical discussion and an outlook on future research topics.

4.1 Contributions to Research and Practice

Since both subordinate research objectives of this doctoral thesis aim at a comprehension objective (RO1) and a design objective (RO2) (see subsection 2.2), the main contributions can be specified accordingly. In total, nine central contributions are proposed by this doctoral thesis. They are briefly explained in the following and summarized by a subsequent list.

The contributions related to the first research objective (RO1) commonly created a sound understanding of the challenge of designing, developing, and implementing DHI in complex HIS landscapes that promote the defragmentation of the domain's status quo. In this context, P1 could provide a characterization of such DHI and a description of the interrelated realm of relevant objectives. It contributed to the analysis stage of this thesis by clarifying how DHI might enhance inter-organizational care approaches via pathway-supporting HIS, strengthen patient empowerment and engagement to promote the patient's proactive role, foster inter-sectoral and inter-disciplinary collaborations, and realize novel data-centered value propositions (Con-1). P2 subsequently derived architectural implications for HIS landscapes, synergistically combining the identified objectives. It also provides a reference architecture approach for pathway-supporting and patient-integrating HIS (Con-2). The rise of AI in healthcare as a prospectively dominating technological building block of future HIS motivated the contribution of P3. It explicitly explored the application of AI approaches within pathway-supporting HIS landscapes and offers a design aid for conceptualizing AI-based DHI within such ecosystems (Con-3). Complementary, P4 addresses the scientific motives of defragmenting DHI projects. It promotes using the DSR-Grid of vom Brocke and Maedche (2019) as DHI project aid and proposes seven knowledge types underpinning intended synergies of science-practice-collaborations (Con-4).

In summary and about the stated research agenda in subsection 2.2, the research questions RQ1.1 to RQ1.4 are answered and the corresponding research objective RO1 (understanding defragmenting DHI in complex HIS landscapes) can be considered achieved.

The knowledge gained by the above-mentioned contributions of problematization has paved the path toward the second research thread of this thesis. All research articles related to RO2 followed the agenda to rethink the role of interoperability for current and future DHI aiming at defragmentation. Thus, P5 to P9 commonly contributed to conceptualizing and contextualizing socio-technical interoperability to support DHI initiatives in science and practice. All articles promote the conclusion that interoperability shall no longer be seen as a technical requirement only. Instead, it offers the potential to be a guiding socio-technical principle for DHI management in the present and the future. This research focus' swift can be retraced within the articles P5 to P8 as all of them explored relevant aspects of DHI diffusion and adoption by literature- and practice-based approaches and investigated their conceptual relation to interoperability (Con-5). Those articles, on the one hand, consolidate critical aspects of DHI diffusion and, on the other, reveal the suitability of interoperability as a conceptual means for their structurization, differentiation, and systematical discussion for scientific or practice-oriented purposes. P5 and P7 explored in more detail how socio-technical interoperability suits a central evaluation top criterion and proposed a DHI evaluation approach for managing a DHI's integration capability (Con-6).

Simultaneously, P6 to P8 elaborated in design-evaluate-cycles (see subsection 2.4) the central design artifact of this thesis – the DHIIF (see Figure 12). It is the resulting object of conceptualization and contextualization and refers to the question of how socio-technical interoperability can (or should) be understood as a guiding principle for DHI management (Con-7). The DHIIF raises a DHI's integration task into a generic or specific target environment on a comparable relevance level as designing and realizing a DHI's value proposition. For DHI aiming at defragmentation as explored by the research of RO1, both tasks are inherently interrelated as their value propositions (partly) depend on the interoperable integration into an existing HIS landscape. For this integration task, the DHIIF provides descriptions of seven thematic interoperability levels which comprise the socio-technical realm of DHI diffusion. Furthermore, the DHIIF explicitly considers a DHI project's organizational circumstances (wider system) and organizational, technological, legal, or socio-cultural dynamics that will more or less likely appear over the DHI process. This holistic approach implicitly emphasizes the reflection of three sensitivity dimensions: the static characterization of a DHI and its intended target environment, a DHI project's wider system, and the longitudinal dynamics of a DHI process. Those sensitivity dimensions lead to this thesis's conclusion that it remains an ideal to describe a sustainably valid and generic set of recommended actions on an operative level for DH innovators. Rather, this thesis suggests the use and application of the DHIIF in distinct contexts as a means for analysis, conceptualization, and evaluation, especially for defining the particular set of relevant interoperability aspects and deriving required strategies and actions.

In that regard, P7 and P8 revealed a continuum of interoperability strategies for each level between compatibility principles to a target environment's status quo and the proactive motivation of changes on the HIS landscape's side (Con-8). Although the distinguished interoperability levels of the DHIIF indicate tendencies, e.g., legal requirements and conditions that need rather be fulfilled than proactively revised, the proposed conceptualization is, analogously to the DHIIF, intended as a management aid that should be applied in distinct DHI contexts. Finally, P9 demonstrates this use case and presents the DHIIF's application in a specific DHI project. Besides this demonstration, P9 also provides an expert-based evaluation of the DHIIF as a conceptual contribution to science and practice (Con-9). Finally, considering the research agenda in subsection 2.2, the research questions RQ2.1 to RQ2.4 are answered and the corresponding research objective RO1 (conceptualization and contextualization of socio-technical interoperability to support DHI management) can be assessed as achieved.

Con-1 Characterization of promising DHI in complex HIS landscapes generally aiming to defragmentation of HIS landscapes and description of the interrelated realm of relevant objectives: inter-organizational care; patient empowerment and engagement; Inter-sectoral collaboration; and realization of novel data-centered value propositions.

Con-2 Provision of architectural implications and reference architecture approach for realizing pathway-based and patient-integrating HIS as a design aid.

Con-3 Conceptualization of AI application within pathway-supporting HIS.

Con-4 Promotion of DSR-Grid as DHI project aid for and description of seven knowledge types to promote synergy of inter-sectoral collaboration of science and healthcare practice in DHI projects.

Con-5 Consolidation of relevant aspects ensuring the successful diffusion of DHI into healthcare practice structured and differentiated by interoperability levels.

Con-6 Conceptualization and Contextualization of socio-technical interoperability as guiding principle for DHI management.

Con-7 Proposal of a DHI evaluation approach for managing a DHI's integration capability.

Con-8 Conceptualization of ensuring strategies for interoperability.

Con-9 Demonstration and Evaluation of DHIIF as conceptualization approach for interoperability in the context of DHI.

The single contributions of each article and the listed contributions that are gained commonly by this thesis provide conceptual value for practice and research. The analytical contributions of Con-1 to Con-4 can support practice-oriented HISR with clarity about interwoven, defragmenting objectives of future DHI, architectural reference points, design aids for AI-based DHI, and structuring aids to combine development and research goals in DHI projects. The main results of this thesis belonging to Con-5 to Con-9 offer value for ISR especially addressing conceptual and scoping issues on interoperability in the era of digital innovation (Hodapp and Hanelt, 2022). It explicitly follows the stated recommendations of utilizing socio-technological perspectives for conceptualization and initiating contextualization and theorization on interoperability mechanisms. An evaluating expert study (see P9 in subsection 3.3.5) revealed that the DHIIF strongly contributes to three of five central questions of the agenda regarding, first, the co-evolution of interoperability and DHI's strategic rationales in DHI, second, the counteracting impact of interoperability on increasing fragmentation, and, third, an appropriate theoretical foundation for studying interoperability in DHI.

In the following subsection 4.2, possibilities of future research, DH practice, and their collaboration are discussed in more detail that might profit from the contributions of this thesis. However, selected usage scenarios of the DHIIF are briefly stated here, which, from the author's view, promise a beneficial impact on the domain. Regarding one of the main motivations of this work, the DHIIF can support particular DHI projects in managing the task of ensuring interoperability, addressing the overall aim to develop a likely to integrate DH artifact. This task is characterized by socio-technical complexity that can be structured and systematized by the DHIIF. Also, it provides a focal point for DHI consortia for determining interoperability strategies and operative activities. From a methodological point of view, the DHIIF might stimulate research looking for DHI process models and methods for DHI management, evaluation, risk profiling, or IS alignment. On a higher managerial level of HIS practice, the DHIIF can improve the organization of HIS environments that proactively promote both the integration of DHI and the progress toward defragmentation of HIS landscapes. Here, the DHIIF can support the definition and application of IS strategies of hospitals, healthcare networks, or regions. For public or private funding programs, conceptualizations like the DHIIF can be used for the funding programs' design and, consequently, might guide assessment and monitoring activities during a funded project. On the applicant's side, the DHIIF might also help formulate project outlines and systemically present a consortium's idea and method set to ensure interoperability and diffusion likeliness of intended project goals.

4.2 Discussion and Outlook

At the end of this dissertation, I would like to open the discussion on future research and practice efforts motivated by the presented results, their limitations, and related questions. In an expanded context, the central design artifact of this thesis – the DHIIF – provides a solid starting point for conceptual refinement, derivation of quantifying measurement tools, and academic-societal discourse on the optimal level of interoperability in healthcare. Without any claim to completeness, limiting and outlooking aspects directly related to the presented contributions are in the following presented. Additionally, I would like to share selected thoughts that may influence the positioning of research and development activities on a higher level of abstraction.

Interrelation of DHIIF levels. The presented conceptualization of interoperability for DHI provides the distinguishment of seven interoperability levels but focuses only a little on their interdependencies. An in-depth analysis of this interrelatedness was not explicitly focused but might be of high interest for further investigation. The interwoven mesh of direct and indirect relations could be uncovered, including the intensity of those ties and their direction of impact (uni- or bi-directional). Eventually, a domain-specific characterization can be derived, which may improve the application of the DHIIF for distinct DHI projects to define ensuring strategies and appropriate action plans. Also, the question could be answered if one level takes the role of a ”super-predator” and might dominate all other levels. Some discussion partners shared the opinion that the Legal and Regulatory level might represent this role as related compatibility requirements overrule design decisions on other levels.

However, this opinion should be proven with more rigor and more comprehensiveness. Starting with the assumption that a tie between each level may be of general relevance, a total amount of 21 connections could be explicitly investigated. As a reciprocal interaction might characterize each tie, a matrix of 42 influence descriptions could be determined by literature- and expert-based argumentation, which, in consequence, could also reveal indirect influences. Figure 16 illustrates the potential interwovenness and points out three examples that might motivate future socio-technical research questions in this regard.

Ex-1: How do Legal and Regulatory requirements determine obligatory connections to distinct IT-Infrastructure and how do these determinations ensure interoperability in practice? Or how do existing infrastructures of intended target environments result in design decisions of DH innovators deviating from governmental directives but ensuring immediate interoperability? (e.g., platform infrastructure of a particular clinic differs technologically from future governmental approaches)

Ex-2: Due to the combinatorial characteristic of digital innovations, value propositions of distinct DHI might require the interaction of different application systems and related personal interactions (depending on the degree of automatization). How does ensuring mechanism on the Application level of interoperability influence how intended users use a DHI appropriately? Or how might a highly prioritized objective of an intuitive, continuous, and automatized use of a DHI result in technical interoperability requirements on the Application level? Or how do interconnected application systems potentially increase the impact of misuses so that awareness, knowledge, and competencies on the user's side have to be appropriately trained?

Ex-3: Value propositions of DHI relate to distinct care or business processes and digitally represent real-world phenomena. Thus, DHI activities related to the Information level can be typically compromised by defining domain knowledge, its coding, and the (eventual) use of appropriate standards. But do care and business processes always guide semantic and syntactic interoperability activities? Within specification and standardization activities, vagueness in human semantics might be uncovered, which becomes problematic when transferring them into the digital world. Here, unambiguity conditions require clarification on the professional side so that interoperability issues on the Information level have to be solved within discussions on Care and Business Process level.

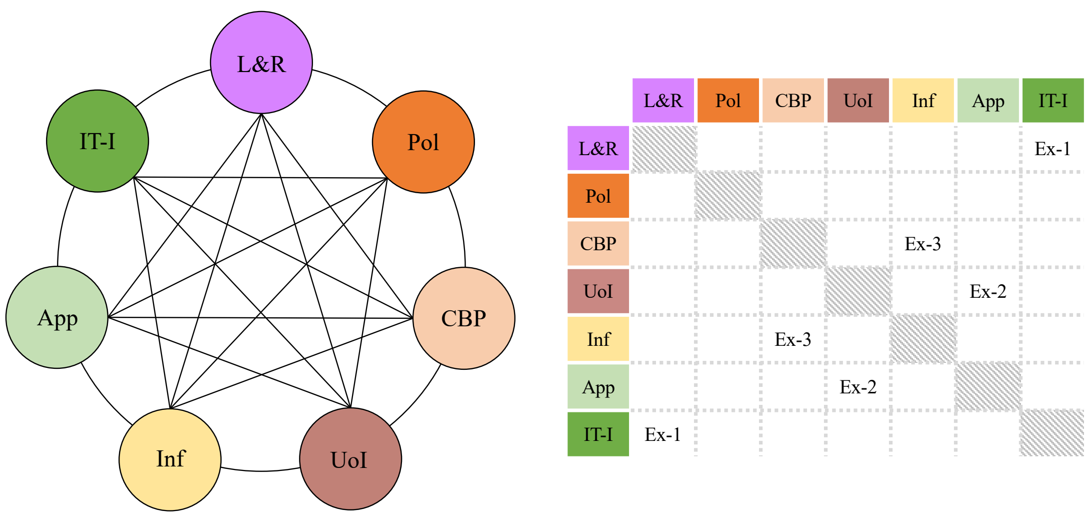

Figure 16: Potential mesh of interrelations between DHIIF levels - selected examples highlighted.

Implications on DHI process models, risk profiling, and cost-benefit-ratio. In the interviews for research paper P8 (see section 12), the question of how established process models are suited to ensure interoperability within a DHI process was also discussed. While this paper does not provide a final answer, it is able to describe the challenge for DH innovators to find the optimal balance of agile and sequential approaches. Along the DHIIF, tendencies were determined regarding which levels require which process principles and which tensions arise accordingly. For example, activities to ensure interoperability on the Legal and Regulatory level need to be typically embedded in sequentially dominated approaches. The current version of the European Medical Device Regulation refers to the V-Model and requires the immutability of the innovation object for official assessment and approval. In contrast, interviewees expressed support for agile methods across all process phases if interoperability is to be promoted on the process, use, and application level. This and other inherent tensions should be considered in future work that can revise established process models and derive design principles for DHI development models. In this context, the DHIIF can help to derive an interoperability-oriented approach for DHI that can be taken up and applied by both DH innovators and regulatory bodies. Building on this, the DHIIF can also be used to design a risk profiling method. Such a method could enable continuous monitoring of a DHI progress, differentially assess the criticality of particular interoperability aspects, and predict the degree of interoperability to be likely achieved. In this context, there is a need for appropriate assessment tools such as those proposed, for instance, in P7 (see section 11), in a related online tool (see "Interoptimeter"[4]), or in other research articles (Liu et al., 2020; Rezaei et al., 2014).

Contribution to IS research agenda on interoperability. As mentioned in the introduction section 1.1, a recently published article summarizes current knowledge on interoperability in the era of digital innovations, identifies research gaps in ISR, and postulates a research agenda that strongly relates to this thesis' motivation (Hodapp and Hanelt, 2022). The authors claim that despite the long-standing presence of interoperability in research and practice, digital innovation uncovers new issues in conceptualization, scoping, and methodology. As stated above, this thesis contributes directly to the authors' request for further work on "filling the notion of interoperability with meaning, precision, and depth".

However, other stated research gaps have not been addressed in particular. For instance, the question remains unanswered about how interoperability and defragmenting DHI can be fostered while potential negative effects must be mitigated simultaneously. DH innovators' activities toward more socio-technical interoperability come along with costs, trade-offs, and changing competition (Kerber and Schweitzer, 2017) so that the resulting risk-benefit-ratio becomes an object relevant to be discussed by academia and practice. Additionally, all three issue types by Hodapp and Hanelt still provide the potential for investigation. From a conceptual point of view, the DHIIF can stimulate initiatives searching for a way to measure socio-technical interoperability and defining what the "right" degree of interoperability might be. Regarding scoping issues, the authors motivate research addressing the interplay of different aspects and the intertwining of actors involved, as mentioned in a few paragraphs above. From a method-

[4]Access to online tool via https://interoptimeter.webspace.tu-dresden.de/ or www.interoptimeter.de

ological point of view, this thesis can only provide a thematic focal point. Here, the stated potential for ISR is highlighted to investigate how data-driven approaches can be used for identifying antecedents of interoperability lacks, how dysfunctional outcomes can be studied, and how outcome comparisons of interoperability mechanisms can be conducted within and across distinct HIS landscapes.

Transition to further research on cultural influences. In section 3.1, reference was made to another paper I collaborated on that deals with cultural impact factors (Otto et al., 2022). Within its discussion section, we suggested the consideration and distinguishment of different concepts about what ”culture” comprises in the DH world. In particular, we recommend differentiating in such investigations between Dimensions of National Culture (Hofstede et al., 2010), Dimensions of Organizational Culture (Hofstede-Insights, 2022), and Institutional Logics (Berente et al., 2019; Hansen and Baroody, 2020; Thornton et al., 2012) as well as their intertwining. Such cultural influence factors are considered within the DHIIF as they are comprised within the broader system of a DHI project. However, an in-depth analysis of cultural influence factors on DHI management and interoperability strategies should be part of further HISR that uses knowledge and methods from social science disciplines more intensively. In this context, I'd like to pick up one culture-related observation mentioned within the interviews of P8 (see section 12): the tension between the need for stability and change at the same time within the DH domain. In more detail, the inherent tension was stated that the healthcare domain and its legal conditions require predictability, secure evidence, and stability. But successful digital innovation requires agility, a constructive failure culture, and final maturation in practice. Further work could address how this oppositional duality might be overcome so that proven mutually supportive relationships between stability and change (Farjoun, 2010) can be brought to life for organizations, individuals, systems, and institutions in healthcare.

Limitations of evaluation and generalization. The selected DSR approach and its realization demand methodologically and evaluation of the central design artifact, the DHIIF (Österle et al., 2011; Sonnenberg and vom Brocke, 2012; Venable et al., 2012). Primarily the papers P7 to P9 present different iterations of the DSR evaluation cycle by a literature-based justification (see subsection 3.3.3), an interview-based validation (see subsection 3.3.4), a survey-based assessment as well as a project-related demonstration (see subsection 3.3.5). However, evidence of effectiveness is not finally proven at this point but could be attacked by further long-term investigations. Therefore, the selected DSR approach receives a slight coloration of ”design science research methodology” as a DSR genre (Peffers et al., 2018, 2007) that prioritize applicable and practically useful artifacts over a formal evaluation process embedded in the design effort. An ADR approach that applies the DHIIF for one or more DHI projects could face this limitation. It would allow valuable investigations on how this conceptualization is used for operative, tactical, and strategic DHI management purposes and how its use can actually ensure a successful DHI's diffusion into practice. Consequently, a final generalization of the design artifact to an IS theory remains a difficult task for further initiatives. According to Lee and Baskerville (2003), this aim requires generalizing activities from theoretical statements to theoretical statements (Type TT), but appropriate methodological support is hard to define.

Further, there is another aspect to add in the context of generalization. The question might occur whether the DHIIF relates only to the healthcare domain or if it offers a generic view on interoperability for digital innovation. Even though it might be an entry point for generic discussions, the conceptual fundament (the ReEIF) and its literature- and expert-based revision were always framed by domain-specificity. But a generalization of the DHIIF for use within other domains might be of interest for further research.

Ethical view on the ideal degree of interoperability. As expressed earlier, this thesis relates to overcoming the fragmentation of current HIS landscapes. It follows the attitude that the status quo lacks in interoperability and that future activities of HIS research, development, and policy building shall prioritize interoperability goals. However, literature also states risks reasoned by interoperability related, for instance, to security, privacy, accountability, reliability, or homogeneity (Hodapp and Hanelt, 2022; Kerber and Schweitzer, 2017). In contrast to the micro-economic skepticism (e.g., interoperability enhancing replaceability of digital products and services), the authors also indicate risks from a macro perspective. This coexistence of benefits and risks for modern healthcare systems motivates the question of whether a maximum of interoperability is undisputedly desirable from all perspectives. Eventually, those risks reason an "optimum" of interoperability on a somehow consented degree. This open question consequently seeks for a normative conclusion about what is right or what is wrong under consideration of distinct criteria. It is an ethical question that requires an academic, interdisciplinary, and societal discussion when a general directive is intended. But this ethical balancing task also occurs within particular DHI project's so that developers, decision-makers, and users will be responsible for "good" interoperable systems in practice. In that regard, this thesis supports ethical debates about the right degree of interoperability and appropriate allocation of responsibilities (Buscher et al., 2013; Martin, 2019; Milosevic, 2021).

Stimulating the comparison of evolution theory in ISR and biology. Domain-specific and generic contributions in ISR frequently use terminologies that refer to biological evolution. For this background, some of my colleagues investigated how biological concepts are suitable to describe evolving design artifacts in ISR (Schlieter et al., 2019). They propose a terminology that distinguishes four evolving relationships: adaption, migration, incorporation, and coevolving. But as stated within the article's discussion, the use of notions derived from evolutionary biology becomes even more valuable when the limits of its suitability are known. Here, an in-depth discourse about digital innovations' unique characteristics of being combinatorial and distributed (Henfridsson et al., 2018; Yoo et al., 2012, 2010) leading to a higher relevance of interoperability (Hodapp and Hanelt, 2022) can stimulate the search for those boundaries. Two contrary ideas: A) The analogy loses suitability when interoperability and interdependencies in IS ecosystems increases. Design artifact types in the sense of digital innovations are no longer comparable to ”species” as they become less delineable due to multiple distributed and combined value propositions. B) The analogy gains appropriateness when interoperability and interdependencies in IS ecosystems increases. Design artifact types remain delineable, and multiple symbiotic interrelations to other artifact types represent the functional complexity of biological ecosystems. Some of the conceptual thoughts on interoperability reflected within this dissertation may provide a starting point for further discussions in this regard. They eventually support the debate of the two ideas that may also require the consideration of different economic philosophies as introduced in subsection 2.3 and appendix E.

Beginning.

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Part II
Doctoral Thesis Papers

5 Paper P1

Table 10: Key information on paper P1 and declaration of authorship.

Paper P1	
Title	**Pathway-Supporting Health Information Systems: A Review**
Author(s)	Tim Scheplitz (TS)
Publication	Proceedings of 16th Annual Conference on Health Informatics meets Digital Health (dHealth 2021), Studies in Health Technology and Informatics, D. Hayn, G. Schreier, und M. Baumgartner, Hrsg. IOS Press, 2021. doi: 10.3233/SHTI210093
Author's contribution[5]	Conception: TS 100% Data processing, evaluation and interpretation: TS 100% Formulation of the manuscript: TS 100%
Additional materials	-

[5]The contributions of the author(s) are structured according to the authorship criteria of the German Research Foundation for good scientific practice (DFG, 2013).

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Pathway-Supporting Health Information Systems: A Review

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Abstract. Care pathways and supporting health information systems (HIS) have been permeate the discipline of Health Information Systems Research (HISR) over years. Traditional objectives of workflow assistance are increasingly extended by interdisciplinary goals from technology, medicine, management and public health research. A systematic literature review is dedicated to this integrating character. It examines the interdisciplinary mesh of objectives associated with care pathways and pathway-supporting HIS in the HISR literature. From 47 identified articles, 6 thematic themes were derived. Their consolidation supports in particular design and development processes as it describes the solution space of future pathway-supporting HIS addressing requirements stated by multiple stakeholders.

Keywords. Care pathways, health information system, pathway systems, review

1. Introduction

In medical practice and research care pathways describe complex sequences of interventions of defined patient groups in defined time periods to support the organization, coordination and decision making of care processes [1]. Different terms are used to emphasize intra-organizational ("clinical pathways"), inter-institutional ("integrated pathways") or patient-centered ("patient pathways") orientations [2]–[4]. Also Health Information Systems Research (HISR) investigates care pathways especially the conception, modeling, realization, and impact of pathway-supporting Health Information Systems (HIS) [5]–[7].

In this context, the research and development work seek to bring original motivations from the process perspective in line with the requirements of innovative disciplines. For example, it is being discussed how patient integration can be intensified along care pathways [7], how data mining methods can describe care pathways retrospectively [8], or how data analytics approaches can contribute to the individualization of care plans [9]. Experiences from practice-oriented digital health projects underline the observation that the objectives of care pathways and pathway-supporting HIS go beyond the traditional process support.

This paper follows up on these observations. If research and development teams want to master the multidisciplinary field of requirements for pathways-supporting HIS, a consolidation of previous work can support them especially in conceptual design and development process. Such a compilation can describe the solution space for pathways-

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supporting HIS, derive design implications, and point to disciplines and professions to be involved. This review paper therefore addresses the question of how the literature discusses scope and challenges of pathway-supporting HIS and which contributions can be used to face the mentioned mission of multidisciplinary requirements engineering. The review thus extends the knowledge from previous reviews on characterization of patient pathways [2] and on support opportunities of clinical pathways by Health Information Technologies [10].

2. Methods

A systematic literature review [11]–[13] for the mentioned research question was conducted in the last quarter of 2020. The following high-quality databases of ISR or HISR were chosen: AIS Senior Basket, Proceedings of the AIS Conferences, recommended eHealth Journals of the AIS SIG Health. The past decade was chosen as the publication period. After abstract and full-text screening, 47 articles were defined as final set for analysis. Only articles that prominently named care pathways as a research context were included. Review articles were not excluded from the analysis set in order to extract implications of their contributions to research and practice. Further details of the search process are given in Figure.1.

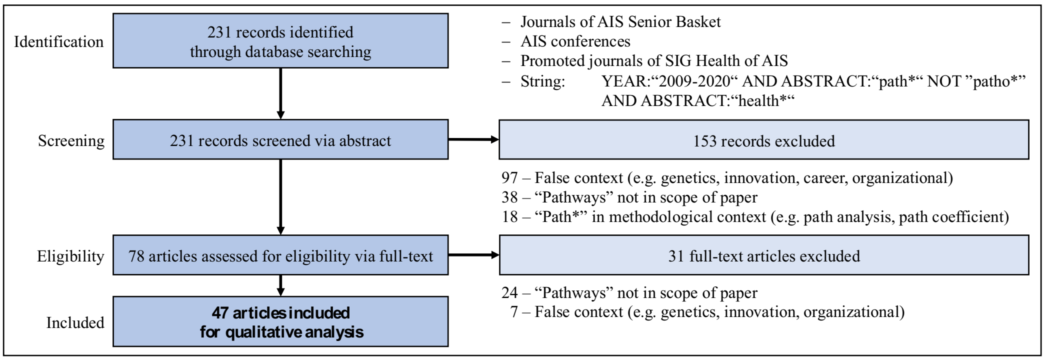

Figure 1. Review process according to PRISMA guidelines [13]

Following the process model of a summarizing content analysis with inductive category formation [14], the analysis material was reduced to those passages in which central goals or contributions related to care pathways or pathway-supporting HIS are described. Paraphrases were constructed and structured interpretatively. Through this structuring step, six themes were identified and validated in group session with three digital health experienced researchers.

3. Results

The 47 identified articles are distributed relatively evenly over the past years. With regard to the distribution across journals or conferences, it can be noted that the majority of the articles found are published in HISR journals recommended by the AIS Health SIG (n=35). Here, 13 articles could be found in the *International Journal of Medical Informatics* and 11 papers in the journal *BMC Medical Informatics and Decision Making*.

A total of 11 papers were identified in the proceedings of the AIS conferences, and only one article in the AIS Senior Basket.

Table 1 presents exemplary the results of paraphrasing step of the six articles published in 2020. It primarily shows how paraphrases have been formulated and offers secondly an insight about newest research on or with pathway-supporting HIS. A complete list of the paraphrasing results of all identified articles will be provided in additional material to this paper.

Table 1. Paraphrases examples of article analysis (only articles published in 2020)

Article [reference]: Summary of contribution's intersection to pathway-supporting HIS
Askari et al. 2020 [15]: Study for professional assessment of the effectiveness and efficiency of clinical pathways and path-supporting HIS in medical care
Cho et al. 2020 [16]: Development of a data-driven method for deriving clinical pathways from electronic health records
Gaveikaite et al. 2020 [17]: Case study along a COPD pathway for potential analysis of telemedicine
Kempa-Liehr et al. 2020 [18]: Modeling tool for clinical pathways and prediction models based on data mining methods and machine learning models for individual improvement of recovery time
Trajano et al. 2020 [19]: Process oriented modeling language for clinical pathways
Ye et al. 2020 [20]: Feasibility study on the use of deep learning prediction models for decision support and derivation of optimal, individual hypertension pathways based on electronic health records

Six themes have been inductively identified out of the paraphrasing results of all 47 articles. Some articles refer to up to two different themes due to their complexity (e.g. [18]). Table 2 shows all themes and sub-topics to give a referenced overview of pathway-related HISR of the last decade. The following additions highlight selected findings or implications for future design and implementation activities of pathway-supporting HIS.

I. Design, development and implementation of pathway-supporting HIS: This theme includes generic approaches as well as descriptions of pathway-supporting HIS and application systems for specific care scenarios. Such work has been established for years. The traditional workflow support of clinical processes is increasingly complemented by articles that present solutions for more complex, cross-institutional and patient-integrating care scenarios. Future work of this theme should concisely characterize the care scenario and parameterize targeted improvements to care-related goals or further outcomes in order to increase reusability.

II. Evaluation and assessment of pathway-supporting HIS: Theme II papers investigate the effects of pathway-supporting HIS. Increasingly complex care scenarios require future evaluative papers to consider all involved stakeholders more comprehensive (e.g. multidisciplinary care teams, patients, expanded health care market) and to discuss competing or synergistic effects and measurable outcomes.

III. Modeling and modeling languages of care pathways: Research with a focus on pathway modeling, modeling languages and tools discuss less the design and realization of application systems but address the underlying pathway models and their genesis. The established knowledge base provides already valuable guidance. However, the changing scope to integrated care scenarios with by multiple professional stakeholders and increasing technization may require additional work in this theme to offer appropriate techniques for precise, comprehensive and consistent pathway models.

IV. Data-driven pathway models and integration of data-based prediction models: Recent advances in data science, machine learning, and related disciplines drive articles in this young theme (earliest publication of this review from 2017). It includes articles that discuss the data-based derivation of care pathways from existing data, e.g.

of EHR. Such retrospective pathway analyses provide the opportunity to compare originally defined care plans with de facto care pathways and to investigate deviations. In consequence, those knowledge might be used to optimize individual care pathways or general pathway templates prospectively or to improve medical guidelines (e.g. for care quality or efficiency). On the other hand, this theme also includes discussions of how pathway-supporting HIS can provide the data basis for data-driven medical decision support systems or management-oriented predictive models (linkage to Theme V). Both sub-themes - pathway-supporting HIS as a source and as a sink of data-driven processing of health information - like to merge and are currently of increasing interest.

V. Conceptual integration of the management perspective: Traditional workflow assistance fosters goals directly related to care processes such as accelerated process flow or lower error rates. Articles of this fifth theme investigate how pathway-supporting HIS can support additional short-, medium- and long-term tasks of healthcare management on micro, meso or macro level (e.g. quality management, resource management, health program management). Future work shall explore how pathway-supporting HIS need to be designed to satisfy this information demand and to offer management decision support. It therefore will probably benefit of popular research efforts of Theme IV.

VI. Care pathways as a means for HISR: Pathway-supporting HIS can be a starting point and data source for diverse research questions. Future design and implementation activities should consider the access to and scientific usability of the processed data and integrate validation and anonymization mechanisms in particular.

Table 2. Analytical results –themes on pathway-supporting HIS

Theme (Number of papers that led to theme): Sub-topics [references]
I. Design, development and implementation of pathway-supporting HIS (n=13):
- Development and implementation of clinical pathway for specific healthcare scenarios [21]–[28]
- Generic conceptualizations and design recommendations [23], [25], [29]–[34]
II. Evaluation and assessment of pathway-supporting HIS (n=16):
- Studies on effectiveness, efficiency and user experience [10], [15], [28], [35]–[43]
- Usage analyses for coordination and communication [35], [37], [43]–[46]
- Maturity model for care pathways and its implementation in HIS [47]
III. Modeling and modeling languages of care pathways (n=8):
- Development of process-oriented modeling languages for care pathways [19]
- Conceptualization and modeling approaches [30], [48], [49]
- Modeling tools for care pathways [18]
- Examples of care pathway modeling (process and final pathways) [22], [24], [40]
IV. Data-driven pathway models and integration of data-based prediction models (n=7):
- Modeling methods or tools for care pathways from electronic health records [16], [18], [20], [37], [51]
- Development of data-based prediction models (Data & Process Mining, Machine Learning, Deep Learning) for medical decision support [18], [20], [37], [52]
- Data-based analysis and decision models from data of pathway-supporting HIS for healthcare and hospital management [50], [51]
V. Conceptual integration of the management perspective (n=5):
- Intersection analysis of Information Systems, Operational Research and Industrial Engineering to solve problems related to care pathways [53]
- Method conception for the embedding of quality management in care pathways [54]
- Path-based data analysis for tactical and strategic hospital management [55]
- Conceptualization and modeling approaches for aligning evidence-based Clinical Practice Guidelines and Clinical Pathways [48], [49]
VI. Care pathways as a means for HISR (n=7):
- Analysis of the Status Quo of the Digital Transformation [56]–[58]
- Analysis of technology support across care pathways [10], [17]
- Analysis of key areas via patient flow pathway mapping [59]
- Studies on personalization of HIS services [60]

4. Discussion

The review results can be used for different tasks by research and development consortia of pathway-supporting HIS and offers an aid for their objectives. Institutions with a need to catch up in IT-based workflow support can draw on the contributions of *Themes I* and *II* to design and implement their own pathway-supporting HIS. The traditional care process support may seem almost obsolete compared to current HISR contributions. However, these themes remain particularly relevant to healthcare actors with low digital maturity. Contributions from *Theme III* should also be considered in this outlined case to enable the creation of the necessary pathway models as a success-critical resource. Theme III can also support consortia with already established pathway-supporting HIS and contribute to improvements of the used pathway models.

From the perspective of HISR and healthcare organizations of high digital maturity, *Themes IV* and *V* are highlighted in particular. Technological advances in data science and related disciplines indicate enhanced potential for both personalized care and learning systems of a macro level for management and medicine. Future work may generate data-based individual improvements in care pathways (e.g., based on patient constitution or resource availability) or address care economic issues at the local (e.g., clinical process improvements) or global level (e.g., regionally adequate care programs). Future contributions will help pathway-supporting HIS to benefit from the technological progress while providing the required valid and consistent data for these mechanisms.

The contribution of this paper is affected by a certain number of *limitations*. For example, the analysis sample from the selected publication organs offers a solid basis for interpretation, but is still restricted. The integration of additional development-focused journals or conferences could provide more differentiation in the design of novel pathway-supporting HIS. Further, the creation of the six research themes is also subject to the limited objectivity of the author, although this influence was counteracted by group sessions with experienced digital health researchers.

How may *future research* stimulate the progress? With the assumption that concrete care scenarios will continue to be main drivers for technological innovation with and for pathway-support HIS, the relationship between care context and system design could be explored in more detail. Such investigations could determine those care scenarios that motivate the development of pathway-supporting HIS in particular or those which benefit only from dedicated functionalities. Therefore, an appropriate description model is required to define characteristics as well as types of care scenarios , which in turn could be linked to concrete care goals on micro or macro level. Those studies should focus on: care setting (outpatient, inpatient, rehabilitation); medical discipline (e.g., oncology, emergency medicine); indications (e.g., COPD, depression); patient's role (autonomous vs. paternalistic); degree of multi-professionality or number of institutions involved.

5. Conclusion

This review identified 47 articles from highly ranked literature on care pathways or pathway-supporting HIS. Through their interpretation, six themes were derived that represent the range of interdisciplinary goals with and for pathway-supporting HIS. Their consolidation supports future design and development processes by describing the solution space for pathway-supporting HIS. In particular, the design of new systems can benefit from this summary and interdisciplinary requirements management of multiple stakeholders can be supported. Among those themes, articles with a scope on data-driven pathway models, the integration of data-based healthcare prediction models as well as the enhancement to pathway-supporting HIS for management and operations currently represent exciting fields of activity for HISR and seeks to future work.

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6 Paper P2

Table 11: Key information on paper P2 and declaration of authorship.

Paper P2	
Title	**A Reference Architecture Approach for Pathway-Based Patient Integration**
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A Reference Architecture Approach for Pathway-based Patient Integration

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***Abstract*— The active integration of a patient into his/her own care process offers great potentials for improving care quality. With this regard, patient portals are frequently referenced for enabling patient integration. Existing solutions primarily focus on the access to electronic health records but do not aim for the integration of cross-institutional information about the course of treatment itself – known as patient pathway. Thus, this paper proposes a reference architecture for the integration of pathway systems into patient portals. High-level requirements have been captured from both a user's perspective and a theory perspective. Therefore, a large-scale patient survey was conducted within a general design science research approach. They were transformed into appropriate modules and components of a reference architecture. Its applicability is demonstratively shown by the development of a patient portal for Multiple Sclerosis patients.**

Keywords— patient pathways, patient portals, reference architecture, integration

I. Introduction

Personalized medicine and patient engagement occupy an important position within the current discussion about improving the continuity of healthcare. Thereby, the informative integration of the patient into his/her own course of treatment plays a central role. Higher adherence to therapy, positive changes of patients' behavior as well as the enhancement of both process and care quality are expected by this type of integration. It provides the basis for the patient to influence his/her own course of treatment and, in consequence, enables the improvement of the patient-individual outcome [1], [2]. A prerequisite is, however, that intended treatment plans including case documentation are accessible plus that the patient is able to relate to his/her treatment and health status. Personal Health Records (PHR), health apps and patient portals [3],[4] generally allow this informative integration [5]. In contrast, the integration of the patient into the treatment process – the patient's participation in cross-institutional patient pathways and therefore a boost of the patient's self-management – still starts out. [6].

This paper addresses the question how cross-institutional patient pathways can be implemented in the context of patient portals. At that point, patient portals are seen as application systems, that allow the integration of the patient into the information systems (IS) landscape of one or more healthcare providers. Apart from functional properties, patient portals can be technically realized in different ways, e. g. web-services or apps.

Focuses of this research are the development of a requirements catalogue and a deduced reference architecture approach for standard-based implementation of pathway-supporting application systems landscape (PAS). Within this paper, the utilization of the suggested reference architecture approach is demonstrated by a patient portal for Multiple Sclerosis (MS) patients.

Methodologically, this work corresponds to design-oriented research [7] and targets the development of a technical artifact. Due to the claim of design-oriented theory construction [8], the reference architecture approach is seen as a design-guiding artifact that can be instantiated in various application systems landscapes. Therefore, established standards as well as a role-oriented description of application components are involved. That allows a comparison with existent system instances (e. g. particular application systems) and the development of new components as well.

The structure of this paper follows the design science research approach postulated by Peffers et al. [9]. Section 1 motivates and clarifies the problem area. Section 2 explains our research design. Within section 3, the role of patient pathways and its relation to patient engagement and patient empowerment (theoretical foundation) are addressed. According to the design goal, the central requirements are elaborated in section 4. Those are transferred to a reference architecture approach as a design artifact in section 5. In section 6, the suggested reference architecture approach is instantiated for a particular use case in terms of a demonstration [9]. Typically, the paper ends with a conclusion, critical discussion and an outlook to further research.

II. Methods

The nominal design science research process according to Peffers et al. describes six research steps. In the following, we describe how this research process is implemented. Our research efforts where initiated by a concrete research context. We are engaged in a project where the main contribution is the creation of a patient portal for multiple sclerosis patients.

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The first step (step 1: problem identification and motivation) was done by analyzing existing patient portals and questioning which functionalities they consider [3]. We found that pathway-oriented portals are not yet implemented. Nevertheless, we argue that an implementation of patient-pathways in patient portals may provide utility by providing the patient a tool to track the quality of his own treatment [10]. Therefore, we investigated the requirements regarding a patient portal (step 2: objectives of a solution).

Based on a survey with MS-patients, we analyzed the requirements for a prospective multiple sclerosis patient portal. We asked the patients for functionalities which they would consider as useful in context of their own disease. We analyzed the answers by doing a category-based coding of the textual answers [11]. The description of requirements follow Braun et al. who classifies different types of requirements for design science research [12]. Based on the results of this survey (user-requirements) and existing literature (theory-based requirements), we derived functional requirements which a pathway-supporting application landscape should fulfil. In order to be disease-independent, we generalized the statements of the patients and described the requirements for the pathway-support landscape without specific disease-oriented properties.

In the step of the artifact design (step 3) we described a reference architecture approach according to the requirements. We applied the architecture in a MS-specific setting. Following Venable et al. the demonstration step (step 4) can be seen as a lightweight evaluation [13]. We demonstrate our reference architecture approach in a case example and show the feasibility and applicability to a specific problem context. Through the generalized requirements we ensure, that the research also contributes to the knowledge base. We conducted an analysis how the resulting instance of the architecture address the requirements that result from the survey. We understand the architecture as a meta-artifact according to Drechsler and Hevner [14].

III. Patient Integration through Patient Pathways

Over the last years, the discussion about concepts, measures and effects of an increasing involvement of patients in their own healthcare processes has been intensified [15]. Two frequently addressed concepts are “patient empowerment” and “patient engagement”. The former describes the deflection of power of decision towards the patient. He or she takes over more responsibility about their health-related questions. In contrast, patient engagement aims more at the behavior of the patient and addresses particular actions made by him/her [16],[17]. Despite discussable evidence, there is a broad consensus about the beneficial impact of patient engagement on improving care quality and care organization [18], especially in context of chronic diseases [19]. Therefore, patient information, -education and -participation are highlighted as primary parts [16], [20]. Thus, the active health-related behavior of a patient in the sense of patient engagement, as indicated by the patient’s informative participation, requires an optimal communication between the healthcare team and the patient [21].

Patient pathways are seen as enabler for both improving patient empowerment and patient engagement. The underlying concept is known as clinical or treatment pathways. A pathway is generally understood as a standard-based, ideal treatment course which unifies multidisciplinary settings, local circumstances and current state of evidence-based research. Primarily, pathways are used for preplanning of particular treatment steps that are connected to temporal or defined status changes [22], [23]. Moreover, patient pathways highlight the relation to the patient. Especially, they serve to ensure seamless care of patients with chronic diseases over different healthcare sectors, patient information and education as well as to planning of treatment processes including consideration of individual needs [10], [24], [25].

European pioneers and their patient portals (e.g. Denmark with sundhed.dk or Estonia with e-tervis.ee) already demonstrate how patient engagement can be realized on a nation-wide scale. The digital access to medical documents, information about received treatments as well as their sharing with authorized people and additional tools for management of appointments or medical prescriptions and communication services are the focusses in these patient portals. Thereby, the integration of the patient as a co-creator of his/her own patient pathway is rarely considered.

IV. Requirements Analysis

The current state of research [23] and the political call for pathway systems (e. g. [26]) argue for its usage and its technical support in general [27], [28]. However, acceptance and enforcement in reality are still insufficient. Therefore, the following types of requirements have been identified from two different perspectives as proposed from Braun et al.: from a user’s perspective (user-requirements) and from a theory perspective (theory-based requirements) [12]. We argue that user-requirements provide an insight into the real-world-context while the theory-based requirements allow a generalization of demands regarding a design artefact.

In the course of this research, we used a patient survey to take the user's perspective and gather initial requirements. Afterwards, we assign the user-requirements to the existing literature on pathway systems. The results of this large-scale patient survey (n=210) supported the desire for planning and tracking tools for patients with chronic diseases. We explicitly asked for disease-related issues patients have to face in their everyday life and for expectations regarding concrete functions of a patient portal for their disease.[1]

More than 80% of the respondents assessed the functionality “view on future care plan and appointments” (*treatment planning*) as “very useful” or “rather useful”. In addition to this prospective context, approximately 70% of the participants rate an “overview over past treatments and appointments” as well as “the management of appointments” at least as “rather useful” (see Fig. 1). Consequently, an operative management view (*treatment organization*) as well as a retrospective view (*treatment monitoring*) for patients are

[1] Other survey sections asked for demographic data, detailed disease conditions as well as the general usage of information and communication technologies

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demanded. These results also confirm the general relevance of pathway-related functionalities from a patient's perspective.

In order to gain a better understanding on how these functions should work, we also asked for qualitative answers. Patients were able to articulate how a feature should work or which information regarding the treatment is relevant for them. For example, the following statements of patients (about what a they require from a patient portal) substantiate the need for pathway-supporting systems:

- "current status of examinations (mine)"
- "announcements of therapy progress reports"
- "what's my personal prognosis for impending disability?"
- "Information about self-efficacy - status of treatment."

Current discussions about patient engagement focus how it should be promoted and how its realization lets promised benefits occur. Thereby, authors always consider both the patient side and the professional side (e.g. [1], [2]). The integration of patients requires corresponding professional activities by the care providers. We addressed this by discussing the survey results with medical specialists regarding their perspective on the three functionalities. In consequence, this led to two perspectives on common requirements (*care provider view* and *patient view*) which are presented in the following paragraph. In line with the procedure of task disaggregation, we zoomed into the originally stated requirements from patients to identify necessary subtasks and related underlying requirements. We align them to the existing theory on patient pathways and clinical pathways. Therefore, the stated requirements intend to ensure the functionality of the intended pathway-supporting system only in coexistence.

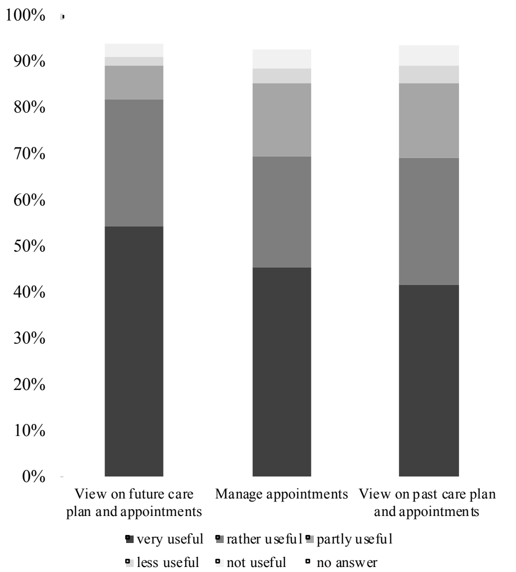

Fig. 1. Selected results of patient survey (n=210)

A. User requirements for pathway systems

Tools for creation and maintenance of pathways should be guided by professional contexts for an adequate consideration of the complexity of healthcare processes [29], [30]. Furthermore, those tools should support all phases of a reasonable pathway lifecycle, i. e. preparation, development, implementation, and maintenance.[31] (see Table I).

TABLE I. TREATMENT PLANNING

No.	*Description*
A1	**Care provider**: Typical pathway variants and corresponding basis for decision-making should be determinable for treatment planning. Preferably, the model-based design and editing should be carried out in an integrated tooling. **Patient**: Therapeutic options and corresponding pathway variants should be visible for the patient. Possible pathways should be presented to the patient.
A2	**Care provider**: Inclusion and exclusion criteria should be deposited for the instantiation of a pathway. The patient-specific pathway should be individually configurable by the care provider. **Patient**: When instantiating the pathway, the patient should be able to understand why a particular pathway configuration was chosen and on which criteria it was designed.

Regarding the professional everyday life, the possibility to adopt case context or patient's demands is necessary while using pathway systems [32] (see Table II). Enabling this opportunity could promote the usage and acceptance of pathway systems.

TABLE II. TREATMENT ORGANIZATION

No.	*Description*
A3	**Care provider:** The care provider should be able to perform ad hoc modifications on the pathway at any time during the treatment. Every modification should be justified and documented for the context of the case. **Patient:** Treatment changes should be communicated with the patient and reasons presented in a comprehensive manner. The patient should be able to request for modifications.
A4	**Care provider:** The use of pathways should be embedded in a continuous process management. The involved agents regularly examine and discuss if and how pathway templates need to be revised. **Patient:** Changes of pathway templates should be made transparent for the patient referring to the individual pathway instance. Differences from standard pathways and additional changes should be communicated.

The use of pathways is mostly motivated by economic thoughts [33]. Additionally, a higher compliance to process plans (process security) is anticipated. However, the standardization in the form of pathways includes the critic that there is a lack of patient relation in terms of adequacy and accessibility [34] (see Table III).

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TABLE III. TREATMENT MONITORING

No.	Description
A5	**Care provider:** The care provider should be able to enter information in the pathway in an understandable way for the patient to support the education of particular patient cohorts. **Patient:** The patient should have access to his/her own pathway and be able to inform him-/herself regarding the progress of his/her therapy based on understandable status information and additional materials.
A6	**Care provider:** The pathway should be individualized and, if required, extended with patient-specific information and functions. **Patient:** Pathway information should be linked to corresponding assistance features and be provided adequately and personalized.
A7	**Care provider:** Information about the current status of the treatment should be entered to the pathway by the care provider and reviewable in the sense of a process-oriented quality management. **Patient:** The patient should be able to analyze the current status of his/her own treatment referring to the originally intended treatment plan and to comprehend deviations.

B. Systems requirements for pathway systems

Based on the user requirements A1-A7, functional requirements are developed and presented in Table IV. They represent a basic set of functional requirements for pathway systems that can - depending to a specific medical scenario – vary regarding to their range of functions and their level of integration. This basic set determines the framework for the intended PAS. A PAS is not to be understood as a particular software product but as a system of different application systems. Basically, such a system includes involved clinical application systems (CAS), the patient portal and its modules as well as external infrastructures, systems and services [35].

TABLE IV. FUNCTIONAL (F) REQUIREMENTS FOR IMPLEMENTING THE PATH SYSTEM

No.	Description
F1	Task and schedule control should be actively carried out in the PAS. Appointments and tasks should be actively communicated into involved systems (CAS, patient portal, etc.).
F2	The PAS should be capable of informing involved applications about changes of patient's status, treatment plan, a particular treatment or of specific values.
F3	By using an appropriate tooling (e. g. modeling tools), pathway templates should be created and managed comfortably as well as provided to involved systems.
F4	Pathway templates should be integrated into the case documentation of the PAS and need to be instantiable individually
F5	Patient pathways should be visible and editable for authorized actors in the context of a patient-specific case. The modification of the planned patient-specific pathway should be possible at any time whereby the possibility to justify modifications is essential.
F6	Evaluation and monitoring functionalities should be carried out centrally for every stakeholder (Management Cockpit). Alternatively, existing process mining tools should be integrable.
F7	Instances of pathways should continuously be adapted to the documentation situation of the involved KAS and other documentation systems.

V. PROPOSAL OF A REFERENCE ARCHITECTURE

Based on the discussed user and systems requirements, components and modules in the sense of architectural building blocks are developed (subsection 4.1) and combined to a reference architecture (subsection 4.2) in the following section. Furthermore, an illustration is given by using the example of the implementation of a patient portal for MS patients (section 5).

A. Pathway-related modules and patient portals

The range of functions of patient portals should reflect the disease-specific informative needs of a patient [3]. Therefore, the configuration or instantiation of a patient portal may vary by selection and specific realization of functions. The modules proposed in Table V describe functionalities which are necessary for the realization of patient pathways within patient portals. That list should not be seen as a completed set due to the possibility that the treatment context can require additional modules.

Generally, the modules are divided in three classes: Kernel modules, specific pathway modules and pathway-associated modules. Kernel modules, also named Kernel [36], include the basis configuration as well as central functionalities and interfaces. Functionalities of specific pathway and pathway-associated modules are dependent on Kernel modules (e.g.

TABLE V. DESCRIPTION OF PATIENT PORTAL MODULES

Module	Description	Reference
Infrastructure/Kernel Modules		
Kernel	This module implements fundamental functionalities and configurations (authentication, identity-, demographic data- and software interface-management as well as metadata configuration).	[36]
Specific Pathway Modules		
Care Plan Module	This module implements that kind of pathway functionalities that can be influenced by patient engagement.	F1-F7
Self-Tracking Module	This module implements health status monitoring.	F6
Pathway-associated modules (see function domains in [3])		
Encounter Module	This module implements functionalities for the management of appointments and other medical or nursing interventions.	F1, F2
Documentation Module	This module implements access functionalities to electronic health records and other medical documentation as well as providing documentation capabilities for the patient.	F2, F4
Assessment Module	This module implements screening and questionnaire functionalities.	F1, F7
Education Module	This module implements the patient specific therapy support functionalities (exercise instruction, explanatory materials, etc.).	F5
Medication Module	This module implements medication-related management and monitoring functionalities.	F7

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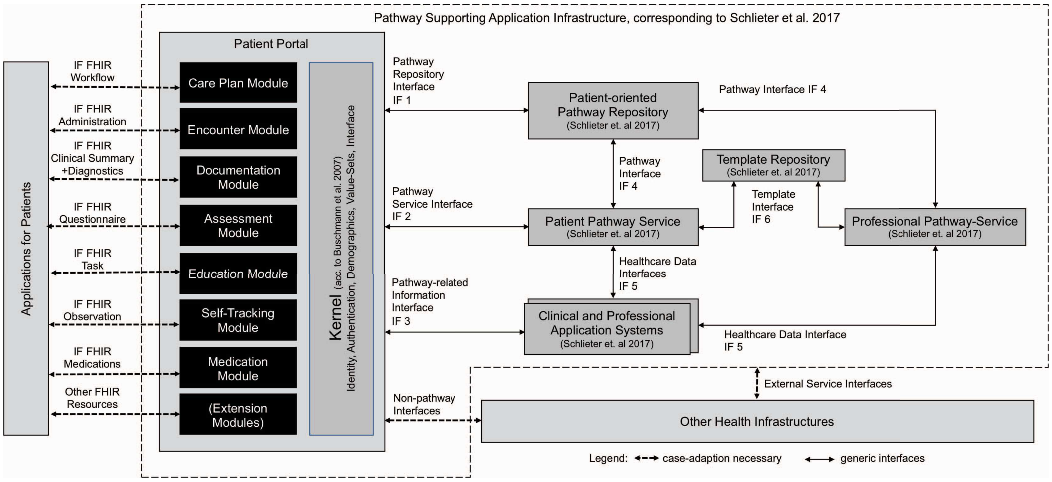

Fig. 2. Reference architecture approach for integration of patient portals in PAS

rights management). The specific pathway modules are responsible for functionalities for representation and execution of particular pathway instances. In contrast, pathway-associated modules describe subject-specific functionalities related to a pathway. For example, within the pathway-associated module "Documentation" a patient is able to let the portal display all documents which are linked to the pathway step "Anamnesis". Furthermore, appointments or linked medications are also available throughout the modules "Encounter" respectively "Medication".

The modules can provide interfaces to external devices (e. g. blood pressure monitors) and applications (e. g. health apps). These interfaces serve as case-dependent integration points because external systems may be used in various contexts. For patient portal interfaces, the proposed reference architecture points explicitly to the Fast Healthcare Interoperability Resources standards (FHIR)[2] to give an orientation which information types have to be provided by the respective module. Generally, interfaces have to be adapted to the specific disease and the particular scenario so that other standards or formats could be used.

B. Integration of patient portals PAS

Fig. 2 shows the proposed reference architecture which sums up both the roles[3] of particular modules as well as the interfaces between them. Therefore, the architecture approach proposed by Schlieter et al. [35] has been taken up and extended by communication relations between backend-services and the patient portal. Additionally, the design of the patient-frontend has been detailed and its integration in suggested pathway systems has been revealed. The presented reference architecture is based on a cross-institutional realization of patient pathways and case documentation. This paradigm of implementation is frequently found for the realization of cross-institutional IS for the exchange of patient data (e.g. [5]).

Pursuant to Fig. 2, the "Patient-oriented Pathway Repository" (PPR) has the responsibility to persist pathway instances. Pathway templates are stored in the "template repository" (TR). The professional control – the use of pathways by the care provider – is ensured by the "Professional Pathways-Service" (PrPS). This component includes all components of pathway instantiation, modification and analysis as well as components of data integration mentioned in [35]. In addition, it enables active pathway changes, automatisms and manipulations done by the care provider responsible for pathway execution.

The component "Patient Pathways Service" (PaPS) serves the execution of pathways from a patient's point of view. It realizes pathway-related functions for the patient and ensures the (e.g. readable) access to pathway information. Also, it offers functionalities which allow a direct involvement of the patient in the treatment process by modifications of pathway instances. In this way, questionnaires, that have to be completed by the patient in dependency to the treatment progress, could be integrated.

The component "Clinical and Professional Application Systems" (CAS) represents existent clinical IT-systems for documentation and management. These systems are part of the PAS if they provide information or functions that are relevant for pathway planning, execution or monitoring.
Different bidirectional interface types are defined between the presented components (see Fig. 2). Table VI shows the interface types, the information and access modalities. Thereby, "Active access" represents the provision of the appropriate information on request. "Reactive access" represents the uncalled provision and automated processing as a reaction of a trigger event.

[2] http://hl7.org/fhir/

[3] Named components of the reference architecture are seen as possible roles of an application system. For example, clinical and professional application systems can be involved in other information infrastructures at the same time (e. g. infrastructures of electronic health records).

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TABLE VI. INTERFACE TYPES (IFT) OF THE REFERENCE ARCHITECTURE

IFT	***Description***	***Information and Access***
IF1 Pathway Repository Interface	This interface is used for direct access to the raw data of the pathway instances. This is the in [35] mentioned access to the repository based on the IHE XDS.b-standard.	Complete pathway instances, active access
IF2 Pathway Service Interface	This interface implements the exchange of single pathway information. That includes interfaces for adjustment and consumption of pathway information. The interface also acts as service interface to trigger functions in the patient pathway component.	Status changes, pathway information, active and reactive access
IF3 Pathway-related Information Interface	This interface is used to exchange pathway-relevant information. It could be information that is directly associated with the execution of the pathway or that has an influence on the pathway's course.	pathway-influencing and -resulting field specific information, active and reactive access
IF4 Pathway Interface	This interface represents the access of the active path service components to the pathway instances.	Pathway instances, active access
IF5 Health-care Data Interfaces	The interface is used to exchange data regarding the manipulation of pathway instances or rather for implementing the pathway course. Using this interface, data is communicated that influences decisions in a pathway.	Information that influence the pathway course, active and reactive access
IF6 Template Interface	The template interface is used to provide and modify pathway templates.	Pathway templates, adjustment of pathway templates, active access
External Service Interfaces	The pathway-services can be dependent if other infrastructures are executed (e.g. application system landscapes for the exchange of laboratory data).	Variable, active and reactive access
Non-pathway Interfaces	Pathways and corresponding modules of the patient portal can refer to particular information and functions. These do not influence or change the course of a pathway. Interfaces for communication of such information are classified as non-pathway interfaces.	Variable, primarily active access regarding the pathway execution

VI. DEMONSTRATION – CASE MULTIPLE SCLEROSIS

A. *Case context – integrated care for Multiple Sclerosis*

MS is a chronic inflammatory, degenerative disease of the central nervous system [37]. Known as the "disease of 1000 faces", MS is characterized by heterogenous, heavily affecting symptoms [38]. Due to the young age of onset, MS patients have some attributes that may influence modern, participative treatment approaches positively. Younger patients have a sound affinity to information technology and a higher competence to explore and use new electronic health services for improving the own health literacy [39], [40].

In the context of the project "Integrated Patient Portal Multiple Sclerosis" (Integriertes Betreuungsportal Multiple Sklerose IBMS), a patient portal for patients of MS is developed. It considers the heterogeneity and individuality of this specific disease. The patient portal will be embedded into the existing IS landscape of the University Hospital Carl Gustav Carus Dresden (UKD) and should include further care providers of the Saxon healthcare region. Therefore, one goal of the project and so for the development of the patient portal is to consider existing systems of the UKD as well as of the region in the sense of a (technical) integration. That contains especially a subject-specific MS documentation system (MSDS3D) and an IHE-based telehealth platform of East-Saxony (THOS) which offers the realization of cross-institutional telemedicine solutions. Another goal of the project is the accessibility to the patient's electronic health record via the patient portal. A patient should be able to adequately comprehend his or her treatment course, medical documentation and health status.

TABLE VII. COMPONENTS AND THEIR INTERFACES IN THE MS PATIENT PORTAL ARCHITECTURE

***Component** (Status of availability) - Task**; Interface:** type: data model*	***Role***
Patient Pathway-Manager (to implement) – patient-side execution of pathways **Interface:** *IF1:* proprietary description (CPMod-Format) [29], FHIR Workflow-resources [4] (active), *IF2:* ICP-Service in terms of a Business Delegate [36], SOAP-Calls proprietary (active)	PaPS
XDS.b-Registry und Repository (existent) – storing of patient data and patient pathways **Interface:** *IF1, IF4:* CPMod for patient pathways, repository-interfaces (XDS.b-based exchange, active)	PPR
ICP-Service (existent) – execution of pathways on care provider's side **Interface:** *IF2:* FHIR Workflow-resources (active and reactive), *IF4, IF6*: CPMod (active) *IF5:* FHIR-resources: Observation (active and reactive), Events (FHIR-resources: Events [5], reactive), Appointment und Task [6] (active and reactive)	PrPS PaPS
MSDS^{3D} (existent) – documentation of MS cases **Interface:** *IF3*: FHIR-communication-resources (reactive), communication of patient data (Non-pathway Interfaces)	CAS
UI-Module Documentation, Care Plan, Encounter, Assessment (to implement) – implementation of patient functions **Interface:** *internally and externally:* FHIR- resources appropriate to interfaces to external applications in reference architecture (see Abb. 1) on basis JSON + Websocket, alternatively REST	Module
Kernel-Module Identity Manager, Demographics Manager, Authentication Manager (to implement) – connection to external services **Interface:** *Non-pathway Interfaces:* FHIR-administration-resources, OAuth, JSON Web Token (JWT)/JSON-Format	Kernel

[4] https://www.hl7.org/fhir/workflow.html
[5] https://www.hl7.org/fhir/event.html
[6] https://www.hl7.org/fhir/task.html, https://www.hl7.org/fhir/appointment.html

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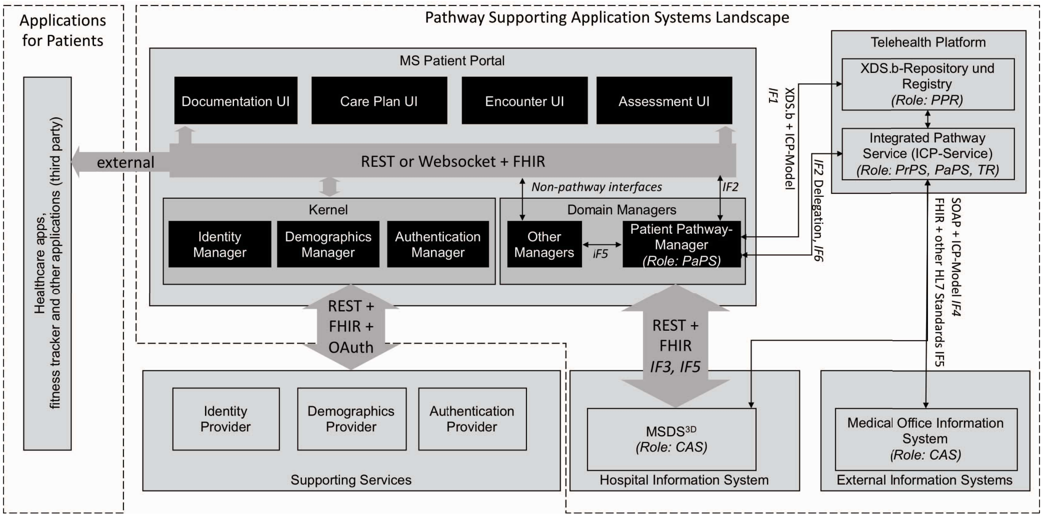

Fig. 3. Application systems architecture of a MS patient portal

B. *Usage of the proposed reference architecture*

For the purposes of the presented case, based on the purposed reference architecture a patient portal for the involved MS center is conceptualized and implemented (see Fig. 3). Therefore, existing application systems have been analyzed and compared to the roles of the reference architecture. Already existent systems are the XDS.b-based electronic health record system and the Integrated Clinical Pathway (ICP) Service that realizes the roles PPR / PrPS, PaPS and TR of the reference architecture as well as the clinical application system MSDS3D (see Table VII) which assumes the role CAS. Additionally, it is intended to implement external application systems of physicians in the sense of CAS. A patient pathway manager becomes developed and integrated in the application systems landscape in the course of the project.

The current application system architecture contains the presentation layer which corresponds to the User Interface (UI) and represents the subject-specific modules of the reference architecture (see Fig. 3, left). The backend consists of an extendable Kernel which represents the Kernel module of the reference architecture (see Fig. 3, left) and of different domain managers. The presentation layer is uncoupled from the backend via standardized REST-based FHIR- or Websocket-interfaces. Thus, the backend additionally serves as middleware that enables the connection of third-party applications (see Fig. 3, left) e. g. the FHIR-based "Apple Health Records" [41], [42].

Relevant to the patient, the Kernel is responsible for the system-wide unambiguous identification, acquisition and provision of demographic data as well as the authentication and access control within the patient portal. The Kernel is designed in a way that external services can be used for the realization of its responsibilities. The domain managers realize the domain-specific business logic whereby one UI module has to be supported by at least one domain manager. The patient pathway manager realizes the logic for the care plan module and uses the existent domain managers which ensures the access to specific data of the CAS.

Enabling single application systems to fulfill their respective role (see Fig. 2) requires specific interfaces to the patient portal as shown within the proposed reference architecture (see Table VI). Due to the use of existent REST-based FHIR and XDS.b interfaces, the semantic interoperability can be ensured (see Table VII). Additionally, these standards have been adapted for the context-specific information needs of patients. Furthermore, the clinical pathway modeling format "CPmod" from [29] has been used.

According to the current development state of the patient portal, the patient navigates via menu item "My Treatment" in Care Plan UI along a timeline and is able to access historic data as well as information about planned treatment activities (see Fig. 3). This data is provided by the Patient Pathway-Manager which ensures further data integrity and user authenticity due to the Kernel. The Patient Pathway-Manager is able to recall data of corresponding pathway instances (IF1) and of the patient's pathway template (IF6) via the THOS. Thus, the patient can be informed about imminent steps of the standard pathway and deviation analysis can be executed.

The case documentation of a clinical documentation system is also accessible via REST-based interface (IF3). Therefore, medical data, e. g. lab results, can be linked to particular steps of a patient's pathway. The patient gets (only) the relevant information of the current steps and an information overflow can be strikingly decreased. Requests, events or helpful hints can be sent to the patient at the same time. Within the project context, a questionnaire component will be integrated for the patient portal.

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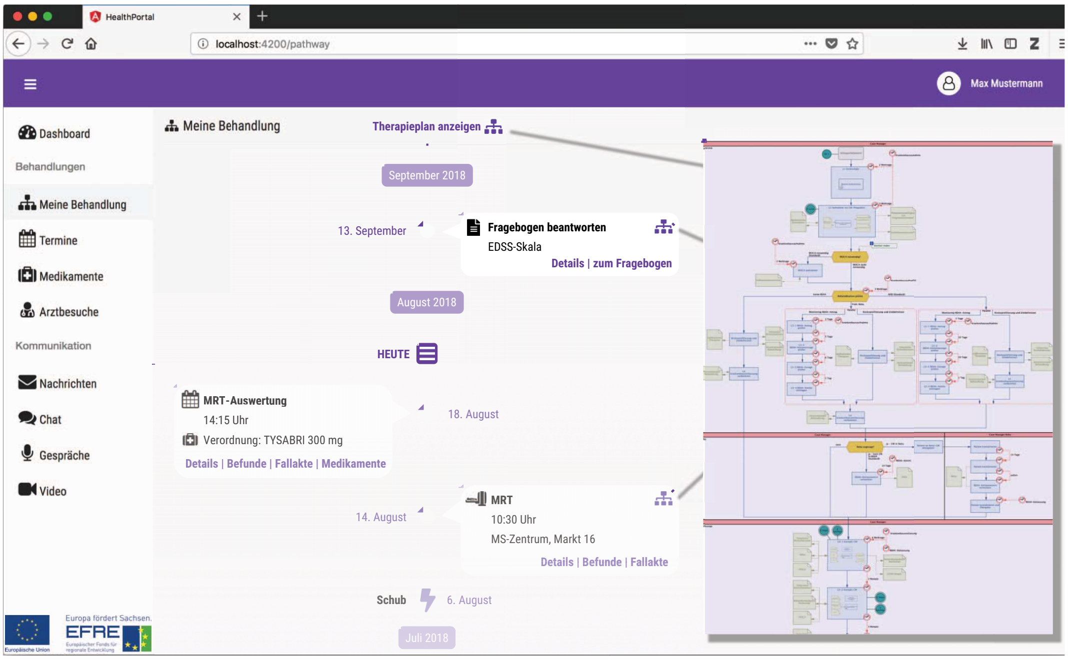

Fig. 4. Screenshot of the patient portal + indicated integration of a pathway template

VII. Discussion and Conclusion

This paper addresses the realization of patient pathways and especially their integration into the context of a patient portal. Based on a catalogue of requirements, a reference architecture approach has been developed. It specifies typical system components, roles and communication relations. A proof-of-concept is proposed by its utilization for the specific case of MS treatment. Therewith, the applicability as well as the instantiation of the generic architecture concept are highlighted [43]. An evaluation of the architectural proposal and of the overall solution from a user's perspective has not been realized so far and is subject of future research.

It has to be mentioned that this article focusses on the functional-technological realization of a pathway-oriented patient portal. Further aspects like usability or organizational efficiency of technological patient integration measures are undiscussed so far. A comprehensive large-scale evaluation with patients is also remaining and is part of further research. In this context, real-world experiences have uncovered that organizational (finance, introduction, education, support) and data security aspects generate a variety of additional boundaries which are not addressed. Their consideration is aimed to be explicitly integrated in the mentioned large-scale evaluation. At this point, we like to promote the consensus of standardized processes and procedures as well as the acceleration of politico-legal adjustments for the digital era. Central electronic health records, e. g. the German TK-safe[7] or the Finnish KANTA Services[8], offer insights into how patient integration can be addressed.

In consequence, there is a need of research and development work of pathway-supporting systems. Therefore, the proposed reference architecture may serve as a design aid. Completed with the catalogue of requirements and the elaborated interface types, this work offers a practical approach to accomplish the transformation process to a pathway-centered patient integration. Additional research might address this topic by setting the focus on the patient's role either as a data consumer (e. g. to be his/her own case manager) or as a data source (e. g. via new medical home devices, health apps or wearables). IS research may answer the questions: How can PAS support the change of a patient's role with new responsibilities and tasks in interorganizational care settings? How should PAS be designed to ensure a conflict-free integration into a heterogenous landscape of professional IS from an organizational and a technological point of view? How might PAS interact with other IS domains like artificial intelligence to extract individual recommendations or knowledge on a healthcare system's level? The lively interdisciplinary discussions will go further and generate fruitful contribution in design and theory.

Acknowledgements

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[7] https://www.tk.de/tk/digitale-gesundheit/

[8] https://www.kanta.fi/en/my-kanta-pages

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7 Paper P3

Table 12: Key information on paper P3 and declaration of authorship.

Paper P3	
Title	**PathwAI Systems in Healthcare - a Framework for Coupling AI and Pathway-based Health Information Systems**
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Publication	Proceedings of 55th Hawaii International Conference on System Sciences (HICSS 2022), Jan. 2022, `https://hdl.handle.net/10125/79838`
Author's contribution[7]	Conception: TS 45%, TW 45%, MB 10% Data processing, evaluation and interpretation: TS 45%, TW 45%, MB 10% Formulation of the manuscript: TS 45%, TW 45%, MB 10%
Additional materials	-

[7] The contributions of the author(s) are structured according to the authorship criteria of the German Research Foundation for good scientific practice (DFG, 2013).

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PathwAI Systems in Healthcare – a Framework for Coupling AI and Pathway-based Health Information Systems

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Abstract

Pathway-based Health Information Systems (HIS) enable planning, execution and improvement of standardized care processes. Adaptive behavior and learning effects are taken to a new level by advances in Artificial Intelligence (AI). Yet, design support to unlock synergies from coupling pathway-based HIS with AI is lacking. This Umbrella Review identifies applied purposes of AI in healthcare, describes the relation to pathway-based HIS, and derives a PathwAI Framework as design support for future research and development activities. Previous findings already provide a large base of approaches to realize personalized care pathways and improve coordination and business operations. Furthermore, potentials for designing learning health systems at micro, meso, and macro levels are formulated, but there is still greater opportunity for future research and design. Pathway-based HIS in this context can not only provide interpretable and interoperable data input, but can be conceptual as well as operational receivers of artificially generated knowledge.

1. Introduction

Artificial Intelligence (AI) promises a digital revolution in healthcare and opens up new potentials for transforming the entire care pathway [1]–[3]. Benefits and opportunities of using AI in healthcare particularly rely in decreasing costs and reduction of inefficiencies while improving the care quality with a more personalized, precise and preventive medicine [4], [5]. Instead of replacing human workforce, the partnership of humans and AI may also bring back humanity to medicine and health professionals can spend more time with their patients [6], [7]. For example, AI-driven applications can support radiologists by diagnosing diseases or even replace particular tasks [1], [8]. Recent achievements of AI-based speech recognition allow to communicate with computers as we do with humans and accelerate documentation tasks of health professionals [3] or facilitate the interaction with virtual coaching systems that support patients in their daily life [2].

While the mentioned examples focus on single interventions, AI may be also used to learn about entire care pathways. Especially against the background of chronic disease scenarios (e.g. cancer, diabetes or multiple sclerosis), that often involve a lifelong patient journey and long-term care, an investigation of the whole pathway is of particular interest [9]. Instead of focusing on single interventions, we experienced in several digital health research projects the benefits of process orientation to find the best holistic approach of digital support to those care scenarios. We therefore put care pathways in the center of our innovation activities to design pathway-based Health Information Systems (HIS), i.e., systems that support process-centered care scenarios [10], [11]. Notably the emergence and availability of national Electronic Health Records (EHRs) that capture the whole patient history across institutions could further drive pathway-based HIS [12]. Analyzing this multimodal data (e.g. diagnoses, conducted treatments, medical parameters or unstructured clinical notes) with advanced analytical techniques of AI could lift pathway-based HIS to a new level [11]. Thus, instead of relying on static process knowledge and manual adjustments based on explicit expert knowledge, coupling AI with pathway-based HIS promises more dynamic and new insights into existing care pathways.

However, to the best of our knowledge, no study has reviewed the approaches and design options of how AI can enrich pathway-based HIS. Therefore, we want to investigate the following research questions:

RQ1: How have pathway-based HIS been enriched by AI so far?

RQ2: What needs a framework that might assist the design and implementation of AI application in relation to pathway-based HIS?

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This paper is structured as follows. In the next section, we introduce the theoretical background on pathway-based HIS and AI in healthcare and motivate the general analysis concept of our work. Section 3 describes the research methodology followed by our results in section 4 (RQ1) and 5 (RQ2). The paper closes with a discussion and an outlook on future research opportunities.

2. Background

2.1 Care pathways and associated systems

A Care Pathway (CP) is a specific, standardized description of a clinical process for a defined combination of symptoms adapted to clinical conditions [13], [14]. It is a multidisciplinary tool to improve quality of care for a specific patient type and to achieve a higher degree of efficiency and a higher grounding in the evidence base [15]. Accordingly, CPs are used as communication tools between professional caregivers to manage and standardize care [16]. Different terms are used to emphasize specific peculiarities and scopes of CPs, such as intra-organizational (clinical pathways), inter-institutional (integrated pathways) or patient-centered (patient pathways) orientations [15], [17], [18]. The common ground is to provide an integrating process view on the care-relevant items, including medical, organizational and administrative aspects, to support the planning, execution and improvement of medical care.

Depending on the maturity of Information and Communication Technology (ICT), the previous usage of CPs seldomly went beyond the organizational level (e.g. checklists, local pdf-files, printed management manuals). But meanwhile, ICT landscapes are starting to change and to adapt process knowledge into HIS design. The resulting continuum of HIS's process awareness goes from not aware to process-aligned HIS design (*process-centered HIS*) until real *pathway-based HIS*, where the CP is a configuring part of the running system. Thus, there are several HIS implementations for a workflow-oriented support of daily care processes [19]–[21], and systems that support process-centered care scenarios [10], [11].

Considering the planning of medical care, HIS can support the design of CPs as well as their adaptation for a specific patient, i.e., mapping patient conditions to CP scopes to identify and customize the best matching CP for an individual case. During the following stage of CP execution, HIS can provide guidance along the CP-defined care process concerning communication and documentation but also support monitoring and adaptation of the specific care process to topical patient conditions. The collected data during CP execution can provide a profound knowledge base for process evaluation and improvement. Based on the data, HIS will be able to support a continuous evaluation and improvement, both, of specific patient-individual CP instances (ad-hoc) and of the underlying CP itself.

2.2 Rising AI in healthcare

Driven by advances in computing power, machine learning and its subfield deep learning has been on the rise since the beginning of the 2000's [22]. Machine Learning (ML) can be considered as automated analytical model building for conducting cognitive tasks and addresses the drawbacks of handcrafted rules [23]. Therefore, ML is nowadays in the center of AI research in healthcare [24]. A term related to ML is "data mining" and can be understood as the process of building ML models [25]. With respect to business processes, the field of process mining has emerged in the last decades and investigates ML approaches to gain knowledge by analyzing event logs [26].

In general, ML techniques can be classified along the three types supervised learning, unsupervised learning and reinforcement learning [23]. Supervised learning refers to problems where a target variable should be predicted and a training dataset with input data (x) and output data (y) is available [23]. Supervised learning is suited to solve classification problems, i.e. prediction of a categorical variable (e.g. disease diagnosis based on a CT image as input), or regression problems, i.e., predicting a continuous variable (e.g. prediction of blood sugar level) [27]. Typical supervised learning techniques are linear and logistic regression, decision trees or Artificial Neural Networks (ANNs) [27]. The idea of deep learning builds on the latter technique (ANNs) and uses complex architectures with deeply stacked layers to increase learning capabilities [23]. In contrast, unsupervised learning aims to generate knowledge about data (patterns and correlations) without a target variable (y) being specified [27]. One typical unsupervised learning technique is clustering (e.g. dividing data from multiple patients into groups of similar patients) [27]. Unlike supervised and unsupervised learning, reinforcement learning doesn't need a training data set beforehand [23]. Algorithms from the field of reinforcement learning (e.g. Q-learning) solve sequential decision making problems to achieve a certain goal by building a model in a "trial and error" process or by expert demonstrations [28]. Hence, a software agent interacts with an environment by taking certain actions that change the environment's state and receives rewards in response to the actions [27]. For healthcare, reinforcement

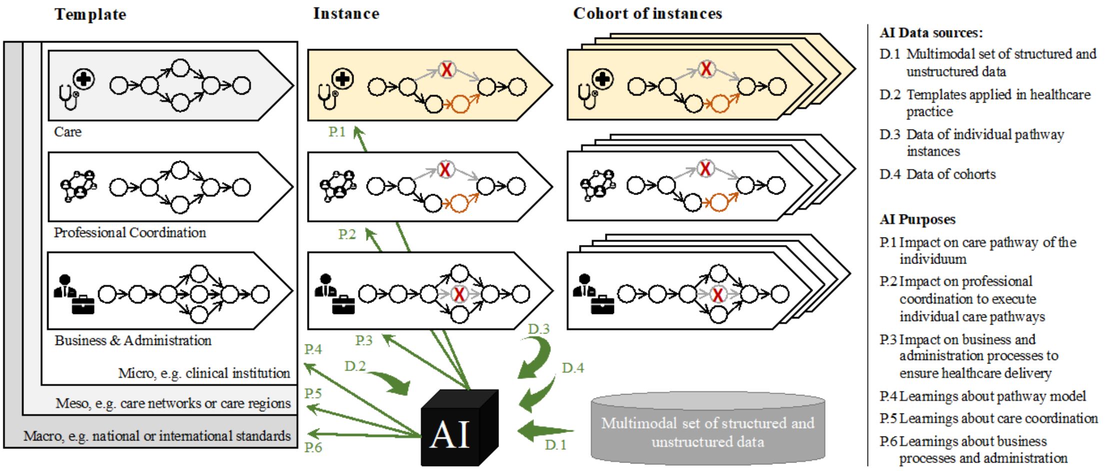

Figure 1. Analysis concept of coupling AI and pathway systems

learning enables personalized treatments such as optimizing therapy plans to the patient and the clinical goals [29], [30].

2.3 Conceptualization of investigation

Considering the variety of mechanisms how AI is able to generate effects in healthcare, there are multiple possibilities to enrich pathway-based HIS with such techniques. We developed an analysis concept that describes general alternatives of AI integration in the context of pathway-based HIS (see Figure 1). It comprises the following elements:

Pathway Template: Model of a care process; Represents standardized process knowledge; Differentiation by views on medical care, coordination of professional care delivery and business as well as administration; Different reference levels describe intra-organizational (micro), cross-institutional (meso), and national or international (macro) levels.

Pathway Instance: Application of the pathway model for a patient; process execution on all views (care, professional coordination, business & administration); pathway systems as application systems to apply, execute and store pathway instances.

Cohorts of pathway instances: Selected set of pathway instances; Cohort building by e.g. indication, symptom, treatment, demographics, time period, etc.

Data sources: Multimodal set of structured and unstructured data; variety of HIS, application systems and devices including, e.g. EHR-systems, clinical information systems, health information data bases, med-tech devices, patient's IT in home environment.

AI: interpreted as black box of algorithms and techniques to generate knowledge from different data in an automated way for defined purposes.

With the simplified understanding of AI as a black box, two aspects come into focus of the investigation. First, for which purposes is AI attempted. And second, what data is needed as input for these purposes. We assume that AI might be coupled with pathway-based HIS to fulfill one or more of these six top-level purposes (see Figure 1). These top-level purposes are analyzed more in detail by this study. Thus, we examine how AI supports ongoing care (P1-P3) as well as general learning effects at micro, meso or macro level (P4-P6). We further assume that AI could basically use four types of data input: multimodal set of structured and unstructured data (D.1), templates applied in healthcare practice (D.2), data of individual pathway instances (D.3) or data of multiple pathway instances selected based on a certain criterion, i.e., cohort of instances (D.4). This proposed distinction is primarily qualitative in nature and should not be understood as physically delineable data repositories. Rather, data structures of pathway-based HIS should be delineated from the set of other data sources. Such data structures represent temporally and causally related sequences of activities as well as conditions and reference applied pathway models, treatment plans, or care cases.

3. Methodology

The recent popularity of AI in healthcare promoted primary studies as well as reviews. In order to align the knowledge aggregated therein with our own objective, an umbrella review was conducted to analyze a large amount of literature in a targeted manner [31]–[33]. Its analytical results were combined with our analysis concept to derive the PathwAI

Framework that seeks to support the design of intelligent, pathway-based HIS.

The literature selection was conducted in end of June 2021. Three databases have been selected for identification of relevant IS or medical literature: *IEEE Xplore*, *AIS Library* and *PubMed*. We therefore used the search strategy mentioned in Table 1. We decided to focus on a short and current time range to balance up-to-dateness of a review of reviews with its retrospectivity.

Table 1. Search strategy of umbrella review

Data field	Terms
Title	"artificial intelligence" OR "AI" OR "ML" OR "learning" OR "mining"
Title	"health*" OR "medic*" OR "care"
Abstract	"review"
Year	2018-2021

Details of selection process are given in Figure 2. We only include articles that a) do not focus on a single AI technique; b) do not focus only one specific medical field, disease, symptom, treatment or intervention; c) state details of review strategy and d) discuss findings in relation to CPs and/or associated processes. Considering the continuum, from not aware to *process-centered HIS* until *pathway-based HIS* (see section 2.1), we rather remained open minded for different technological solutions than stuck to a strict inclusion criterion on dedicated types of systems. Both such a definition and its application would have been difficult to implement. Finally, seven articles matched the inclusion criteria for full text analysis (Table 2).

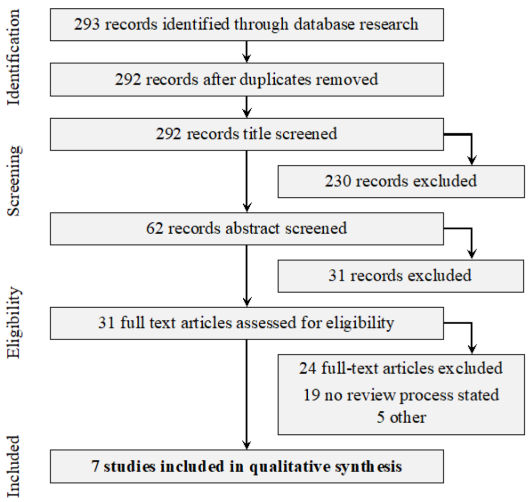

Figure 2. Review details according to PRISMA [34]

Table 2. Analyzed reviews sorted by year

Authors	Title	Year
Kueper et al. [35]	Artificial Intelligence and Primary Care Research: A Scoping Review	2020
Triantafyllidis & Tsanas [36]	Applications of Machine Learning in Real-Life Digital Health Interventions: Review of the Literature	2019
Shickel et al. [37]	Deep EHR: A Survey of Recent Advances in Deep Learning Techniques for EHR Analysis	2018
Erdogan & Tarhan [38]	Systematic Mapping of Process Mining Studies in Healthcare	2018
Batista & Solanas [39]	Process Mining in Healthcare: A Systematic Review	2018
Xiao et al. [40]	Opportunities and challenges in developing deep learning models using electronic health records data: a systematic review	2018
Islam et al. [41]	A Systematic Review on Healthcare Analytics: Application and Theoretical Perspective of Data Mining	2018

4. Findings

4.1 Purposes of AI mentioned in reviews and implementation approaches

As summarized in Table 3, there are several AI techniques conceivable to address the defined purposes. Therefore, we want to focus on a subset of techniques that were particularly emphasized in the reviewed articles and concisely state how they could leverage pathway-based HIS. One promising AI technique for analyzing CPs represented as the longitudinal sequential patient history in EHRs are concept embeddings [37], [40]. Against the background that CPs can span several decades of lifetime, the idea behind medical concept embeddings is to generate aggregated representations of medical concepts in the pathway. These aggregations are low-dimensional vectors capturing the latent relationships (e.g. preceding and succeeding diagnoses or treatments) [37]. Therefore, approaches originating from the field of Natural Language Processing (NLP) are used such as word2vec (capturing the context of words in a corpus) with adaptations for the medical domain (e.g. med2vec) [37], [42]. For instance, the skip-gram architecture of ANNs [40] can be used to predict the context for a certain input word or in case of CPs, predict adjacent diagnoses or treatments based on a certain medical concept. As an example, one could imagine that a predecessor of a CT scan of the abdomen could be abdominal pain, followed by a surgery to remove the appendix after imaging. However, common approaches based on word2vec generated concept embeddings fail to capture the actual timestamp relationships, i.e., it is not represented if event B happened one week or one year before event A (see Zhu et al. [43] for an advanced approach). While a medical concept embedding thus may provide new insights into a cohort of pathway instances, one can go one step further and derive also abstract patient representations. This can be achieved by aggregating the medical concept embeddings contained in the CP of the patient [44]. In a next step, similarity metrics can be calculated between pairwise patient representations and may facilitate scenarios such as analysis of comparative treatment effectiveness and personalized medicine [43]. Furthermore, clinical phenotyping can be considered as an application of concept embeddings by matching patient vectors to a defined phenotype vector [40]. In addition, one can use the abstract patient representations as input for predictive models (e.g. to predict risks or clinical outcomes). Several studies also reveal that this approach can increase the predictive performance compared to raw data input [37].

Considering that pathway data is sequential in nature, Recurrent Neural Networks (RNNs), a special type of ANNs that are able to capture long-term dependencies, are particularly suitable for prediction problems [37], [40]. In general, for supporting diagnostics and therapy, one may distinguish with respect to prediction tasks between identification and classification of diseases, as well as sequential prediction of diagnoses and clinical events. With respect to the output, one may further distinguish between outputs without (e.g. general risk for a certain disease) and with temporal constraints (e.g. timespan to next hospital visit and diagnosis) [37]. Furthermore, identified purposes that also rely on prediction problems encompass referral support, forecasting of service demand, disease or infection control, patient management and efficiency improvement.

In addition to these techniques which are particularly rooted in the field of deep learning, there is a vast body of literature on techniques from the process mining field. For example, clustering is often considered as a pre-processing step in the discovery of new processes, i.e., aggregating the event logs of a cohort of pathway instances to identify the underlying pathway template(s) [38], [39]. Frequently used clustering algorithms with respect to process mining are Trace Clustering, K-Means and Hierarchical clustering algorithms, whereas for process discovery, the Heuristic Miner and Fuzzy Miner algorithms dominate in the literature [38], [39]. Based on the discovered processes, templates may be derived that could serve to check on how a business process or CP instance align with the template (conformance checking) [39]. Furthermore, there are process mining techniques available to extend the pathway template based on the observed pathway instances (process enhancement) [39].

Last but not least, given that structured event logs with timestamps are often not available, as EHRs usually contain mixed data (structured and unstructured), advanced information extraction techniques may be applied to reconstruct and derive the CP. Especially for dealing with unstructured data (e.g. clinical notes), advanced NLP techniques are particularly useful for extracting single concepts, temporal events, relations or expand abbreviations [37], [40], [41].

4.2 Allocation to top-level purposes

Within the interpretation phase, we were able to make an argumentative allocation to the defined top-level purposes of our analysis concept. Rarely was a one-to-one mapping identified (e.g. *Disease identification and classification* for P.1). More frequently, assignments to two to three top-level purposes were determined. The close connection between the process views (medical, coordination, business), a primarily abstract description of the purposes by the reviews, and the logical coexistence of added benefits are the main reasons for this. The latter can be illustrated by *clinical phenotyping*. On the one hand, knowledge about phenotypes is extracted as a model (P.4), and on the other hand, patients (pathway instances) can subsequently be assigned to learned phenotypes for individualization of care processes (P.1). The allocation made (see Table 3 and Figure 3) leaves room for further interpretation and should therefore be classified as a suggestion by the authors.

4.3 Relation to pathway-based HIS

In addition to conceptual links, systemic input and output relationships were also explored to describe the role of pathway-based HIS in interaction with AI. Even authors of analyzed reviews did not mention explicitly the relation between AI applications and pathway concept or realizing pathway-based HIS, their contributions indicate implicitly whether pathway-based HIS do “only” provide interpretable and interoperable data as input of AI techniques or pathway based HIS and AI occur in a synergetic loop, where outputs of AI affect pathway models or instances. These analysis results are embedded within the PathwAI Framework (see Figure 3) and also leaves room for further interpretation. Again, it should therefore be classified as a suggestion by the authors and used as aid for architectural design activities.

Table 3. Findings of umbrella review - purposes of AI application in relation to pathway-based HIS

Purpose of AI application	Description	Purpose group	Ref
Diagnostic and therapeutic decision support	AI provided information to inform diagnosis and treatment decisions. Diagnostic applications typically seek for onset or probability that a patient has a particular condition or recommend diagnosis categories. Diagnostic decision support is used to describe and/or predict various conditions or events. Therapeutic decision support includes any management or care provided (or absence of unnecessary actions) to a patient with specific health condition(s) or symptom(s). Therapeutic applications result typically from diagnostic decision support. They are often used to predict or define a personalized treatment, e.g. medication or treatment plans, for improvements in quality outcomes or efficiency.	P.1, P.2, P.3	[35], [36], [40], [41]
⎿ Disease identification and classification	AI used to screen and detect whether specific diseases can be confirmed. Different types of Classifications are applicable: disease specific (categorical or multi-label) or disease non-specific (normal, preictal or seizure subject).	P.1	[40], [41]
⎿ Medical concept embedding	AI used to derive abstract representation of clinical concepts based on analysis of real cohorts. It aggregates medical concepts that occur frequently together. Concept embedding is often an intermediate, descriptive step for building a predictive model of previous and next steps from a certain position in the pathway for better performance.	P.1, P.4	[37], [40]
⎿ Clinical phenotyping	AI used to discover phenotypes via feature representation and investigates association of pathway instance to different phenotypes. First, phenotypes are extracted as new knowledge out of cohorts of instances, e.g. by prevalence of a condition or patterns of patient profiles. Second, single instances are matched with discovered phenotypes. Third, treatments might be personalized, e.g. by pathway instance adaptions. Clinical phenotyping is considered as a type of concept embedding.	P.1, P.4	[35]–[37], [40]
⎿ Sequential prediction in diagnostics	AI predicts future diagnoses based on past longitudinal event sequences (patient's history), e.g. onset of new disease condition, risk of in-hospital mortality, discharge diagnoses. Differentiation of static (categorical or numeric) or temporal (time stamp or range included in prediction)	P.1	[37], [40]
⎿ Sequential prediction of clinical events	AI predicts future clinical events based on past longitudinal event sequences (patient's history), e.g. unplanned hospital admission/ readmission, length of stay. Differentiation of static (categorical or numeric) or temporal (time stamp or range included in prediction)	P.2, P.3	[36], [37], [40]
Process clustering	AI identifies groups of similar business processes or care pathways based on analysis of a cohort of instances.	P.1, P.2, P.3	[38], [39]
Process discovery and proof of conformance	AI used to derive retrospectively or ad hoc business process or care pathway instance based on analysis of a single or a cohort of instances. Often follows a check on how a business process or care pathway instance align with the underlying template.	P.1, P.2, P.3	[38], [39]
Referral support	AI provided information to support decisions about referring patients to specialist services or AI assisted with technical aspects of the referral process.	P.2	[35]
Health care utilization analyses	AI provided information about interactions with or processes within health care systems, for example frequency or quantity of patient visits.	P.2, P.3	[35]
Forecasting of service demand	AI used to predict demand of healthcare services on macro level	P.2, P.3	[41]
Disease or infection control	AI used to monitor and predict dynamic of diseases or infections on macro level	P.2, P.3	[41]
Efficiency improvement	AI used to predict service demand on micro level and improve resource utilization and allocation (decision support)	P.2, P.3	[41]
Patient management	AI used to adapt scheduling and forecasting based on patient conditions and behavior (decision support)	P.2, P.3	[41]
Performance quantification	AI used to quantify performance of medical service delivery	P.3	[41]
Information extraction	AI used to extract knowledge from structured or unstructured data	P.4, P.5, P.6	[35], [41]
⎿ Process enhancement	AI used to extent pathway templates with information from event logs.	P.4, P.5, P.6	[38], [39]
⎿ Derivation of healthcare programs	AI used to improve design of national healthcare programs (macro level)	P.4, P.5, P.6	[41]

5. PathwAI Framework

The PathwAI Framework (see Figure 3) sorts the identified purposes of AI applications to enhance top-level impacts on individual CPs (P.1), its coordination (P.2) and related business as well as administration processes (P.3). Impacts on these intertwined process views effect ongoing individual care delivery and may result consequently in improved care delivery of population. Besides this distinction, the proposed framework further indicates purposes by its context of learning: learnings about pathway models (P.4), learnings about care coordination (P.5) and learnings about business processes and administration of healthcare (P.6). Here, AI is applied to extract knowledge that should be used to develop new pathway models (templates) on micro (e.g. institutional procedures), meso (e.g. integrated pathway of care networks) and macro level (e.g. national guidelines).

Either new AI applications tend to one or more of the purposes mentioned, all techniques require a sound data input that ensure interpretability and interoperability. Pathway-based HIS could therefore play a critical role, take the potentials to a new level and master the challenge of data accessibility and quality. Such systems are able to ensure comprehensive and structured data sets of individual pathway instances (D.3) that are linked to selected templates (D.2) and in consequence of cohorts of specific interest (D.4). Paired with the increasing amount of accessible and valid health information from various data sources like EHR, smart devices of patients as well as specialized medical databases (D.1), the coupling of AI and pathway-based HIS promises impactful and strong support for individualized care and learning health systems.

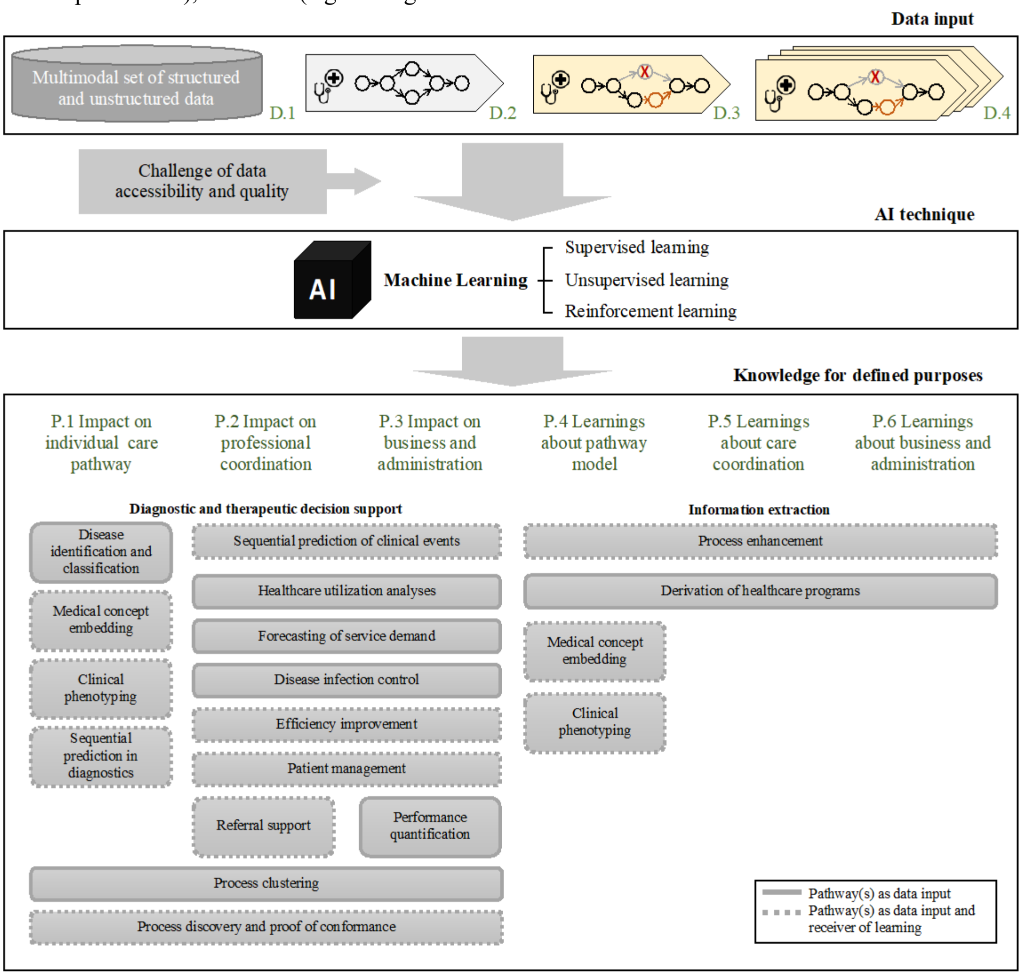

Figure 3. PathwAI Framework - pathway-oriented application of AI in healthcare

6. Discussion

6.1 Limitations

As a qualitative research paper, the presented contributions are subject to some limitations. While the selection and analysis of the literature was conducted independently by two researchers, limitations of objectivity remain due to the authors interpretations. Additionally, umbrella reviews seek to interpret prior interpretations done by the authors of selected reviews which are also limited in its objectivity. This "inheritance of subjectivity" might be counteracted by the inclusion criterion of required review strategies. Looking at the parameters of the selection process and the list of analyzed contributions, two further limiting aspects can be identified: Comprehensiveness and timeliness.

6.1.1 Comprehensiveness. In the final proof of eligibility, 18 of 31 articles were excluded due to missing or insufficient description of review details. It is not always clear whether this is reasoned due to a lack of a systematic procedure or an unsatisfactory presentation. Either way, we decided to look back on excluded papers of this last selection step. Thus, we checked three additional articles with the most intensified resonance [1], [45], [46] (count of citations assessed via Google Scholar).

6.1.2 Timeliness. The high number of primary studies reflects the topic's current relevance. However, the speed of technological progress contrasts the fact that five out of eight articles were published in 2018. Thus, the critique occurs that recent progress could not be sufficiently taken into account. Also, reviews, especially umbrella reviews, hold a retrospective analysis position and generate only limited insights for the present and future. Analogous to the previous critique, we additionally checked three articles published in 2021 to strengthen the awareness of current research [47]–[49].

6.2 Consideration of additional reviews

6.2.1 Reviews of high relevance. The requirement of a presented systematic review process excluded three articles which enjoy increased attention in the scientific discourse. Since IS research should benefit from review methods of other disciplines [50], these articles were selected to identify additions to previous findings. All in all, the additional reviews align with our assumptions stated in section 2.3 and generally confirm our framework. But they highlight those top-level purposes, that were not discussed prominently within the analyzed reviews (P.4, P.5, P.6).

In their review paper in Nature Medicine journal, He et al. show further alternatives, including: treatment alignment with guidelines (P.1), efficiency increase of hospital management (P.5, P.6), epidemiological registries for population management (P.5, P.6), outcome assessment on quality (P.5, P.6) and the development of disease prevention guidelines (P.5, P.6) [1].

Ching et al. describe AI applications in diagnostics, biological studies and therapeutics, especially in medications [45]. They point out, that AI is also applied for longitudinal analysis for high value knowledge extraction in different contexts (P.4, P.5, P.6). They differentiate the potential to improve choices of interventions (P.1) and methods for the development of new interventions (P.4). Thereby, the prediction of actions to change the outcome in a certain way are even more challenging than prediction of outcomes under specified conditions.

Miotto et al. summarize in their review, how AI is able to use EHR data for prediction and classification tasks based on a patient's history [46]. Comparing the findings of this umbrella review, their results primarily confirm purposes of AI applications that enhance quality of diagnostic or therapeutic interventions.

6.2.2 Recently published reviews. Also, recent publications confirm the PathwAI Framework. The review of Enticott et al. focusses rather on data driven scenarios in Learning Health Systems than on applied AI techniques, which principally correspond to top-level purposes on knowledge extraction (P.4, P.5, P.6) [48]. The authors highlight benefits in evidence-based care (P.4), clinical organization or system-level performance (P.5, P.6) and concretize it, e.g. compliance with clinical guidelines and a coexistence of standardization and specialization of care.

Koteluk et al. and Bharadwaj et al. confirm benefits in diagnostic and therapeutic processes especially in terms of personalization, organization and velocity of action [47], [49].

6.3 Future research

The results of our review reveal that process-related applications of AI are well established so far and under ongoing research for realizing personalized and efficient CPs including their organization, coordination and management. Further, the results indicate that synergies can be unlocked by design and implementation of intelligent, pathway-based HIS. Hence, a design method or design principles to support those activities shall be investigated in subsequent work. However, the results also show that research on applications for gaining general knowledge about pathway templates are still in its infants but deep learning approaches could make a significant contribution here in the future. Likewise, the application of AI techniques to learn especially on meso and macro layer has so far been little described in the literature and could be addressed in future research. With regard to achieving the notion of personalized medicine, AI-empowered clinical phenotyping will be a significant driver. Especially with advanced and ubiquitous digital health applications on the patients' side such as "virtual coaches", new data can be obtained that could enable new insights on CPs outside the clinical environment. Additionally, future research should elaborate how reinforcement learning could leverage pathway-supporting HIS. Reinforcement learning could provide a powerful framework for fully autonomous and adaptive CPs (similar to autonomous driving) but patient safety considerations should always come first [51]. Finally, future studies should demonstrate the usefulness of the proposed framework as guidance for designing and implementing AI applications with relation to pathway-based HIS.

6. Conclusion

This umbrella review offers a high-level overview on how HIS can be improved by ensuring synergies of pathway-based HIS and the application of AI within such HIS landscapes. A systematized analysis of purposes and interdependencies led to the proposed PathwAI Framework. It aims to guide research and development teams in designing data-driven, learning HIS. It offers a structured view on the bandwidth of possible improvements in healthcare and, thus, guidance for interdisciplinary innovation teams of clinicians, technologists and health systems managers. This study finally provides evidence on AI applications that have already been investigated, developed and applied in relation to CPs. Future research shall further focus on the symbiosis of AI within pathway-based HIS to ensure adaptive, multi-level learning and high-performance HIS.

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8 Paper P4

Table 13: Key information on paper P4 and declaration of authorship.

Paper P4	
Title	**Forschung in Digitalen Innovationsprojekten - zwischen Praxistauglichkeit und wissenschaftlicher Relevanz**
Author(s)	Tim Scheplitz (TS) Martin Benedict (MB) Hannes Schlieter (HS) Stefanie Kaczmarek (SK) Marcel Susky (MS)
Publication	HMD Praxis der Wirtschaftsinformatik, 57(2), 257-273., Feb. 2020, doi: `10.1365/s40702-020-00601-2`
Author's contribution[8]	Conception: TS 20%, MB 35%, HS 25%, SK 10%, MS 10% Data processing, evaluation and interpretation: TS 20%, MB 35%, HS 25%, SK 10%, MS 10% Formulation of the manuscript: TS 20%, MB 35%, HS 25%, SK 10%, MS 10%
Additional materials	-

[8]The contributions of the author(s) are structured according to the authorship criteria of the German Research Foundation for good scientific practice (DFG, 2013).

HMD (2020) 57:257–273
https://doi.org/10.1365/s40702-020-00601-2

SCHWERPUNKT

Forschung in Digitalen Innovationsprojekten – zwischen Praxistauglichkeit und wissenschaftlicher Relevanz

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Zusammenfassung Ergebnisse Digitaler Innovationsprojekte (DIP) sind zumeist neue Artefakte von Informationssystemen, welche stark an die Resultate gestaltungsorientierter Forschung erinnern – dem sogenannten Design Science. Dennoch halten die Erkenntnisse aus DIP der Praxis nicht hinreichend Einzug in die wissenschaftliche Gemeinschaft. So zum Beispiel im Gesundheitswesen. Hier werden zwar verstärkt DIP forciert, ihre zentralen Erkenntnisse zur erfolgreichen Gestaltung jedoch selten in die Community transportiert. Ebenso wenig haben sich abseits klassischer Publikationswege Standards zur Kommunikation von erarbeitetem Wissen etabliert. Explizites und implizites Wissen, als Projektresultate nebst der Innovation selbst, können für die Organisation und Durchführung von vergleichbaren Projekten von kritischer Bedeutung sein kann. Ihre Kommunikation und strukturierte Bereitstellung wurden bislang in der Wissenschaft wenig adressiert. Das Ziel dieses Beitrags ist daher einen Weg aufzuzeigen, wie Wissen aus DIP im Gesundheitswesen besser extrahiert und kommuniziert werden kann. Dazu wird ein bestehender Ansatz zur Systematisierung gestaltungsorientierter Forschungsprojekte, das Design Science Grid, in drei Fallstudien angewendet. Aus dieser Anwendung werden sieben

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verschiedene Typen von Wissen beschrieben, die aus DIP im Gesundheitswesen resultieren können. Für künftige Praxis-Forschungs-Projekte wird damit ein Weg zur Systematisierung von Ergebnissen aufgezeigt. Die gefundenen Wissenstypen können dabei als Ausgangspunkt einer Klassifizierung von zu erzielenden Kontributionen dienen.

Schlüsselwörter Digitale Innovationsprojekte · Multi-Fallstudie · Wissenstypen · Design Science Research

Research in Digital Innovation Projects—Between Practicability and Scientific Relevance

Abstract Project results of digital innovation projects (DIP) develop innovative artefacts of different shapes and forms which are strongly reminiscent of results from design-oriented research activities (design science). Nevertheless, the findings from DIP in the healthcare sector often do not find their way into the scientific debate. Although the implementation of such projects is strongly promoted in the health care system, design recommendations or even standards for communicating the results have not been established. Explicit and implicit knowledge, as project results in addition to the innovation itself, can be of critical importance for the organization and implementation of similar projects. Their communication and structured provision have so far been little addressed in science. The aim of this paper is therefore to show a way how knowledge from DIP can be better extracted and communicated. For this purpose, an existing approach to systematize design-oriented research projects, the Design Science Grid, will be applied in three case studies. Seven different types of knowledge that can result from DIP in health care are described. For future practice-oriented research projects, a way to systematize results is thus shown. The knowledge types found can serve as a starting point for a classification of project goals.

Keywords Digital Innovation Projects · Multi-Case Study · Knowledge Types · Design Science Research

1 Einleitung

Im Zeitalter der Digitalen Transformation des öffentlichen, privaten und wirtschaftlichen Lebens erfährt der wirtschaftsinformatorischen Forschung eine wichtige Bedeutung diesen Wandel zu erklären und zu gestalten. Dennoch bestimmt auch die Debatte zur Praxisrelevanz von Forschungsergebnissen und die wissenschaftliche Qualität von innovativen Praxisarbeiten den aktuellen Diskurs. Digitale Innovationsprojekte (im weiteren Verlauf als „DIP“ abgekürzt) im Gesundheitswesen gelten innerhalb dieses Wandels als wesentliche Triebkraft (Laurenza et al. 2018). Ihre Projektergebnisse sind typischerweise Kombinationen aus integrierten Versorgungsmodellen und innovativen Systemlösungen (Digitale Artefakte) unterschiedlicher Form und Ausprägung. Diese Ergebnisse ähneln in ihrer Art den Resultaten gestaltungsorientierter Forschungstätigkeit (in der Fachwelt auch als Design Science Research tituliert) (Österle et al. 2011; Hevner et al. 2019).

Die Untersuchung von Werner (2019) unterstreicht eine Diskrepanz, die zwischen den zur Umsetzung verwendeten Forschungsmethoden und solchen, die international als publikationswürdig anerkannt sind, besteht. Während zu den tatsächlich verwendeten Forschungsmethoden Systementwicklungsansätze wie das Prototyping, Umfragen bzw. Interviews gehören, zählen zu den häufig publizierten Forschungsmethoden die konzeptuelle Deduktion als auch die quantitativ/qualitativ-empirische Forschung (Werner 2019).

Gleichzeitig lässt sich beobachten, dass sich die Relevanz und Bedeutung von rein wissenschaftlich entwickelten Methoden für die Forschungsergebnisse marginalisieren. Nicht umsonst gilt die Evaluation von Design Science-Kontributionen abseits von konstruierten Szenarien, als zentrale Herausforderungen der Wissenschaftsgemeinschaft (Frank 1998; Venable et al. 2012). Beispielsweise werden in DIP im Gesundheitswesen häufig genannte Forschungsmethoden (Prototyping und qualitativ-empirische Forschung) angewendet (Fichman et al. 2014). Die mangelnde Anerkennung solcher Forschungsergebnisse führt jedoch nur zu einem schwachen Transfer bzw. Verschränkung praxisorientierter Forschung und akademischer Verwertung. Als Resultat erhalten Erkenntnisse aus DIP im Gesundheitswesen nur schwerlich Einzug in die Wissenschaft. Hingegen ist gerade die Auseinandersetzung mit Defiziten, welche die Umsetzung von DIP im Gesundheitswesen betreffen, für die Forschung und Praxis unerlässlich bspw. zur Untersuchung neuer Versorgungsmodelle und Erforschung theoretischer Erklärungsansätze.

Innerhalb von DIP entsteht neben explizitem Wissen häufig auch implizites Wissen, welches durch Externalisierung (Otto and Österle 2010) für die Organisation und Durchführung von Nachfolgeprojekten bedeutend sein kann. Insbesondere spielen der Umgang mit implizitem sowie explizitem Wissen und dessen Aufbereitung eine wichtige Rolle für die Reichweite und letztlich auch für die Implikationen die aus Forschungs- und Praxisprojekten erwachsen. Der vorliegende Beitrag widmet sich diesen Themen und stellt die Fragen

1. Wie kann Wissen aus praxisorientierten Konsortialprojekten im Gesundheitswesen systematisch erfasst und explizieren werden?
2. Wie kann das gewonnene Wissen für zukünftige DIP im Gesundheitswesen aufbereiten werden?

Ziel des Beitrags ist die Stärkung der Präsenz von DIP innerhalb der wissenschaftlichen Diskussion und Verbesserung der Akzeptanz ihrer Erkenntnisse innerhalb wissenschaftlicher Publikationen. Hierzu wird im vorliegenden Beitrag der aktuelle wissenschaftliche Diskurs zusammengefasst und eine Typologie von Wissensbeiträgen von gestaltungsorientierten Projekten vorgestellt. Mit ihrer Hilfe sind eine systematische Klassifizierung und Beschreibung von DIP sowie der dazugehörigen Wissensbeiträge möglich. Anhand von drei Fallbeispielen wird zudem gezeigt, wie diese Systematisierung auch praktisch genutzt werden kann. Darüber hinaus werden auf Basis der Fallbeispiele Archetypen für den Wissensbeitrag innerhalb Digitaler Gesundheitsinnovationen skizziert.

Dieser Beitrag gliedert sich wie folgt: Der Einleitung folgen die Grundlagen zu Digitalen Innovationen und deren Verknüpfung mit dem Gesundheitswesen in Abschn. 2. In Abschn. 3 wird der aktuelle Stand der Forschung zu Wissenstypen in der Wirtschaftsinformatikforschung zusammengefasst und das „Design Science Research Grid" als Systematisierungsansatz für DIP vorgestellt. Anschließend werden im Rahmen einer Fallstudie, drei Projekte aus der Integrierten Versorgung beschrieben. Es folgt eine exemplarische Systematisierung von Wissensbeiträgen und die Ableitung von potentiellen Wissenstypen (Abschn. 4). Der Beitrag endet mit einer kritischen Diskussion und gibt einem Ausblick auf künftige Forschungsvorhaben.

2 Digitale Innovationen im Gesundheitswesen

Bei einer Digitalen Innovation handelt es sich um eine Produkt-, Service- oder Geschäftsmodellinnovation, die an den Einsatz von digitaler Technologie geknüpft ist. Eine Digitale Innovation kann einerseits als Mittel im Innovationsentwicklungsprozess betrachtet werden und andererseits als Ergebnis. Das Phänomen der Digitalen Innovation umfasst neue digitale Technologien, die Digitalisierung von Informationen, die digital ermöglichte Generativität und ein Innovationsmanagement mit einer größeren Reichweite von Innovationen über Unternehmensgrenzen hinweg (Yoo et al. 2010).

Digitale Innovationen haben in den vergangenen Jahren verstärkt Einzug in vielen Bereichen des individuellen und gesellschaftlichen Lebens erhalten und stellen eine treibende Kraft für Transformationsprozesse dar. Während Digitale Innovationen sich in anderen Branchen früh verbreiteten und sich weiterhin rasch entwickeln, bleibt der Einsatz von digitalen Technologien im Gesundheitssektor nach wie vor hinter seinen Möglichkeiten zurück. Ein Grund dafür ist in der Schwierigkeit zu sehen, ein solch komplexes, historisch gewachsenes und hoch reguliertes System wie das Gesundheitssystem durch digitale Technologien mit kurzen Produktlebenszyklen abrupt, spürbar und nachhaltig zu verbessern. Trotz der komplexen Rahmenbedingungen bleibt der Handlungsbedarf bestehen.

In Anbetracht der alternden Gesellschaft, der Zunahme multimorbider Krankheitssituationen sowie dem anhaltenden Fachkräftemangel sind innovative Ideen zur Neuausrichtung des Gesundheitssektors gefragt. Mit der Verabschiedung des Gesetzes zur Stärkung der Versorgung in der gesetzlichen Krankenversicherung hat die Bundesregierung einen wesentlichen Schritt dazu beigetragen. Es setzt u. a. stärkere Anreize für die Integration von Digitalen Innovationen in der Versorgung sowie in der Versorgungsforschung und adressiert insbesondere unterversorgte oder strukturschwache Gebiete. Das kürzlich verabschiedete Digitale Versorgungsgesetz schließt sich dieser Bewegung an und fördert u. a. die Einführung Digitaler Innovationen in den Gesundheitsmarkt.

Die Gesetzgebung hat grundsätzlich den Handlungsbedarf ihrerseits erkannt, die Freisetzung der vielseitigen Potenziale Digitaler Innovationen zu beschleunigen. Neben der Erprobung bzw. Etablierung von neuen zeitgemäßen und bedarfsgerechten intersektoralen Versorgungsmodellen ermöglichen sie auch die Verbesserung der Versorgungsqualität (Herrmann et al. 2018). Sie können über den gesamten

Leistungserbringungsprozess hinweg integriert werden. Im Bereich der Prävention fördern digitale Anwendungen bspw. mehr Bewegung oder eine gesündere Ernährung. Im Rahmen der Diagnostik können sie der Entscheidungsunterstützung der Ärzte dienen oder auf Ebene der Therapie mit Hilfe von Medikationsplänen Unterstützung leisten. Ebenfalls sind Digitale Innovationen im Zuge der Rehabilitation, indem Virtual Coaches eingesetzt werden, denkbar. Um die benannten Potenziale auszuschöpfen, bedarf es wiederum einer stärkeren Verzahnung der einzelnen Versorgungssektoren. Derzeit agieren die einzelnen Sektoren und Fachdisziplinen zumeist unabhängig voneinander und die Patientenzentriertheit steht nicht im Vordergrund ihrer Aktivitäten. Dabei bedarf insbesondere die Versorgung multimorbider und chronischer Krankheitsbilder eine unterbrechungsfreie und aufeinander abgestimmte Behandlung, da bei Mehrfacherkrankungen häufiger Komplikationen auftreten als bei Routineprozeduren (Matusiewicz et al. 2017).

3 Gestaltungswissen in Digitalen Innovationsprojekten

3.1 Grundlagen des Gestaltungswissens

Forschungsseitig lässt sich die Wirtschaftsinformatik über zwei verschiedene Ziele erklären: dem Erkenntnisziel und dem Gestaltungsziel (Becker et al. 2003). Beide Ziele fokussieren auf die Generierung von Wissen. Dabei ist die Form des resultierenden Wissens jedoch für beide Ziele unterschiedlich. Das erste Ziel fokussiert die Erzeugung beschreibenden Wissens (deskriptives Wissen). Deskriptives Wissen trägt dazu bei, Phänomene unterschiedlicher Natur durch Beobachtung, Klassifikation, Messung oder Katalogisierung zu begreifen. Infolgedessen lassen sich daraus Erkenntnisse in Form von Naturgesetzen, Prinzipien und Theorien ableiten. Ein Gestaltungsziel adressiert die Entwicklung von Gestaltungswissen (präskriptives Wissen). Im Gegensatz zum deskriptiven Wissen bezieht sich das präskriptive Wissen darauf, wie bestimmte Probleme gelöst (z. B. technische Regelwerke) oder bestimmte soziotechnische Systeme entwickelt werden können (z. B. Systemanforderungen, Architekturkonzepte). Das präskriptive Wissen kann seinerseits in Lösungsdesignentitäten und Lösungsdesignwissen unterteilt werden. Unter Lösungsdesignentitäten versteht man Artefakte wie Modelle und Methoden, aber auch Artefaktinstanzen, Designprozesse und Artefaktentwicklungsprozesse. Lösungsdesignwissen kann in Form von technologischen Regeln, Wissen zur Realisierung von Entitäten (Anforderungen, Prinzipien, Merkmale) sowie Wissen für Designprozesse (Methoden, Techniken) festgehalten werden (Drechsler and Hevner 2018).

Beschreibendes und gestaltendendes Wissen stehen in einem engen Zusammenhang. Deskriptives Wissen unterstützt beispielsweise bei der Problemdefinition als auch bei der Umsetzung von Gestaltungszielen. So können identifizierte Verhaltensweisen von Nutzern (deskriptives Wissen) bei der Beschreibung von Gestaltungsregeln für Mensch-System-Interaktion berücksichtigt werden (Drechsler and Hevner 2018).

In Abgrenzung zu dem Wissen aus der allgemeinen Wissensbasis der Wirtschaftsinformatik steht das Wissen, welches aus einzelnen Projekten stammt. DIP im Gesundheitswesen bilden dabei einen konkreten Typ von Projekten, die als spezifischen Problemraum den Einsatz digitaler Lösungen im Gesundheitswesen adressieren. Wissen aus solchen Projekten wird im folgenden Projektwissen genannt und weist ein eher zeitweiliges, nicht bzw. nur im Projektkontext erprobtes hochspezifisches Wesen auf. Dieses Wissen umfasst die Projektergebnisse als auch die Erfahrungen und impliziten Erkenntnisse der einzelnen Stakeholder.

Wissen aus Innovationsprojekten kann sowohl in deskriptives als auch in präskriptives Wissen transformiert werden. Diese Transformation erfolgt durch die systematische Gestaltung von Artefakten und der darauf aufbauenden Evaluation von Gestaltungsergebnissen (March and Smith 1995). Darüber hinaus gibt es weitere Wissensquellen, aus denen das Wissen für DIP gewonnen werden kann, z. B. aus dem eigenen Erfahrungsschatz oder aus der Zusammenarbeit in Konsortien und kreativen Tätigkeiten. Der Bereich des Projektwissens enthält Wissen über den Problem- und Lösungsraum eines Projekts. Kenntnisse über den Problemraum umfassen das Wissen um Zusammenhänge, die Problemidentifikation und Gütekriterien. Die Entwicklung solchen Wissens ist dabei nicht immer direkt durch methodische Planung generierbar, sondern ergibt sich auch aus dem nicht vollständig vorhersehbaren Projektverlauf. Beispielsweise kann eine für ein konkretes Problem geschaffene Softwarearchitektur durch eine nachträgliche Generalisierung für eine Problemklasse aufbereitet und als wiederverwendbares Konstrukt der Wissensbasis zurückgeführt werden. Hierbei muss das Generalisierungs-potential erkannt, das entstandene Projektwissen expliziert und transformiert werden. Dabei ist die Generalisierung sowohl des Problems als auch der Lösung notwendig (Drechsler and Hevner 2018).

Bis Forschende ein genaues Problemverständnis entwickelt und den Problemkontext durchdrungen haben, werden im Projektkontext mehrere Iterationen der Wissensanhäufung durchlaufen. So nutzen, produzieren (durch Ersetzen/ Weiterentwickeln) und verwerfen sowohl Praktiker als auch Wissenschaftler diverse Wissenseinheiten ehe eine endgültig passfähige Lösung gefunden ist. Dieser Sachverhalt dient als Motivation bzw. Anknüpfungspunkt, sich im Rahmen der vorliegenden Arbeit mit dem Bedarf der Transformation von Wissen in eine konkrete Domäne zu beschäftigen (Otto and Österle 2010). Die Anwendung von Wissen aus der Wissensbasis in die Versorgungsrealität und vice versa (Wissenstransformation) kann auf verschiedenen Wegen erfolgen und unterschiedlich dokumentiert sein (siehe Abb. 1). Beispielsweise können Systemspezifikationen (oder einzelne Bestandteile) oder auch immaterielle Ideen einzelner Forscher Gegenstand dieses Transformationsprozesses sein. Bei diesem Prozess wird jedoch nicht nur auf etabliertes Wissen zurückgegriffen, sondern auch auf ungetestetes und temporäres Wissen, welches im Rahmen von unstrukturierten, kreativen und heuristischen Verfahrensweisen erzeugt wurde. Antizipiert wird dabei, dass dieses Wissen im Zuge der Projektzusammenarbeit geschaffen und vereinzelt unter Mitgliedern geteilt wurde. Gegenüber der Außenwelt werden typischerweise die Projektendergebnisse offengelegt, nicht jedoch die Überlegungen und Erfahrungen, die bei der Erzeugung dieser eine Rolle spielen (Drechsler and Hevner 2018).

Es ist möglich, die Wissenstransformation aus DIP näher zu formalisieren. Hierfür kommen vier verschiedene Formen der Wissenstransformation in Betracht: die direkte Übernahme von Wissen (1), die Abstraktion (2), die Generalisierung (3) und

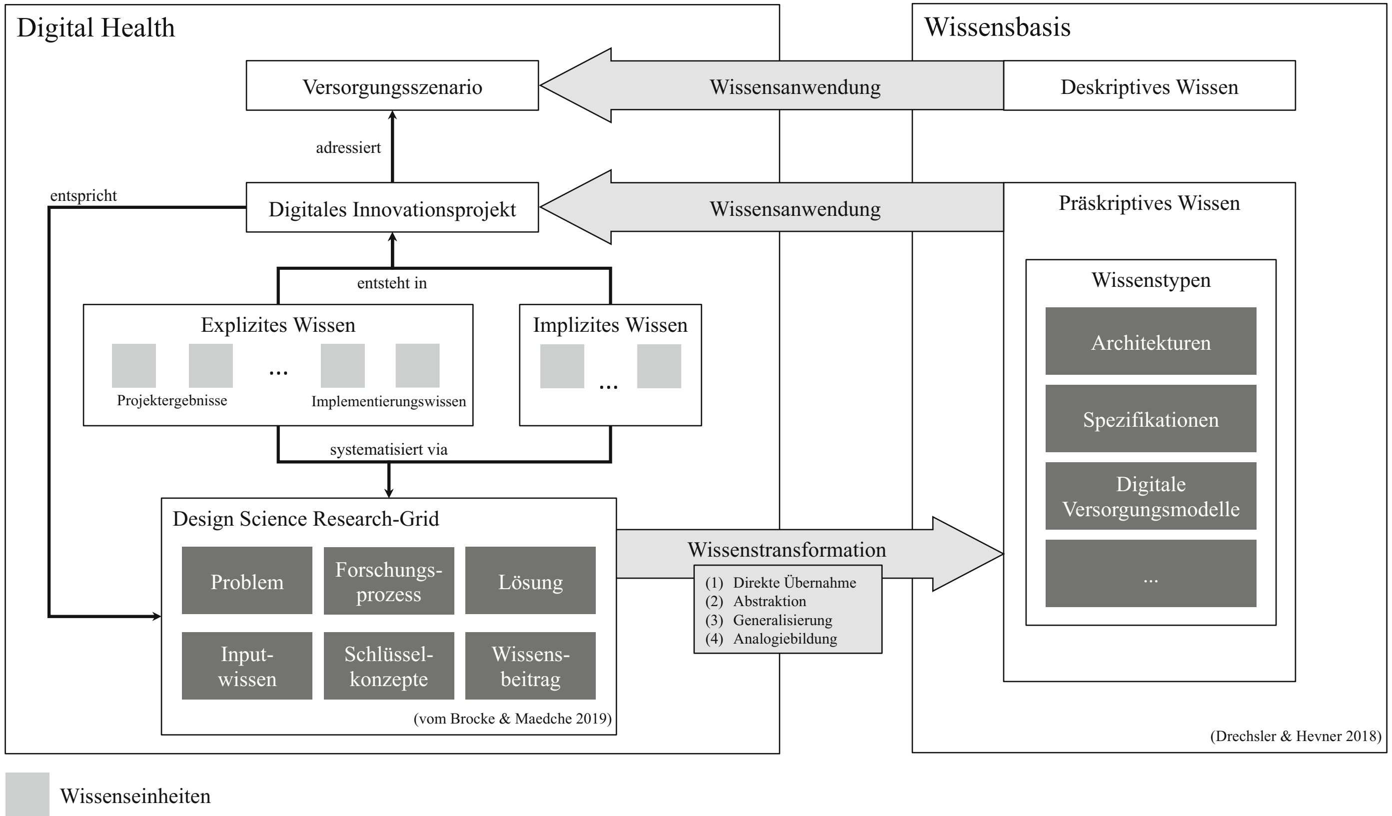

Abb. 1 Übergang von Wissen in Digitalen Innovationsprojekten (DIP)

die Analogiebildung (4). Bei der direkten Übernahme des Wissens erfolgt die Eins-zu-Eins-Wiedergabe der im Rahmen eines DIP gewonnenen Erkenntnisse. Bei der Abstraktion dagegen werden anhand gewonnener Erkenntnisse aus DIP allgemeingültige Regeln und Konzepte abgeleitet, z. B. in Form einer Referenzarchitektur aus konkreten heterogenen Architekturen. Unter Generalisierung ist die Verallgemeinerung gleichartiger Wissenseinheiten aus spezifischem Wissen zu verstehen, z. B. die Ableitung einer domänenspezifischen Referenzarchitektur. Bei der Analogiebildung wird das neuerschaffene Wissen derart aufgearbeitet, dass es in Bezug auf ein spezifisches Merkmal im Vergleich zum bestehenden Wissen als ähnlich wahrgenommen wird.

3.2 Design Science Research-Grid

DIP sind durch eine rasante Weiterentwicklung der neusten Informations- und Kommunikationstechnologien und variierende Anforderungen gekennzeichnet. Eine sorgfältige und angemessene Planung der praktischen Projektverläufe ist folglich eine beinah selbstverständliche Kernaufgabe des Projektmanagements. Bei kombinierten Forschungs-Praxis-Projekten sollten auch intendierte Forschungsergebnisse sinnvoll strukturiert und geplant werden. Vom Brocke and Maedche (2019) schlagen in diesem Zusammenhang das Design Science Research Grid vor, das aus sechs Kerndimensionen besteht (Tab. 1). Es soll Forschende bei der effektiven Planung und Kommunikation des Design Science Research-Projekts unterstützen, indem die wichtigsten Aspekte strukturiert beschrieben und abgebildet werden. Zu den sechs Kerndimensionen, die projektspezifisch gewichtet und angeordneten werden können, gehören die Problem- und Lösungsbeschreibung, das entsprechende Input- und Outputwissen sowie der Forschungsprozess inkl. Schlüsselkonzepten.

Die *Problembeschreibung* dient der anschließenden Identifikation möglicher Lösungen für ein konkretes Problem, welches sich in einem Problemraum mit entsprechendem Kontext (Domäne, Stakeholder, Zeit und Ort, Gütekriterien) bewegt. Das *Input-* bzw. *Outputwissen* (weiter als *Wissensbeitrag* bezeichnet) bezieht sich auf das genutzte Vorwissen sowie dasjenige Wissen, welches Ergebnis eines Design Science Research Projekts bzw. eines DIP ist. Wie im vorherigen Kapitel beschrieben, kommen hierfür verschiedene Wissensbasen in Frage, z. B. deskriptives oder präskriptives Wissen. Der *Forschungsprozess* adressiert die zur Lösung des konkreten Problems vorgesehenen und notwendigen Forschungsaktivitäten. Unterscheiden

Tab. 1 Design Science Grid nach vom Brocke and Maedche (2019)

Name des gestaltungsorientierten Projekts		
Problem: Konkrete Problembeschreibung, welche das Problem konkret innerhalb der Domäne verortet	*Forschungsprozess:* Expliziertes Vorgehen der gestaltungsorientierten Forschung	*Lösung:* Resultat des Erkenntnisprozesses im Sinne von Gestaltungsprinzipien, generischen Lösungsartefakten
Inputwissen: Zugrundeliegendes Inputwissen im Sinne von beschreibenden Theorien und präskriptiven Gestaltungswissens	*Schlüsselkonzepte:* Schlüsselkonzepte, die zur Umsetzung des Projektes verwendet werden	*Wissensbeitrag:* Gestaltungswissen, welches sich innerhalb des Forschungsprojekt generiert und zur Problemlösung beigetragen hat

lassen sich hier bspw. Entwicklungs- und Evaluationsaktivitäten sowie Forschungsmethoden, wie Literaturrecherchen. Wesentliche Konzepte, auf die im Verlauf des Design Science Research Projekts bzw. DIP zurückgegriffen wird, bilden die *Schlüsselkonzepte*. Die *Lösungsbeschreibung* adressiert die Lösung des Problems, indem es die Form der Lösung (Konstrukt, Model, Methode, Instanz) näher spezifiziert (vom Brocke and Maedche 2019).

3.3 Fallbetrachtung Digitaler Innovationsprojekte im Gesundheitswesen

Die nachfolgend beschriebenen Projekte sind den Bereichen der Integrierten Versorgung und Telemedizin zuzuordnen. Unter den Projektpartnern befinden sich Experten aus den Fachgebieten Medizin sowie der System- und Softwareentwicklung. Darüber hinaus erfolgt eine Kooperation mit den zentralen Informations- und Projektmanagementeinrichtungen der Krankenhäuser. Einige Projektpartner sind in mehreren Projekten involviert, z. B. ein Anbieter von medizinischen Fallunterlagen und das örtliche Universitätsklinikum. Im Rahmen der Multi-Fallstudie werden drei Projekte betrachtet, die als erklärende Anwendungsfälle der Untersuchung dienen. Alle drei Projekte haben die Entwicklung mindestens einer Digitalen Innovation im Gesundheitswesen für eine Integrierte Versorgungsumgebung, ihre Verbreitung in die Gesundheitspraxis und damit ihre Integration in die bestehende Informationssystemlandschaft zum Ziel.

Ein gemeinsames Ziel der Projekte ist die Etablierung einer krankheitsspezifischen elektronischen Fallakte. Nebst internen Strukturen unterscheiden sich die Projekte in der Art und Weise, wie sie von Informationssystemen betroffen sind. Außerdem werden verschiedene digitale Lösungen in diesem Zusammenhang realisiert. In den Projekten werden unterschiedliche Krankheitsbilder betrachtet. Dabei erfordert jedes Krankheitsbild für sich einen anderen Lösungsansatz und insbesondere auch andere IT-Artefakte. Im Folgenden werden die wesentlichen Inhalte der drei Projekte vorgestellt und in Tab. 2 zusammengefasst.

Das Projekt *STROKE* zielt auf die informationelle Verbindung zwischen einer existenten eHealth-Plattform mit schlaganfallspezifischen Diensten und IT-Systemen von Hausärzten sowie Spezialisten für die ambulante Nachsorge. Hierdurch soll der Nachsorgeprozess von Schlaganfallpatienten verbessert werden, indem ein integrierter Informationsfluss zwischen Case Managern und Hausärzten ermöglicht wird. Im Mittelpunkt dieses Kommunikationsszenarios steht ein schlaganfallspezifisches Clinical Document Architecture-Dokument (CDA Schlaganfallpass), das von allen beteiligten Leistungserbringern der Nachsorge gemeinsam genutzt wird.

Das Projekt *NEURO* beschäftigt sich mit der Entwicklung eines Integrierten Versorgungsportals für Patienten der Multiplen Sklerose, einer chronischen neurologisch degenerativen Erkrankung. Das Hauptziel ist es, eine bessere Verbindung zwischen Fachkräften, Patienten sowie (informell) unterstützenden Pflegediensten herzustellen. So werden Patienten und Angehörige bei der Krankheitsbewältigung besser unterstützt. Portalnutzer sollen Zugang zu ihren Fallakten erhalten und individuelle, kontextsensitive Dienste nutzen können, z. B. Erinnerungsfunktionen für Medikamente, therapeutische Übungen und spezifische Fragebögen.

Tab. 2 Überblick der Fallbeispiele mit DSR-Charakter

Name	Innovation	Artefakt(e)	Medizinische Domäne	Partner
STROKE	Verbesserung des Nachsorgemanagements durch Integration von Allgemeinmedizinern	Integrationsinfrastruktur für Anwendungssysteme von Ärzten	Schlaganfallnachsorge	Fach- und Allgemeinmediziner Anbieter von Dokumentationssystemen Anbieter von Kommunikationsservern
NEURO	Patienteneinbindung in die Versorgungsprozesse durch ein integriertes Patientenportal	Patientenportal, Interorganisationale Fallakte	Multiple Sklerose Versorgung	Fachmediziner und Wissenschaftler Anbieter von Dokumentationssysteme Anbieter von Fallaktensystemen IT-Abteilung des Universitätsklinikums
PSYCHO	Institutionelle Information-, Kommunikation- und Wissensaustausch zwischen medizinischen Experten über ein digitales Netzwerk	Interorganisationale Fallakte, integrierte professionelle Tools und Apps	Psychotraumatologische Versorgung	Psychologen und Fachmediziner Anbieter von Fallaktensystemen IT-Abteilung des Universitätskrankenhauses Mobile App Entwickler

Das Projekt *PSYCHO* zielt auf eine Verbesserung der interorganisationalen Behandlung von psychotraumatologischen Patienten ab. Mit Hilfe moderner Informations- und Kommunikationstechnologien wird die Kommunikation aller Beteiligten über relativ große Entfernungen hinweg optimiert. Infolgedessen soll eine fallspezifische Dokumentation institutsübergreifend verfügbar gemacht werden. Zusätzliche Instrumente und Verfahren für ein standardisiertes Screening und eine standardisierte Diagnose werden entwickelt und bewertet.

3.4 Methodik zur Systematisierung der Wissensbeiträge

Zwischen dem von Drechsler and Hevner (2018) vorgeschlagenen konzeputellen Framework, dass die Nutzung, die Produktion bzw. den Beitrag von Wissen veranschaulicht (Abschn. 3.1), und dem Design Science Research Grid (Abschn. 3.2) nach vom Brocke and Maedche (2019) bestehen deutliche Parallelen. Am Anfang eines Innovationsprojekts steht stets die Beschreibung des Problemraums. Der Problemraum enthält in beiden Konzepten Aussagen über den Projektkontext, die konkreten Probleme und Gütekriterien. Gemäß vom Brocke and Maedche (2019) kann Inputwissen sowohl deskriptives als auch präskriptives Wissen sein. Bei Outputwissen handelt es sich um rein gestaltungsorientiertes Wissen. Dieses gestaltungsorientierte Wissen bildet die Grundlage für die Lösungsraumbeschreibung. Drechsler eand Hevner (2018) dagegen sehen Inputwissen als rein deskriptives Wissen an. Die im

Tab. 3 Design Science Research Grid für das Projekt STROKE

STROKE		
Problem: – *Konkrete Probleme:* Fehlende Integration von Haus- und Fachärzten in eine bestehende digitale Telemedizinplattform für die ambulante Nachsorge – *Domäne/Krankheitsbild:* Schlaganfall – *Stakeholder:* Haus- und Fachärzte sowie weiterbehandelnde Fachgruppen	*Forschungsprozess:* – Analyse und Entwicklung von Versorgungsprozessen und Patientenpfaden – Systementwicklung der Integrationsarchitektur zur Integration von Hausärzten – Evaluation der Integrationslösung mit Pilotpraxen	*Lösung:* – Erweitertes klinische Pfadmodell für die Integration hausärztlicher Leistungen in die Schlaganfallnachsorge – Systemarchitektur zur Integration der beteiligten Arztpraxissysteme – Integrationsmodelle für verschiedene Typen von Arztpraxen – Erweiterter digitaler Schlaganfallpass
Inputwissen: – Medizinisches Fachwissen über Erkrankung und ihre Behandlung – Standardisierte Infrastruktur (Telemedizinplattform) für die Schlaganfall-Akutversorgung – Integrierter Versorgungspfad: Akutphase bis ambulante Nachsorge – Schnittstellenformate und Technische Standards (IHE XDS.b; HL7 CDA)	*Schlüsselkonzepte:* – Informationsobjekte und -flüsse – Organisatorische und technische Einbindung von Leistungserbringern – Anwendungssysteme – Schnittstellenspezifikationen	*Wissensbeitrag:* – *WS1.* Technische Spezifikation der Systemintegration – *WS2.* Architekturmodelle inkl. Schnittstellenkonzept – *WS3.* Vorgehensmodell zur Einbindung niedergelassener Ärzte – *WS4.* Stufenkonzept zur Integration von Hausärzten in einrichtungsübergreifende Versorgungskonzepte

Tab. 4 Design Science Research Grid für das Projekt NEURO

NEURO		
Problembeschreibung: – *Konkrete Probleme:* Bedarf an ortsungebundenen Versorgungsprozessen; Defizite in der Einbindung formeller und informeller Teilhaber – *Domäne/Krankheitsbild:* Multiple Sklerose – *Stakeholder:* Patienten, informelle und formelle Leistungserbringer	*Forschungsprozess:* – Systematische Prozessanalyse des interorganisationalen Patientenpfads – Durchführung Patientenbefragung – Ableitung Gestaltungsempfehlungen – Agiles Prototyping eines pfadbasierten Patientenportals – Entwicklung wiederverwendbarer Referenzmodelle und Entwurfsmuster	*Lösung:* – Patientenportal – Implementierung von Patientenpfaden in ein Patientenportal – Systemarchitektur zur Integration verschiedener Anwendungssysteme – Spezifikation einer MS-Fallaktenstruktur, Austauschformate und Schnittstellen
Inputwissen: – Medizinisches Fachwissen über Erkrankung und ihre Behandlung – Methodenwissen Agile Softwareentwicklung – Multiple Sklerose Dokumentationssystem – Patient Empowerment – IT-Standards der Medizininformatik – Elektronische Fallakte – Application Programming Interface Design-Ansätze	*Schlüsselkonzepte:* – Patientenpfade – Softwarearchitektur – Schnittstellenspezifikation	*Wissensbeitrag:* – *WN1.* Generische Portalkomponenten – *WN2.* Abbildung von Patientenpfade via FHIR – *WN3.* Bedarfe von MS-Patienten hinsichtlich der digitalen Integration in den Behandlungsverlauf – *WN4.* Referenzarchitektur für die Patientenintegration – *WN5.* Wiederverwendbare Digital Health-Muster zur Patientenintegration – *WN6.* Usability-Empfehlungen – *WN7.* Scrum im Digital Health Kontext

Rahmen von DIP verwendeten Forschungsprozesse und Schlüsselkonzepte sind bezogen auf das konzeptuelle Framework als ein Teil des Lösungsraums zu verstehen.

Anhand der vorab beschriebenen Fallbetrachtungen (Abschn. 3.3) ist das in den einzelnen DIP gesammelte Wissen mittels des Design Science Research-Grids systematisiert (siehe Tab. 3, 4 und 5). Dabei sind insbesondere die Wissensbeiträge je DIP hervorgehoben (grau hinterlegt), aus welchen die grundlegenden Wissenstypen im nachfolgenden Kapitel resultieren. Ihre Identifikation erfolgt induktiv aus den einzelnen in den Projekten identifizierten Wissensbeiträgen (siehe Abschn. 3.5). Die einzelnen Inhalte in den projektspezifischen Design Science Research-Grids wurden durch eine Analyse der Ergebnisdokumente, Protokolle und anderer Projektunterlagen des jeweiligen Projektes ermittelt. Soweit entstandenes Wissen innerhalb der Projektdokumentation expliziert wurde, konnte dieses in das entsprechende Grid direkt übertragen werden. Implizites Wissen kann jedoch selten alleinig über den Ansatz der Projektarchäologie identifiziert werden. Daher wurden in Diskussionen innerhalb der Projektkonsortien bzw. innerhalb abgrenzbarer Gruppen die Projekte, Verläufe, Ergebnisse und bereits expliziertes Wissen reflektiert. Die theoretischen Hintergründe des Gestaltungswissens (Abschn. 3.1) sowie die innerhalb des Grids involvierten Aspekte inklusive ihrer Systematisierung (Abschn. 3.2) dienten hierbei

Tab. 5 Design Science Research Grid für das Projekt PSYCHO

PSYCHO		
Problembeschreibung: – *Konkrete Probleme:* Verbesserungswürdige Kommunikation und Interoperabilität in der Behandlungskette von Traumafolgestörungen – *Domäne/Krankheitsbild:* Psychotraumatologie – *Stakeholder:* professionelle Versorgungsteilhaber	*Forschungsprozess:* – Fokusgruppen zur Konzeption einer elektronischen Fallakten – Prototypenerstellung – Entwicklung von Integrationskonzepten für Partner eines interorganisationalen Netzwerks – Requirements Engineering für einrichtungsübergreifenden Fallakte – Spezifikation der Austauch- und elektronischen Dokumentenformate	*Lösung:* – Spezifikation der Fallaktenstruktur, Austauschformate und Schnittstellen – Anforderungsprofil für eine elektronische Fallakte in der Psychotraumatologie – Systemarchitektur zur Integration von Patienten- und Diagnose-Apps – FHIR-Fragebögen für die psychotraumatologische Aufnahme
Inputwissen: – Wissen über die Erkrankung und deren langfristige Auswirkungen – Elektronische Fallakte – IT-Standards der Medizininformatik – Organisationale Integrationsmodelle – Qualitative Erhebungsansätze für konsentierte Wissensbanken – Existierende Diagnostik-Apps	*Schlüsselkonzepte:* – Interorganisationales Informationssystem – Patientenpfade – Elektronische Fallakte – Systemarchitektur – Schnittstellenspezifikation	*Wissensbeitrag:* – *WP1.* Psychotraumatologische Patientenpfade – *WP2.* Metadaten für interorganisationale psychotraumatologische Fallakten – *WP3.* Methodik zur Entwicklung interorganisationaler Fallakten via Fokusgruppen – *WP4.* CDA-Spezifikation des Psychotraumatologischen Arztbriefs – *WP5.* Überführungskonzept FHIR-CDA – *WP6.* FHIR-Profilierung Psychotraumatologie – *WP7.* Referenzarchitektur

als Moderationshilfe und lenkten die Diskussionen zur erfolgreichen Identifikation impliziter Wissensbeiträge der DIP.

3.5 Wissenstypen Digitaler Innovationsprojekte im Gesundheitswesen

Anhand der Wissensbeiträge, die in den Fallstudien zusammengetragen wurden, wird im Folgenden eine Klassifikation abgeleitet. Dabei wurden die einzelnen Wissensbeiträge bezüglich vergleichbarer Eigenschaften klassifiziert und Wissenstypen zugeordnet. Die Wissenstypen sind dabei Spezialisierungen der Schlüsselkonzepte des Design Science: Konzepte, Modelle, Methoden und Instanziierungen (Drechsler and Hevner 2018). Im Ergebnis konnten sieben Wissenstypen klassifiziert werden. Dazu zählen technologische Architekturen, Spezifikationen, Digitale Versorgungsmodelle, Medizinische Fachmodelle, Integrationsmodelle, Gestaltungsempfehlungen und Methoden. Folgend werden diese Wissenstypen vorgestellt sowie die wesentlichen Charakteristika herausgearbeitet. Aufgrund ihrer Genese stehen die abgeleiteten Wissenstypen in direktem Bezug zur Domäne des Digital Health. Eine Adaption in andere Fachdomänen ist Gegenstand anschließender Forschung. Beispielsweise könnte der Wissenstyp „Digitale Versorgungsmodelle“ für die Privatwirtschaft durch einen Wissenstyp „Geschäftsmodelle“ substituiert werden.

Architekturen Architekturen sind ein wichtiger Wissenstyp von DIP. Sie beschreiben technologische Komponenten, systematisieren ihre Rollen und setzen diese zueinander in Beziehung. In Hinblick auf Integrationsaufgaben zeigen sie die zentralen Ansatzpunkte für Abstimmungsbedarf innerhalb eines Konsortiums auf und vermitteln Arbeitsaufgaben. Im Sinne eines Wissenstyps können Architekturen als Referenz für ähnliche Projekte dienen, insbesondere wenn damit Fragen des Datenschutzes, der Entkopplung von Komponenten und Verteilung von Arbeitsaufgaben vorgedacht sind. Typische Wissenschaftsgebiete zur Veröffentlichung von Architekturen sind die Informatik, Wirtschaftsinformatik und Medizinische Informatik. Hierbei bietet sich insbesondere das Forschungsgebiet der Referenzarchitekturen und Informationssystemmodellierung an.

Typisierte Wissensbeiträge: WS2, WN4, WP7.

Spezifikationen Spezifikationen beschreiben in detaillierter Form, wie konkrete Systembestandteile einer Architektur ausgestaltet sein sollten. Sie verlassen Betrachtungen von Architekturen und wenden sich dem Entwurf einer konkreten Lösung zu. Eine Spezifikation kann im Gesundheitswesen sowohl fachbezogen (z. B. Spezifikation eines digitalen Schlaganfallpasses) als auch technologisch (z. B. FHIR-Profil zum Austausch von Fragebögen) beschrieben werden, wobei die Grenzen fließend sind. Häufig sind Spezifikationen im Bereich Digital Health mit dieser Aufgabe konfrontiert, eine adäquate Balance zwischen medizinischen Fachmodellen und technologischen Detaillierungen zu finden. Die Veröffentlichung von Spezifikationen kann im Kontext von Standardisierungsgremien im Bereich der Medizinischen Informatik erfolgen. Auch wird die konkrete Implementierung von Standards im Kontext von Fallstudien in diesem Bereich veröffentlicht.

Typisierte Wissensbeiträge: WS1, WN2, WP4, WP6.

Digitale Versorgungsmodelle Ein Digitales Versorgungsmodell beschreibt ähnlich den Geschäftsmodellen in der Privatwirtschaft die zentralen und logischen Funktionsweisen innerhalb eines definierten Leistungsgeflechts von Akteuren. Typischerweise beschreiben sie eine idealisierte und koordinierte Versorgung für den Patienten über verschiedene Leistungserbringer hinweg. Digitale Versorgungsmodelle heben hierbei die Verwendung von digitaler Technologie zur Leistungserbringung hervor, fassen das Leistungsgeflecht und Leistungsversprechen sowie die zentralen Geschäftsprozesse zusammen. Im Kontext der vorgestellten Fallstudien werden drei verschiedene Versorgungsmodelle abgebildet. Die typischen Forschungsgebiete zur Veröffentlichung von Versorgungsmodellen finden sich im Bereich der Versorgungsforschung, im Bereich von Public Health sowie in der Gesundheitsökonomie und der gesundheitsorientierten Betriebswirtschaftslehre.

Typisierte Wissensbeiträge: WS4, WN3.

Medizinische Fachmodelle Medizinische Fachmodelle beschreiben strukturelle (z. B. semantische Repräsentationen) oder dynamische (z. B. Patientenpfade) Aspekte des Versorgungsszenarios. Sie dienen als visuelle und zugleich (semi-)formale Repräsentation medizinischer Sachverhalte. Sie können sowohl durch Fachexperten zum Aufbau eigener Versorgungsmodelle als auch durch IT-Spezialisten zur Herleitung von Spezifikationen verwendet werden. Medizinische Fachmodelle können im Bereich der Medizin bzw. der medizinischen Dokumentation als auch in der medizinischen Informatik veröffentlicht.

Typisierte Wissensbeiträge: WP1, WP2.

Integrationsmodelle Integrationsmodelle beschreiben sowohl methodisch als auch strukturell, wie Partner im Bereich der Digitalen Versorgungsmodelle miteinander fachliche als auch technologische Zusammenarbeit praktizieren können und wie diese Zusammenarbeit initiiert werden kann. Die Veröffentlichung solcher Wissensbeiträge kann im Teilgebiet Enterprise Integration im Wissenschaftsbereich der Wirtschaftsinformatik, in der Medizinischen Informatik sowie in der Versorgungsforschung erfolgen.

Typisierte Wissensbeiträge: WN5, WN3.

Gestaltungsempfehlungen Gestaltungsempfehlungen können sowohl Digitale Versorgungsmodelle als auch medizinische Technologien adressieren. Sie leiten aus dem Kontext eines solchen Modells bzw. einer solchen Technologie Empfehlungen für die fachliche und technische Ausgestaltung ab. Dabei berücksichtigen sie das organisationale Umfeld und beteiligte Stakeholder (z. B. User Interface-Nutzungsprinzipien für bestimmte Patientenkohorten). Sie können auch aus konkreten Implementierungen resultieren. Je nach Ausprägung lassen sich diese in allen Bereichen des Gesundheitswesens als auch der Informatik einbringen.

Typisierte Wissensbeiträge: WN1, WN6, WP5.

Methoden Im Zuge von Projekten im Bereich der Digitalen Innovation werden verschiedene Vorgehen zur Entwicklung neuer Artefakte eingesetzt (z. B. Anwendung von Fokusgruppen zur Erhebung einer konsentierten einrichtungsübergreifenden Aktenstruktur). Die Formalisierung und Generalisierung dieser methodischen Herangehensweisen zu einem wiederverwendbaren Wissensbeitrag können durch Digital Health Projekte adressiert werden. Solche Methoden können sowohl in der Wirtschaftsinformatik, Medizinischen Informatik als auch der Versorgungsforschung veröffentlicht werden.

Typisierte Wissensbeiträge: WS3, WN7, WP3.

4 Kritische Würdigung und Ausblick

Im vorliegenden Beitrag wurde untersucht, welche Konzepte und Ansätze der aktuelle wissenschaftliche Diskurs zur Systematisierung von Wissensbeiträgen in gestaltungsorientierten Projekten bereithält. Hierfür wurden zunächst das Design Science Research-Grids nach vom Brocke and Maedche (2019) eingeführt und die Rolle von deskriptivem und präskriptivem Wissen innerhalb der Forschung erörtert. Da Praxisprojekten oftmals die Struktur fehlt, ihre Innovation(en) und Resultate in geeigneter Form in generalisierbares präskriptives Wissen zu überführen, bietet dieses Grid einen guten Moderationsrahmen zur Analyse und Explikation von Wissen innerhalb solcher Praxisprojekte. Dies bedarf aber ebenso Sensibilität innerhalb der Projektorganisation für eine frühzeitiges Erheben der Informationen sowie der notwendigen Kommunikation innerhalb des Projektkonsortiums.

Die durchgeführte Fallstudie illustriert anhand von drei DIP, wie eine solche Systematisierung aussehen kann. Sie zeigt aber auch auf, dass insbesondere die Generalisierung der Artefakttypen insoweit herausfordernd ist, als dass die Innovationshöhe eines DIP nicht automatisch aus der Grid-basierten Beschreibung hervorgeht und sich im Vergleich zum Problem-Lösungsraum weniger gut darstellen lässt.

Die Explikation von präskriptiven Gestaltungswissen wird jedoch wesentlich aufgewertet und in eine einheitliche Struktur gebracht, sodass dieses leichter von ähnlichen Projektkonstellationen als Input(wissen) verwendet werden kann. Gleichzeitig verbindet sich damit die Herausforderung, dass zur Kommunikation des Wissensbeitrags (Output) generalisierte Wissenstypen genutzt werden sollten. Dadurch können die Lösungen auch für problemähnliche Konstellationen einen Beitrag liefern. Die vorgestellten Wissenstypen können als Konkretisierungen klassischer Artefakttypen innerhalb der gestaltungsorientierten Forschung betrachtet werden. Ihre Reichweite und Gültigkeit sind aufgrund ihrer induktiven Ableitung limitiert auf die zugrundeliegenden Kontexte des Forschungs- und Entwicklungsbereichs Digital Health. Bei den vorgestellten Wissenstypen handelt es sich somit um keine abgeschlossene Menge. Vielmehr zeigt der Beitrag, wie entstehendes Wissen systematisiert werden kann und wie ein entsprechender Wissenstyp gekennzeichnet ist. Wenngleich die Wissenstypen induktiv entstanden sind, können sie doch als Referenz und Legitimation für Forschungsziele dienen.

Aus wissenschaftlicher Sicht können die Wissenstypen außerdem dazu beitragen, Digital Health-Projekte zu klassifizieren. Mit dem Tupel von Problemraum, Wissenstyp und angewandtem Versorgungsmodell können typische Archetypen verbunden werden, welche wiederum als Muster für ähnliche Projekte herangezogen werden können. Ebenfalls ist ihre Nutzung zur Evaluation von bestehenden Implementierungen möglich.

In anschließenden Untersuchungen sollte der vorgeschlagene Ansatz weiter erprobt und seitens der Fachanwender kritisch evaluiert werden. Hierbei sollte insbesondere untersucht werden, innerhalb welcher Phasen eines Umsetzungsprojektes bereits welche Informationen aufzunehmen sind. Unabhängig davon sollte auch analysiert werden, wie bestehende Entwicklungsmethoden z. B. Agile Softwareentwicklung mit dem Anspruch einer systematischen Wissensexplikation in Einklang gebracht werden können.

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9 Paper P5

Table 14: Key information on paper P5 and declaration of authorship.

Paper P5	
Title	**Overcoming Diffusion Barriers of Digital Health Innovations Conception of an Assessment Method**
Author(s)	Richard Hobeck (RH) Tim Scheplitz (TS) Hannes Schlieter (HS)
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Additional materials	-

[9]The contributions of the author(s) are structured according to the authorship criteria of the German Research Foundation for good scientific practice (DFG, 2013).

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Overcoming Diffusion Barriers of Digital Health Innovations: Conception of an Assessment Method

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Abstract

Digital health innovations (DHIs) contribute to improving the health sector by revitalizing availability and continuity of care as well as mitigating rising costs. DHIs getting increasing support from health insurance companies and governmental institutions, but still struggle on their way to standard care in national healthcare systems. One of the central challenges is the multitude of diffusion barriers, which are either little known or difficult to handle in complexity and therefore pose a high risk for the translation into the healthcare practice. This paper steps into this discourse with a design-oriented research approach. A systematic literature review identified DHI barriers that are further evolved to a concept for assessing barrier resilience. On that basis, a framework to systematically administer diffusion barriers to DHI in Germany was developed. Innovators may use the proposed framework to assess the likelihood of a successful implementation and to ensure smooth scaling up process of their DHI.

1. Introduction

Digital technology and the United Nations Sustainable Development Goals (SDGs) [1] are interwoven on a variety of levels. One example of this interplay is the third objective of the SDGs aiming at health-related action areas in which digital technology, in form of digital health, represents a significant element to achieve the formulated sustainability goals [2], [3]. Restraining this connection, however, digital healthcare solutions often face the *scaling-up problem* – a phenomenon that describes how digital health innovations (DHIs) are retained from finding their way into standard care. Solutions that have a demonstrable effect on care can frequently not unfold their benefits for the general public. Recently, regulatory measures such as the German Digital Healthcare Act show that political decisions support the digital transformation of the health sector and that digital health applications are acknowledged in care alongside medication [4]. Nevertheless, the basic problem remains: the complex and regulated healthcare environment imposes a large number of barriers to health innovations that are little known, especially to smaller innovators, and thus present a high risk to the successful development and exploitation of DHIs [5]. Small and medium-sized enterprises often struggle to identify such barriers and miss out on taking appropriate mitigation measures early on to ensure proper development and marketing of their solutions [6].

Therefore, we present an evaluation approach to support the early analysis and identification of possible deficits in targeting propagation barriers. Thus, we help to increase the accessibility of digital health applications and thereby the availability of healthcare for communities. Evaluation is used when informed decisions are to be made. The evaluation approach in this paper utilizes theoretical knowledge on propagation barriers of health innovations. Practitioners benefit from getting a concise outline of propagation-related strengths and weaknesses of their DHI in key figures. This can serve as a useful tool to develop sustainable digital health solutions that keep up with high expectations posed upon them and at the same time help researchers to further investigate the phenomenon of the scaling-up problem [7]. The design objective of this article is therefore linked to the question:

What does an approach to assess the barrier resilience of Digital Health Innovations look like?

A DHI in the context of this paper is the use of information and communication technology to deliver health or health-related services [3]. Nested in diffusion theory [8] and scaling-up of innovations [9], this paper builds on a body of preliminary work covering two domains: (1) diffusion barriers of DHIs and methodologies to reveal them as in analysing the lessons learned of DHI projects [10] and providing *generic* classifying taxonomies of DHI diffusion barriers [11]; and (2) a number of evaluation frameworks of DHIs.

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This paper complements recent initiatives to develop DHI evaluation frameworks [12], [13] by adding a categorization of existing evaluation approaches for health innovations and deriving an assessment framework from propagation barriers in healthcare. We add to the existing literature by newly accumulating knowledge from the two domains and providing an artifact as an applicable implementation of theory as design science [14]. The framework is exemplarily made-to-measure the German healthcare environment in order to show the applicability and utility of the approach in a concrete healthcare market. Generally, Germany can also serve as a representative example among OECD states with Social Health Insurance, i.e., societal actors decide on regulations and financing while services are largely provided by private for-profit actors [15]. The final assessment, however, needs to be tailored to the specific national context.

Starting with researching propagation barriers focusing on DHIs in Germany, the identified corpus of contributions centered around these barriers is examined. Next, we present our methodology (Section 2) and provide an overview of existing evaluation approaches (Section 3). Based on that, an assessment approach tailored to the German healthcare environment is designed (Section 4). The resulting framework is tested using an exemplary project in the German healthcare market with a phenotypical character for DHIs (Section 5). The paper closes with a discussion of the results (Section 6) and concluding remarks as well as an outlook on further research (Section 7).

2. Methodology

The methodological approach is based on the Design Science Research (DSR) principles [16] and aligned with a DSR process (DSRP) model [14]. The relevance and problem identification (*DSRP Phase 1*) as well as the design objective (*DSRP Phase* 2) was elaborated in Section 1. The artifact is constructed in multiple steps (*DSRP Phase 3*) as follows: In order to comply with DSR-guidelines and to ground the research on rigorous practices, a systematic literature search was carried out to accumulate literature broaching the issue of diffusion barriers in healthcare [17]. Based on this, the research results were analyzed using inductive category formation by Mayring to identify propagation barriers of DHIs in general and specific barriers in Germany [18]. Next, existing approaches to evaluating digital health solutions were identified in a second literature search. To map the ground covered by preliminary research, a taxonomy was created helping to categorize existing DHI assessment approaches [19]. The categorization revealed an existing artifact that is iterated to fit the needs of an evaluation tool synthesized for the German environment [20]. Finally, this paper's framework is applied (*DSRP Phase* 4) and evaluated (*DSRP Phase 5*) using a practical example.

Identification of propagation barriers. In order to identify existing literature on propagation barriers in the German healthcare system, scientific databases were searched for relevant contributions on August 4, 2018 [17], [21]. The search term consisted of three elements to which synonyms in German and English were added: (1) barriers (*obstacles*, *hurdles*, *resistance*, etc.), (2) propagation mechanisms (*scaling-up*, *translation*, *diffusion*, etc.) and (3) digital health innovations (*eHealth*, *telemedicine*, *telehealth*, etc.). The search queries were applied to the databases *EBSCOhost*, *ScienceDirect*, *IEEE Xplore*, *SpringerLink*, *PubMed* and *AIS Electronic Library* (+368). Duplicates, non-English and non-German contributions as well as contribution types such as dictionary entries and announcements were removed from the corpus (-158). From the remaining publications, relevant contributions were selected on the basis of an inclusion criterion, which was checked against the respective abstract [22], [23]. The inclusion question was: *Are barriers to the spread of digital solutions in the healthcare system or the basic parameters for digital innovations in the German healthcare system being investigated?* (-191). In a final acquisition step, this selection was subjected to a backward reference search (+3). One publication was not accessible (-1), creating an overall literature corpus of 21 publications.

Inductive category formation is used to map the material on propagation barriers distortion-free [18]. For the first step of the category formation, the aim of the process has to be defined. The aim is to extract the barriers to propagation of DHIs in the German healthcare system from the body of literature, consisting of 21 publications. Next, a selection criterion will be defined to determine which passages of text are used to induce the formation of categories. If sections are found that can be assigned to the selection criterion, the first category is formulated as close as possible to the text formulation and confirm to the level of abstraction. Further categories are formed from the following text passages that fit into the selection if they can not be subsumed under existing categories. The categories are revised in an intermediate step before the material is completely worked through and the categorization can be interpreted. The result is depicted in Table.1.

Analysis of existing assessment approaches. A second systematic literature search was carried out to record the state of research on evaluating the spread of digital health solutions on November 12, 2018 [17], [21]. Into this search, both, scientific contributions (+225) and grey literature (+20) were included. The

Table.1 Categories of propagation barriers

Super-categories	Categories and selected references
(1) Reimbursement and Financing	Remuneration conditions cross-sectoral; Remuneration conditions in the stationary sector; Reimbursement in the outpatient sector; Non-remuneration of cost savings; Infrastructure costs; High initial costs; Low willingness to pay on the second healthcare market [19]-[23]
(2) Regulations and Guidelines	Health market approval conditions; Legal data protection regulations; Lack of standardised regulations: Liability risks; Ban on remote treatment [19]-[21], [24]
(3) Technical Barriers	Technical maintenance; Infrastructural barriers; Lack of security/reliability of medical data; Lack of technical interoperability/compatibility [19]-[22]
(4) Proof of Effectiveness	Deficit in studies; Missing certification method; Lack of evidence of efficacy; Lack of evaluation methodology [20]-[23]
(5) Proof of Efficiency	Lack of efficiency evidence; Duration of efficiency assessment [23]
(6) User Acceptance	Knowledge and competence-related barriers; Insufficient relative advantage; Necessary process changes; Resistance of the practitioner to changes in established practices; Questions of trust towards the provider; Unsuitable organizational structure of the adopters; Stigmatization of the patient; Reading/spelling deficit of the patient; Conservative attitude of physicians towards innovations; Lack of technical affinity or knowledge among physicians and patients; Fear of job loss on the part of the physician [19]-[22],[25]-[27]

search queries combined (1) types of digital health innovations (*eHealth*, *telemedicine*, etc.), (2) artifact types (*framework*, *model*, etc.) and (3) an element related to evaluation (*quality management*, *evaluation*, etc.). The search was carried out in the scientific databases *PubMed*, *ScienceDirect*, *EBSCOhost* and *SpringerLink*, as well as for grey literature with the search engine *Google*. Contributions were selected qualitatively for closer examination (-218). A forward reference search revealed additional relevant literature (+4). The second literature corpus, consisting of 31 publications, was categorized using a taxonomy to get an overview of the scope of preliminary work at transparent standards [19].

Synthesis of the DHI assessment approach. Investigating existing evaluation approaches of digital health innovations, revealed that no distinct tool helping to address propagation barriers in the German healthcare system exists. This paper sets out to fill the lack of a Germany-centered solution to help practitioners dispatch propagation issues of their health innovations. Therefore, an evaluation sheet will be developed to assess how effectively barriers to the spread of digital health applications were dealt with. Since the draft to be designed contains an evaluation aspect, the *Roadmap for Planning an Evaluation Concept for the Area of E-Health* is used for the development of the artifact [24]. Complying with DSR-guidelines, the approach is finally demonstrated and evaluated [16].

3. Status of research

Research on the propagation barriers as well as evaluation approaches for DHIs already exist. This section presents an overview of these publications and derives barriers under consideration in this article from the literature base. Afterward, existing assessment frameworks are scrutinized according to their ability to suit the requirements imposed by the environment the German healthcare system operates in.

Identification of barriers to the spread of digital health innovations in Germany. Based on the first literature search, propagation barriers for innovations are identified through inductive category formation. Since the formed categories shall reflect propagation barriers, the selection criterion is: *Propagation barrier for digital health innovations that are unique to the healthcare context and can be transferred to the German context*. Categories that specifically refer to a non-German context are not formed (e.g. barriers from guidelines in sub-Saharan Africa). Thus, 33 categories were identified. In summary, six super-categories were formed (see also Table.1 for details):

(1) Reimbursement and Financing relates to barriers associated with monetary and budgeting issues as well as reimbursement of digital solutions in the public healthcare system [11], [25]–[28]. *(2) Regulations and Guidelines* sum up hurdles posed by statutory compulsions that have to be complied with [11], [25], [26], [29]. *(3) Technical Barriers* originate in technological restrictions or difficulties [11], [25]–[27], while *(4) Medical Proof of Effectiveness* confirms the medical properties of an innovation in healthcare [11], [26]–[28]. *(5) Economic Proof of Efficiency* encompasses issues around validating the return of investment of an innovation. [28] *(6) User Acceptance* focuses on social and organizational factors influencing the propagation of DHIs [11], [25]–[27], [30]–[32].

Mapping of existing DHI assessment approaches. Subsequently, a taxonomy was created to categorize the preliminary work containing evaluation approaches of DHIs. The aim is to find out to what extent the mentioned barriers to propagation have already been considered in evaluations of other authors. The taxonomy was created in seven iteration steps, resulting in seven taxonomy dimensions [19].

The first iteration distinguishes whether a contribution is applicable to a practical problem (*Concrete*), or whether it is a draft, a requirements analysis, a naming of critical factors, a recommendation or a plea for evaluation (*Abstract*). The second iteration differentiates between objects under consideration along the span of DHIs, as described in Otto et al. 2018. Iteration number three distinguishes between the intended geographical sphere of influence of the contribution (*Global/No Specification*, *Developed Non-EU Country*, *Developing Country*, *EU*, *Non-German EU-country* and *Germany*). The next iteration creates a dimension to document the extent to which a contribution addresses the propagation barriers earlier identified with inductive category formation. The fifth iteration differentiates whether a contribution considers the overall quality of an intervention concept (*Quality of the Intervention Concept*), whether it supports an increased spread of the intervention (*Diffusion Related*), whether it focuses on the condition of an innovation (*State Evaluation*) or the successful implementation of the intervention (*Successful Implementation*). Iteration number six distinguishes whether an evaluation approach makes a summary statement (*Summative*), whether it is conducted in parallel to an implementation of the measure and influences it (*Formative*), or whether a contribution explores evaluation abstractly and no statement can be assigned to the mode (e.g. a plea for alignment of evaluation with certain standards, *Too Abstract for a Mode*) [18]. The last iteration categorizes contributions proposing or delivering a quantitative (*Ordinal*) or a qualitative (*Nominal*) evaluation result. A publication under consideration may be too vague to make a statement about the evaluation result (*Too Abstract for a Result*). The resulting taxonomy displaying the identified dimensions and characteristics is depicted in Table.2.

The taxonomy was applied to describe and categorize 31 identified assessment approaches in the second literature search (Section 2 *Analysis of existing assessment approaches*). The results reveal that so far, no contribution has been made that allows assessing which propagation barriers were being addressed by a DHI in the context of the German healthcare system.[1] That implies that only little guidance exists for practitioners in this field to support development efforts and make a DHI fit for seamless spread. Therefore, an adequate evaluation approach is developed in the next section.

[1] The complete list of analyzed assessment approaches and results of applied taxonomy will be provided as an additional data source.

4. Synthesizing the evaluation approach

An evaluation approach helps stakeholders to assess the extent to which potential for scaling-up an innovation is being exploited and supports with recommending measures for successful market diffusion. This goal is worked towards in this section by synthesizing an evaluation approach that offers the opportunity to gather propagation barrier-related information about DHIs systematically and produce quantitative results indicating the innovation's barrier resilience [24]. The approach is designed in accordance with the evaluation standards *Usefulness*, *Feasibility*, *Fairness* and *Accuracy* [33].

For the artifact design, an existing scoring system will be altered and refined as intended in a DSR-artifact iteration [16]. This scoring system originally is the backbone of the *MAPS-Tool* (*mHealth Assessment and Planning for Scale*, WHO 2015), a framework examining mHealth-solutions focussing on their suitability for scaling-up along defined categories (*Axis of Scale*). Each category contains several globally applicable questions on the measures taken to achieve scaling goals. The quantification system that was employed is a four-stage point system.

Each category is rated depending on the response option picked by the surveyor: *No* (0 points), *In Progress* (1 point), *Executed* (2 points); *Documented* (3 points) or *Not Applicable* (3 points). Non-fulfillment (*No*) expresses the previous disregard of the barrier aspect and is thus interpreted negatively. From there the rating increases leading to the documented confrontation with barriers (*Documented*), relating to testified efforts being made, and thus scores highest due to its traceability. If questions are not applicable, they are assessed positively to avoid influencing the overall picture unfavorably. Since five criteria are asked for each barrier, each of which is evaluated with up to three points, the evaluation sheet is based on a 15-point system. The modification of the *MAPS-Tool* concerns the frame of reference of the evaluation, which is alienated from generic global criteria and finds its unique feature compared to other approaches through the special reference to German propagation barriers.

Table.2 Taxonomy of existing evaluation approaches for digital health innovations

<table>
<tr><th>Dimensions</th><th colspan="60">Characteristics</th></tr>
<tr><td>Level of Abstraction</td><td colspan="30">Concrete</td><td colspan="30">Abstract</td></tr>
<tr><td>Object of Reflection</td><td colspan="12">eHealth</td><td colspan="12">Telemedicine</td><td colspan="12">Telehealth</td><td colspan="12">mHealth</td><td colspan="12">Digital Health</td></tr>
<tr><td>Regional Limitation</td><td colspan="10">Global/No Specification</td><td colspan="10">Developed Non-EU-Country</td><td colspan="10">Developing Country</td><td colspan="10">EU</td><td colspan="10">Non-German EU-Country</td><td colspan="10">Germany</td></tr>
<tr><td>Aspect of Consideration</td><td colspan="10">Reimbursement and Financing</td><td colspan="10">Regulations and Guidelines</td><td colspan="10">Technical Barriers</td><td colspan="10">Medical Proof of Effectiveness</td><td colspan="10">Economic Proof of Efficiency</td><td colspan="10">User Acceptance</td></tr>
<tr><td>Context of Consideration</td><td colspan="15">Quality of the Intervention Concept</td><td colspan="15">Diffusion Related</td><td colspan="15">Status Evaluation</td><td colspan="15">Successful Implementation</td></tr>
<tr><td>Mode</td><td colspan="20">Summative</td><td colspan="20">Formative</td><td colspan="20">Too Abstract for a Mode</td></tr>
<tr><td>Scale of Results</td><td colspan="20">Ordinal</td><td colspan="20">Nominal</td><td colspan="20">Too Abstract for a Result</td></tr>
</table>

Furthermore, it is made applicable for every kind of DHI, including mHealth, telemedicine, telemonitoring, eHealth and alike [10]. Thus, a thorough analysis of the German healthcare system was conducted along the barriers for DHIs to concretize the six super-categories in appropriate assessment items. The adaptation of the following assessment approach to other national specifications requires an appropriate adjustment of this step of analysis and design.

(1) Reimbursement and Financing was covered with an analysis of possibilities for reimbursement in the ambulant and stationery sector as well as the intersectoral reimbursement.

(2) Regulations and Guidelines incorporate findings related to the E-Health-Law (SGB V), like the registration of DHIs in the a public online interoperability register (gematik's vesta information portal [34]), as well as data security regulations (DSGVO/GDPR), laws regarding medical products including Conformité Européenne (CE) certification, and IT security regulations with policies for critical infrastructure (KRITIS).

(3) Technical Barriers were considered including technical (HL7, DICOM, xDT) and semantic communication standards (OPS, ICD, SNOMED CT, LOINC) as well as technical security requirements for medical devices (93/42/EWG) and data security considerations (§ 64 BDSG). Additionally, transmission technology and special user needs have to be considered.

(4) Proof of Medical Effectiveness contains measures assuring compliance with the principle of evidence-based medicine in the public healthcare system, the role of clinical trials (93/42/EWG) and peculiarities of health technology assessments (HTAs).

(5) Economic Proof of Efficiency encompasses actions towards the efficiency command (§ 12 SGB V) in the German public healthcare system and variations of health-economic analysis as well as cost types to prove equal or better care provision for lower costs.

Finally, *(6) User Acceptance* utilized the Technology Acceptance Model to analyze patient and practitioner needs [35]. The resulting assessment form can be seen in Table.3. The scores for the aspects in question can be documented in the left column.

5. Demonstration

The newly developed artifact will be demonstrated on a phenotypical digital health solution with a user base in Germany. The case study is based on the application *mySugr*: *your intelligent diabetes diary*. Among the functions of *mySugr*[2] are collecting and graphically processing information on diabetes (e.g. blood sugar, meals, medication, physical activities) in the form of a diary to optimize therapy outcomes and mitigate the course of the disease [36].

1) Reimbursement and Financing. *mySugr* is a medical device and therefore belongs to the first health market [37]. The app is available in a free basic version and can be extended in its functions by using a version with costs. Since April 2018, some private health insurance companies reimbursed the costs for using the application [38]; from July 2018, this was also offered by a selection of public health insurance companies. Various financing models of the public and private sectors were considered, implemented and documented. Patient-financed, as well as health insurance-financed models, are available. Score: 15

[2] Information about *mySugr* has been collected from company websites. Details may differ due to national specifications.

Table.3 Assessment form for DHI-applications

#	1) Reimbursement and Financing	No	Progr.	Exec.	Doc./NA
F1	Possibilities for reimbursement within an examination and treatment method in the public healthcare system were considered.	0	1	2	3
F2	Possibilities of remuneration through selective contractual remuneration within the public healthcare system were considered.	0	1	2	3
F3	Possibilities of direct contractual remuneration by a statutory or private health insurance were considered.	0	1	2	3
F4	Financing models for remuneration from private demand on the secondary health market were considered.	0	1	2	3
F5	The benefits and risks of the financing models were evaluated and included in transition plans.	0	1	2	3
#	**2) Regulations and Guidelines**	**No**	**Progr.**	**Exec.**	**Doc./NA**
F6	Scenarios for the innovation's application are designed in such a way that service providers do not risk violating the ban on remote treatment.	0	1	2	3
F7	Data protection rules were taken into account when designing the application.	0	1	2	3
F8	It was examined whether the application falls under the regulations of the Medical Devices Act and measures were taken accordingly.	0	1	2	3
F9	It was checked whether the application is part of critical infrastructure (KRITIS) and the design of the application was planned according to the legal requirements.	0	1	2	3
F10	The registration in the vesta information portal was carried out and it was examined to have used standards included in the lists of the gematik.	0	1	2	3
#	**3) Technical Barriers**	**No**	**Progr.**	**Exec.**	**Doc./NA**
F11	The application and the infrastructure are designed in such a way that an infringement of personal data protection rights can be ruled out.	0	1	2	3
F12	The application is designed in such a way that compliance with legal security regulations cannot be questioned.	0	1	2	3
F13	In order to achieve interoperability, the need to comply with technical standards was reviewed and, if necessary, implemented.	0	1	2	3
F14	It was examined whether the latency caused by the technical infrastructure used does not restrict the usability of the application.	0	1	2	3
F15	The application is designed in such a way that user-specific requirements have been implemented.	0	1	2	3
#	**4) Medical Proof of Effectiveness**	**No**	**Progr.**	**Exec.**	**Doc./NA**
F16	Evidence of the medical efficacy of the application has been provided.	0	1	2	3
F17	It was examined whether a medical proof of efficacy must be carried out for the approval of the application and if necessary arranged.	0	1	2	3
F18	The approval of the responsible authorities and commissions was obtained for the preparation of the medical proof of efficacy.	0	1	2	3
F19	It was examined whether the current state of studies is sufficient to prove the medical effectiveness, in order not to endanger the remuneration model.	0	1	2	3
F20	Information on the testing mechanisms and times is available and it is planned in such a way that it does not endanger the business model.	0	1	2	3
#	**5) Economic Proof of Efficiency**	**No**	**Progr.**	**Exec.**	**Doc./NA**
F21	Evidence of the economic efficiency of the application has been produced.	0	1	2	3
F22	When preparing the evidence, measures were taken to exclude the risk of the result being jeopardised by difficulties with data collection.	0	1	2	3
F23	Various cost aspects (direct, indirect, intangible costs) were taken into account in the preparation of the economic efficiency report.	0	1	2	3
F24	It was examined whether the study situation is sufficient to prove the economic efficiency in order not to endanger the remuneration model.	0	1	2	3
F25	The evaluation design of the economic proof of effectiveness was chosen in such a way that the interests of the addressee are taken into account.	0	1	2	3
#	**6) User Acceptance**	**No**	**Progr.**	**Exec.**	**Doc./NA**
F26	The fulfilment of the special needs of the user groups is clearly communicated.	0	1	2	3
F27	Training measures are prepared for initial and further user training and resources are provided for implementation.	0	1	2	3
F28	Measures have been taken to counteract possible stigmatisation of users.	0	1	2	3
F29	Support for the processing of user queries are available.	0	1	2	3
F30	Measures have been taken to simplify the integration of the application into the daily supply routine.	0	1	2	3

2) Regulations and Guidelines. The application is designed as a tracker and diary of diabetes data and does not include remote treatment functions [39]. *mySugr* ensures compliance with various data protection guidelines in the data protection declaration [40]. In addition, the app is approved as a *Class I* medical device (one module as *Class II*). The application is not critical infrastructure so that special requirements for KRITIS do not apply. Deductions apply because *mySugr* is not registered in the *vesta Informationsportal*. Score: 12

3) Technical Barriers. The technical design of the diabetes tracker for the protection of personal data is reassured in company statements [41], with reference to the use of the *Amazon Web Services* cloud infrastructure and its certificates and compliance with standards and guidelines. The security design is again proven by the *CE* conformity of *mySugr*. The application is interoperable with various blood glucose monitoring devices [39]. The transmission of larger amounts of data does not result from the application's use cases so that latency times do not have to be considered. The user ratings confirm that the app mostly fulfills user-specific requirements [43]. Number of points: 13

4) Medical Proof of Efficacy. The medical efficacy of *mySugr* has been demonstrated and published [44], [45]. Thereby, the present state of studies was improved, and the reimbursement model was backed-up with clinical data. Testing times and mechanisms did not pose a lasting threat to the existence of the project. Score: 15

5) Economic Proof of Efficiency. Support from investors for the development team indicates proved efficiency. Financing rounds between 2014 and 2015 ended with a monetary backing of several million euros [46] and culminated in the takeover by *Roche* in 2017 [47]. Score: 15

6) User Acceptance. The application is specifically designed to meet the documentation needs of diabetics. Despite the very good ratings on *Google Play*, there are hints from users in the comments about the app's inadequacies [43]. The *mySugr* website offers training courses on how to use the app [48]. Stigmatization of users is prevented with a humorous character of application and the creation of a sense of community in the user base through blog entries and newsletters. Support is available on a variety of channels [49]. Studies were conducted to measure user satisfaction, in which the application was rated positively [50]. Score: 13

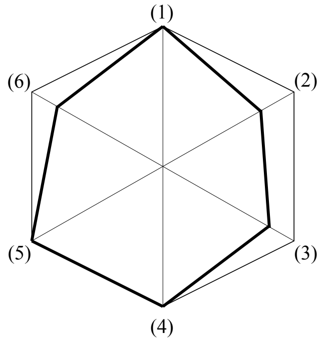

Figure 1. Visualization scoring "mySugr"

The demonstration showed that the presented approach to propagation barrier assessment is applicable to a popular DHI that is used on the German market. It helps to analyze which hurdles imposed on DHIs by the German healthcare system were addressed by *mySugr*-developers and which would still need some attention in order to speed up the spread of the application and reach a higher volume of users.

6. Discussion

Based on the results of the former sections, the designed assessment approach is evaluated with respect to the standards of the German association for evaluation [33]. **Usefulness.** The result of the assessment of *mySugr* coincides with the actual successful propagation development of the application. The next step would be to examine low scored areas and take measures to address under-considered barriers. Whether those measures lead to practice-relevant changes for the application could not be clarified in the demonstration. However, the evaluation remains a visible confirmation for outsiders reflecting the strong positioning of *mySugr*, which presents a benefit. **Feasibility.** The feasibility of the assessment largely depends on the robustness of the information base for the solution under consideration. In the case of *mySugr*, the company's tendency to openly communicate with its userbase contributed to a highly feasible assessment. However, with the knowledge of a company insider, statements could have been made more accurately. **Fairness.** Measures must be taken to ensure that all information necessary for an assessment is available to all stakeholders at all times, i.e. that assessments of solutions take place under the same (fair) conditions for third parties. One possibility could be to access standardized data for assessment in the *vesta Informationsportal*, although it is often provided insufficiently. In order to preserve the feasibility of an evaluation to cover the full range of DHIs, fairly generic evaluation questions had to be used which could have compromised the accuracy of the evaluation of an mHealth application. **Accuracy.** The assessment of *mySugr* resulted in an overall positive score indicating that most of the propagation barriers were addressed and dealt with, which is reflected in the successful market dissemination of the app. However, compromises had to be made regarding the assessment parameters (*No*, *In Progress*, *Executed*, *Documented/Not Applicable*). They are not linked to the quality of a measure taken and its sustainable effectiveness, which affects the effective barrier resilience of an application. Therefore, more resilient metrics for the assessment of barrier aspects have to be introduced.

This article contributes to diffusion and adoption research in healthcare. It offers insides into the aspects of healthcare-specific diffusion barriers by integrating former research in the area and applying a distinct focus on the German environment. The resulting categorization offered a frame for investigating the German healthcare system under more narrow thematic limitations. Additionally, a review of preliminary research on healthcare innovation barriers was provided. These two preparatory steps lead to the design of an easy-to-use approach to assess the readiness of an innovation to successfully spread. Usefulness and functionality of DHI play only a secondary role in this approach. Sustainable value is rather added by shifting from functionality-focused thinking towards dissemination-centered considerations. Summarizing this paper's scientific relevance: it enriches existent knowledge about DHI diffusion into healthcare markets by a formative assessment method that allows the determination of how a DHI may take the hurdles of concrete diffusion barriers. In a broader sense, the presented measures imply design principles of DHI.

The presented artifact is aligned with the EU interoperability framework. The proposed evaluation approach supports innovators and development teams struggling with the complexity of DHI diffusion into day-to-day healthcare. As *interoperability* is considered highly relevant to ensure DHI diffusion success, research and consensus processes of eHealth Network (a task network of the European Commission) led to the *Refined European Interoperability Framework (ReEIF)* in 2015 as a general definition for eHealth interoperability. The contribution of this paper is aligned with this consensus as categories and super-categories address the six interoperability levels of ReEIF (Legal and regulatory; Policy; Care Process; Information; Applications; IT-Infrastructure) [51]. Thus, the proposed assessment approach breaks down the complexity of DHI diffusion while offering an aid kit for struggling innovators.

The presented artifact is also subject to limitations. One limitation results from the methodology of the literature-based research approach deriving barriers with inductive category formation. This practice results in categories formed on the one hand regardless of contemporary significance, on the other hand relying on the assumption that relevant barriers were already being discovered in preliminary research. Thus, it can not be guaranteed that the barriers found have practical relevance, which requires research in the field and can be worked on by conducting expert interviews. Additionally, the categories that were formed and represent propagation barriers exist in de facto interdependence but were considered as being separate in this paper. That could lead to false compartmentalization of the healthcare system during the attempt to create the assessment approach. Another basic potentially misleading assumption was created around the unified understanding of the terminology summed up in the term *digital health* during the research on existing evaluation frameworks. Thus, subsequent categorizations of named approaches might have suffered from ambiguity. Furthermore, the evaluation revealed that the quality of the information fed into the assessment model is pivotal for the assessment outcome. Hence the reliability of the information used in the artifact application has to be ensured. Moreover, proof is required that the assessment approach followed by the scoring system does indeed support hands-on decision making. This is especially true, since the descriptions of the healthcare environment the assessment is based on, was only briefly broached and is currently not to the innovator's disposal in case a category scored low. Finally, the frame in which this approach to DHI assessment is tailored to is currently limited to the German healthcare context. That limitation was necessary to create a usefully specific, manageable framework in the first place, seeing the German healthcare system as fairly homogeneous. Since that focus was set in such an early stage of research, the migration of the assessment framework to another region might require fundamental content changes early on. However, the methodology would be just as applicable and an expansion to other OECD member states with Social Health Insurance [15] might require slight modifications only.

7. Conclusion

This paper discussed a central issue of digital health innovations – even highly optimized DHIs with strong problem-solving potential do not necessarily scale-up in the intended environment. A crucial factor for that are system-imposed barriers that have to be taken into consideration to introduce innovations to end-users and unfold expected benefits for care provision. To tackle this issue, a first draft of an evaluation approach was developed to determine the resilience of DHIs to propagation barriers in the German healthcare system. Apart from improving the approach by additional research on the limitations, the assessment can be extended to a stakeholder perspective by linking propagation barriers to corresponding interest groups in the healthcare system. These interest groups often have contradicting goals and different levels of influence on DHI-diffusion success. Thus, the extension would benefit the overall approach by weighting barriers stakeholder-sensitively which adds more accuracy to the scoring. In practice, the presented approach could be implemented as an evaluation tool on a platform for digital health solutions using the already available ordinal scoring or adding a nominal dimension, describing addressable barrier aspects based on the assessment in greater detail. Such services could either provide guidance to developers working on DHIs or assist with investment decisions into promising innovations. Thus, the approach introduced in this paper can contribute to using scarce resources in healthcare more sustainably.

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10 Paper P6

Table 15: Key information on paper P6 and declaration of authorship.

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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.

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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

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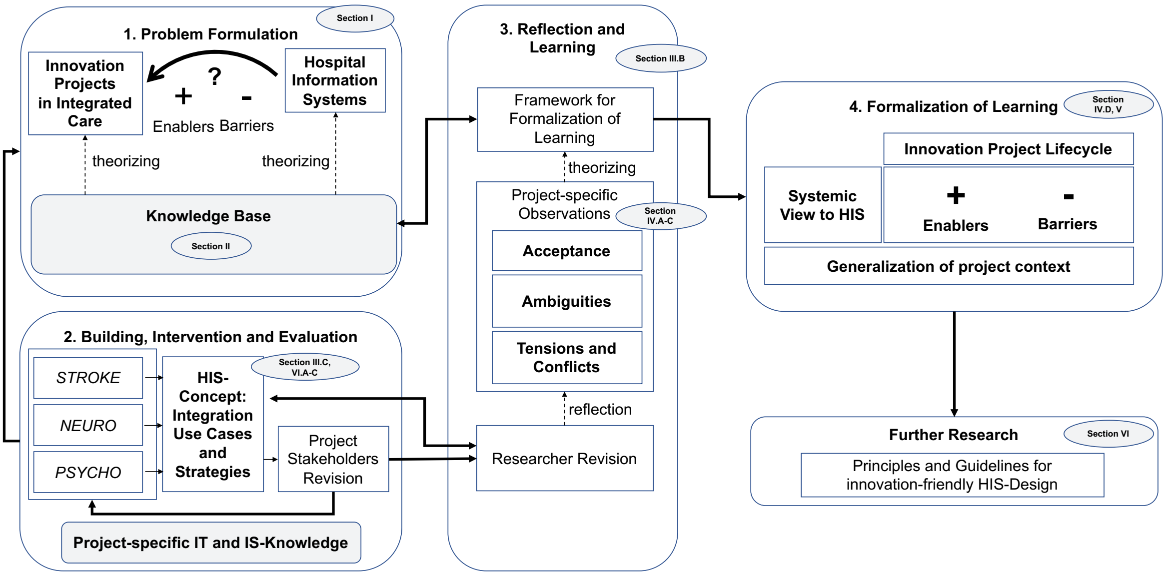

Figure 1. Research design, adoption of ADR method of SEIN ET AL. (2011)

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

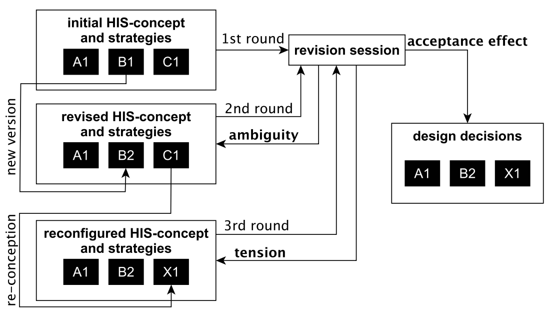

Figure 1. Instantiation of the build, intervention and evaluation-cycles

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

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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 an 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 pracitioners	Integration infrastructure for application systems of physicians	Stroke Aftercare	· 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	· 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	· Medical experts from multiple hospitals · Provider of clinical documentation system · Provider of case record system · Information systems department of university hospital · Mobile app developers

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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 chronical 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 chronical 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

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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 todays medication plan. Therefore, we proposed the implementation of a CDA-based implementation guide [1] 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 FHIR [2] 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 uses 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/

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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

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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.

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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 Antilope 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 Antilope 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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11 Paper P7

Table 16: Key information on paper P7 and declaration of authorship

Publication P6	
Title	**Ensuring Socio-technical Interoperability in Digital Health Innovation Processes: An Evaluation Approach**
Author(s)	Tim Scheplitz
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Author's contribution[11]	Conception: TS 100% Data processing, evaluation and interpretation: TS 100% Formulation of the manuscript: TS 100%
Additional materials	-

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Ensuring Socio-technical Interoperability in Digital Health Innovation Processes: An Evaluation Approach

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Keywords: Digital Health Innovation, Evaluation, Interoperability, ReEIF.

Abstract: Integrating Digital Health Innovations (DHI) into healthcare practice remains a challenging task for innovators. They continuously seek for actionable ways to fulfil the complex web of requirements set by the target environment. A socio-technical understanding of interoperability offers structurization to this complexity and becomes a key property that innovators want to ensure during the innovation process. Nevertheless, scientific guidance remains abstract rather than applicable. This research paper builds on this point and follows the question how innovators can evaluate their DHI process holistically and tangibly to promote the later integration into complex healthcare systems. It therefore presents an evaluation approach based on the Refined eHealth European Interoperability Framework (ReEIF) and results of a qualitative content analysis. Here, detailed descriptions of the six ReEIF levels and 181 potential parameters for a self-assessment tool have been derived from prior literature. These findings stimulate future research on interdependencies within identified aspects of socio-technical interoperability and promote applicable tools for digital health innovators.

1 INTRODUCTION

Successful implementation of Digital Health Innovations (DHI) into daily healthcare remains a challenging task for science and practice. Prior research is facing this issue from different points of view. It provides definitional relationships of key concepts and types of digital health soultions (Iyawa et al., 2016; Otto et al., 2018), consolidates valuable insights of domain-specific diffusion barriers (Hobeck et al., 2021; Otto and Harst, 2019), and derives success factors to overcome hurdles (Kowatsch et al., 2019; Otto, 2019). Also, such scientifically stated knowledge already found its way into international political programs, recommendations and interdisciplinary frameworks (European Commision, 2019; WHO, 2015). Despite this knowledge gain, the capability to foster DHI and to create intelligent and valuable digital health systems varies immensely from country to country (Prim et al., 2017).

Extending the knowledge base might also cause an increase of complexity, that innovators have to be aware of and that they have to manage. They face the challenge to overview all crucial factors valid for their context and to derive the right actions at the right time. Practice-oriented research lacks thereby in offering usefull supporting tools to ensure the later integration into complex health systems and their Health Information Systems (HIS) landscapes.

This paper adresses the practice-oriented focus mentioned above. It follows the research question how innovators can be supported in evaluating their DHI process holistically to promote the later integration into complex healthcare systems. It presents an evaluation approach that will lead to an evaluation tool for DHI practioners in further work. This approach seeks to assess the integration capability of DHI in the modern healthcare practice. It uses a socio-technical understanding of Digital Health (DH) interoperability, basically defined as the ability of two or more (health information) systems to effectively and efficiently perform tasks together (HIMSS, 2020; HL7 International, 2021). Thus, interoperability is required on different technical and non-technical levels when a DHI has to be integrated into healthcare practice. The presented approach bases on a European consented framework of socio-technical interoperability, the Refined eHealth

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Ensuring Socio-technical Interoperability in Digital Health Innovation Processes: An Evaluation Approach.
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European Interoperability Framework (ReEIF), to structure the complex requirement environment (eHealth Network, 2015). Furthermore, this paper presents results of a qualitative content analysis of existing, domain-specific evaluation approaches to operationalize the chosen key property. For all six interoperability levels defined in the ReEIF, comprehensive descriptions as well as a set of potential evaluation parameters were formulated.

This paper is structured as follows: Within the next section, foundations of this work are given by presenting its practice-oriented motivation, the conceptual evaluation approach as well as a socio-technical interpretation of interoperability in the DH domain. After presenting methodical details in section 3, findings of the analysis are presented for each ReEIF level as enriched descriptions. Further thoughts on ensuring interoperability from an innovator's perspective are discussed before limitations and a conclusion of this work are given.

2 FOUNDATIONS

2.1 Use Case of DHI Practice

This work is intended to stimulate both research and practice, but focusses primarily the latter perspective of DH innovators. In this paper, "DH innovators" describe one or more professionals who are responsible for the management of a DHI process starting from defining an initial idea and ending (hopefully) in integration of a new DH artifact into healthcare practice. The DHI process itself might differ due to the artifact's specificity, intended usage scenario and organizational circumstances but somehow pass typical stages of idea creation, conceptualization, requirements analysis, development and prototyping as well as a final integration into existing HIS landscapes. Whether a DHI process is managed by using agile process models like SCRUM, traditional sequential development models (e.g., Waterfall- or V-model) or hybrid models, evaluating the current progress with intended objectives is always essential. Also, evaluation is broadly used from a quality management perspective within Plan-Do-Check-Act cycles as stated, for instance, in DIN EN ISO 9000, ISO/IEC 20000 or ISO/IEC 27001.

In all mentioned stages of a DHI process, innovators are confronted with the domain's complexity. Various interdisciplinary requirements have to be managed to reach the inherent goal of a successful integration into healthcare practice. This task becomes even more crucial as it is mandatory for further scaling objectives. Thus, innovators shall be supported in continuous or repeating evaluation activities to assess how the ongoing DHI process ensure the integration capability of their DHI artifact in a pilot environment or, later on, in healthcare practice.

2.2 Evaluation Approach

Based on the formulated support scenario for DH innovators, a contextual concept of an evaluation tool was created (see Figure 1). For completeness, this concept is presented here in simplified form. Starting by the target group, Innovators aim to develop one or more DHI and integrate the new artifact(s) successfully into healthcare practice. They are thereby confronted with the challenge of managing technical and non-technical requirements set by the target environment. Here, an evaluation tool (working title "Interoptimeter") intends to support innovators assessing the integration capability of their innovation (evaluation object). The "Interoptimeter" provides self-assessment questionnaires with selected items from different interoperability perspectives and presents innovators a structured report. This report includes information about how different interoperability perspectives are already addressed and what topics DH innovators should pay more intention to in further work.

As motivated above, socio-technical interoperability is used as a key property to ensure this integration task (evaluation top criterion). It describes the ability of two or more systems - in this case the DHI as an artifact) and the target environment of the digital healthcare practice - to harmonize with each other and to perform common tasks effectively and efficiently. For this purpose, "socio-technical interoperability" is generally systematized via the ReEIF that defines six interoperability levels for the DH domain (evaluation sub-criteria). Details of this conceptualization are presented in the following sections.

Typical for frameworks, the ReEIF systemizes interoperability but does not provide their tangible operationalization. Here, the presented research wants to contribute on this need. It strives for actionable activities, tasks, or duties that can be reviewed within a self-assessment by innovators. The conducted qualitative content analysis enhanced existing descriptions and derived potential evaluation parameters. In Figure 1 the parts of the overall evaluation approach that are served by the results presented here are highlighted in dark gray.

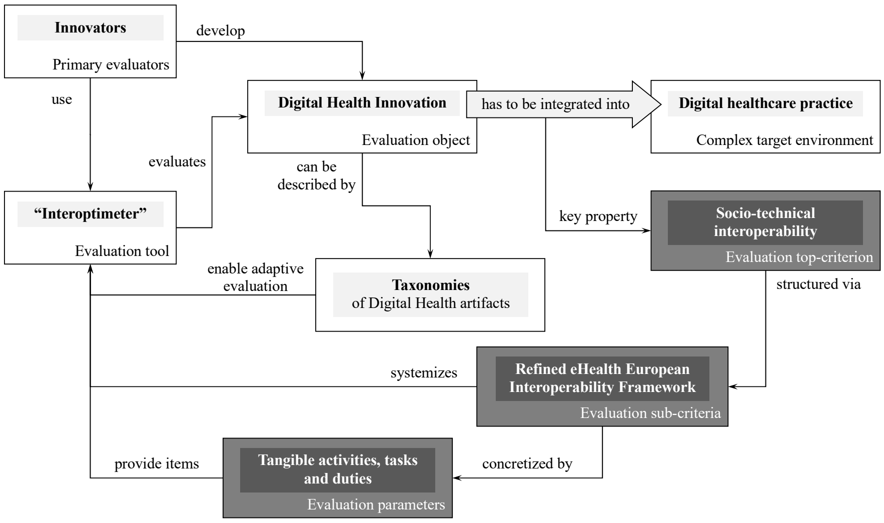

Figure 1: Paper's focus (dark gray) within concept of the “Interoptimeter” evaluation tool.

The evaluation approach also takes differences of DHI types into account. For this purpose, established taxonomies are to be used for systematic description of a DHI. Such characterizations enable adaptive evaluation activities as evaluation parameters can be sorted or filtered by relevance. However, the design of this functionality is the focus of future research and is only mentioned here as a supplement.

2.3 Interoperability as Key Property

Interoperability is basically defined as the ability of two or more application or information systems to effectively and efficiently perform tasks together (Gibbons et al., 2007; HIMSS, 2020; HL7 International, 2021; Zeinali et al., 2016). Following the socio-technical understanding of HIS research, interoperability is understood as a construct of technical and non-technical dimensions (da Silva Serapião Leal et al., 2019; Kuziemsky and Weber-Jahnke, 2009). Within this paper, the attribute “socio-technical“ is provocatively chosen to highlight the societal dimensions besides technical interpretations. Socio-technical interoperability is seen as a key property for a DHI’s successful integration as this general construct comprises the ability of the DHI and the status quo environment to commonly perform on four general perspectives. (Figure 2).

These perspectives might be simplified as follows: Interoperability of a DHI and its target environment requires a symbiosis according to:

- Existing Technical Systems that collaborate directly or indirectly with a DHI
- People who use a DHI or who are affected by its usage (professionals and patients)
- Organizations that manage a DHI’s operation
- Regulations that define duties and limits

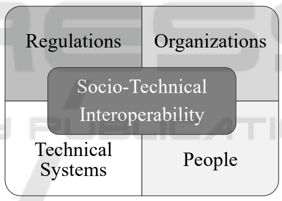

Figure 2: Construct of socio-technical interoperability.

2.4 ReEIF Model

In 2015, the European Commission's Working Group “eHealth Network” published the *Refined eHealth European Interoperability Framework (ReEIF)* (eHealth Network, 2015; European Commission et al., 2013). This unifying framework is primarily intended to support activities in the context of interoperability and standardization challenges. It thereby provides a structuring benefit for communication and decision-making processes regarding DH solutions. In this sense, the ReEIF serves as a consented language for the analysis of DH solutions. It defines six technical and non-technical levels of interoperability within the context of DH: *Legal & Regulatory, Policy, Care Process, Information, Applications and IT Infrastructure.* Figure 3 presents the explanations of each of the ReEIF's interoperability levels. The eHealth Network

Refined eHealth European Interoperability Framework (ReEIF)	
Legal & Regulatory	On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region.
Policy	On this level, contracts and agreements between organisations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. In governance documents the governance of collaboration is anchored.
Care Process	After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver the integrated care.
Information	This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.
Applications	On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import using these communication standards. Another aspect in this level is the integration and processing of exchanged information in user-friendly applications.
IT Infrastructure	The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the "generic" interoperability standards and protocols.

Figure 3: Description of ReEIF Levels by eHealth Network, 2015.

formulates these in light of interoperability between two or more organizations. Despite some vagueness for the context of integrating DHI as artifacts into practice, the explanations still allow for delineation of relevant topics especially in the light of DHI for interorganizational healthcare delivery.

From a top-down perspective, the ReEIF is already part of international recommendations. The WHO recommends its member states to adopt the ReEIF within their eHealth strategies and action plans to support all involved stakeholders on the way from innovation to implementation (Peterson et al., 2016). The eStandard initiative (2015-2017) also built on the ReEIF conceptualization and provided, among other outputs, the "Interoperability guideline for eHealth deployment projects" as well as a "Roadmap for a sustainable and collaborative standard development" to promote cross-border interoperability, use and evaluation of domain-specific standards and beneficial eHealth systems for the European people (eStandards, 2017a, 2017b; Schulz et al., 2019).

The research community applied the ReEIF in selected contributions. Scientists from Greece postulated an adopted framework for digital transformation of the national health system that facilitates especially citizen empowerment, health process alignment and integration of information technology (Katehakis and Kouroubali, 2019; Kouroubali and Katehakis, 2019). Dutch researchers contributed a reference architecture for primary care that uses the ReEIF to define essential functionalities which need to be ensured by future digital platforms or ecosystems (d'Hollosy et al., 2018). Overall, there are single contributions from science and leading international institutions that push the adoption of the ReEIF but, to the author's knowledge, its transfer to guidance for DHI practice remains uncomplete.

3 METHODS

The presented evaluation concept requires a suitable operationalization of socio-technical interoperability regarding the development of an innovative DH artifact and its integration into modern healthcare practice. A structuring, deductive Qualitative Content Analysis (QCA) according to Mayring was conducted to identify actionable evaluation items for all ReEIF levels (Mayring, 2014). Details of the research activities are listed below.

3.1 Literature Selection

Criteria-based evaluations are often underpinned by literature-guided definitions of the evaluation criteria and corresponding parameters (Alalwany, 2010). Socio-technical interoperability was chosen as the evaluation top criterion and further structured into six sub-criteria covered by the six levels of the ReEIF. In order to derive adequate parameters from existing evaluation concepts, an explorative literature review was opened. The PubMed, ScienceDirect, EBSCOHost, and SpringerLink databases were searched for articles between 2009 and 2019 that combined "digital health" or related terms ["eHealth", "mhealth", "telemedicine", "telehealth"] (Otto et al., 2020) with "evaluation" or "assessment" in the title or abstract. Only articles that discuss evaluation in the context of integration efforts of DHI into practice were included. Therefore, articles have to address DHI diffusion, adoption, implementation or integration as their contribution objective. Additionally, only articles that discuss DHI from a generic point of view have been included. Thus, articles that focus on single DHI or on DHI for a specific medical context were excluded from analysis. 34 contributions were finally selected (see Appendix 1). These contributions include concepts, methods, frameworks as well as initiatives or programs for DHI evaluation.

3.2 Qualitative Content Analysis

The 34 relevant sources were selected as the analysis set for a deductive, qualitative content analysis (Mayring, 2014). A structuring approach was implemented to detect concretizing text passages for each ReEIF level. In this regard, the definitions listed in Figure 3 were set as detection criteria. Passages were assigned to a ReEIF level if they concretize that definition for the scenario of DHI integration to a tangible item of action or consideration.

The free online tool QCAmap was used to perform the coding collaboratively with four research assistants. After about 10% of the material run, a check of the coding rules took place. At this point, we identified the issue that a consistent degree of abstraction is difficult to apply during coding. We decided to continue for the moment as we could not define a suitable rule as well as anchor examples and added a second analysis iteration afterwards. Here, we decided to whether a marking was suitable to provide an actionable parameter for our evaluation approach (low degree of abstraction) or enriched a more detailed description of a ReEIF level (medium degree of abstraction). Both objectives of the conducted QCA are illustrated in Figure 4.

After completion of the material run, approximately 4500 markings were set. The coding results are provided as a raw data set in Appendix 2 to ensure the traceability of detected findings. As mentioned, the markings showed differences in the degree of abstraction but could be subsumed into 122 descriptive aspects and 181 potential parameters.

The aspects for the detailed description of the ReEIF levels are distributed as follows: Legal & Regulatory 8; Policy 21; Care Process 49; Information 20; Application 7; IT-Infrastructure 17.

The detected potential evaluation items are distributed as follows: Legal & Regulatory 13; Policy 66; Care Process 39; Information 11; Application 32; IT-Infrastructure 20.

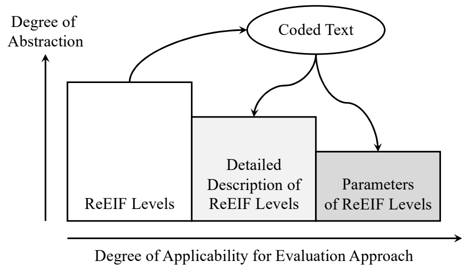

Figure 4: Objectives of QCA.

4 FINDINGS

The extent of findings allows only a condensed presentation of the analysis results at this place. For each ReEIF level, detailed descriptions are given below that are taken from those detected text passages that represent concretizations but no actionable parameters for evaluation. These detailed descriptions enrich the existing explanations of ReEIF given in Figure 3 and adopt them for the context of integration activities of DHI into healthcare practice. A complete list of these descriptive aspects can be found in Appendix 3. Within Appendix 4, all potential evaluation parameters are formulated as self-assessment questions and are offered specially to practice.

As mentioned above, Appendix 2 provides the raw data set of literature markings which are source of the following findings. In addition, Table 1 highlights those sources that particularly shaped the findings for each ReEIF level. Due to their extent, the reports of PAHO and WHO as well as the study by Dattakumar et al. caused a majority of the markings across all ReEIF levels (approximately 60%) and are therefore listed separately. However, this observation is purely quantitative in nature and is relativized by the adjusting subsumption of the second analysis iteration. The qualitative influence of articles of smaller length is particularly highlighted for the contributions of Lau & Price 2017 and Greenhalgh et al. 2017, as they also push a holistic, socio-technical approach to increase the adaptation of DHI into healthcare practice.

Table 1: Most influential sources of each ReEIF level.

ReEIF Level	Key Resource
Overall	Dattakumar et al., 2013; PAHO, 2016; WHO, 2016; WHO, 2015
Legal & Regulatory	Kowatsch et al., 2019; Momentum, 2012
Policy	Chang, 2015; Khoja et al., 2013; Kowatsch et al., 2019; Lau and Price, 2017; Scirocco, 2016
Care Process	Chang, 2015; Lau et al., 2017; Lau and Price, 2017; National Quality Forum, 2017
Information	HIMSS Analytics, 2017; Lau et al., 2017
Application	Chang, 2015; Kowatsch et al., 2019; Tamburis et al., 2012
IT-Infrastructure	Chang, 2015; Khoja et al., 2013; Van Dyk et al., 2012

4.1 Legal & Regulatory

This level describes fundamental as well as domain-specific public regulations and laws at regional, national or international level with regard to certain rights and values, esp. equity, equality, justice, security, liability, privacy, confidentiality and ethics. They regulate and ensure, among other things, personal rights, medical procedural rules, public structures of healthcare delivery, and data processing conditions. To ensure interoperability in this dimension, DH innovators can take action by identifying relevant regulations and guidelines, ensuring compliance to them, and/or requesting of specific consulting services and advisory.

Ensuring interoperability on the "Legal & Regulatory" level is mostly understood from the innovator's perspective of a specific DHI as being aware of and comply with the current and/or future legal circumstances. Unlinked from a specific DHI project, there might be also opportunities for innovators to participate in design or reformation processes on a legal level depending on an innovator's influence, position and possibilities to invest the required amount of time.

4.2 Policy

This interoperability level includes basic as well as specific policies or guidelines between organizations, esp. between the organizational background of innovators and contractually involved parties (Clinicians, IT businesses, funding agencies and individuals (e.g., Patient) and their compliance (governance). Also, intraorganizational policies (for instance of single hospitals) are of interest for innovators, as they eventually ensure or inhibit the adoption of a DHI within clinical practice. Those policies need to be clarified, negotiated, documented, communicated and fulfilled by innovators and appropriate parties regarding aspects like: organizational compatibility; liability; sustainability; safety, security and privacy; competencies; quality assurance & management; value propositions; business principles; technical support; operations and maintenance; working collaborations and cooperation; education and training as well as licenses and accreditations.

Ensuring interoperability on the "Policy" level requires, trivially speaking, the negotiation and confirmation of agreements between all involved stakeholders of a DHI. Depending on the specific DHI, its usage context and its innovational degree, this task becomes more or less complex. As policy activities refer to a broad variety of aspects that are also part of other interoperability levels and due to the unknown balance between compatibility to existing policies and the need for new agreements, the required efforts shall be rather over- than underestimated.

4.3 Care Process

This interoperability level addresses the alignment or reorganization of: workflows of care delivery; business and administrative processes; healthcare models and programs; care plans and pathways as well as personal interaction and communication. This includes (re)definitions and statements about: cooperation; coordination; competences and responsibilities; liability of practice as well as error prevention and risk descriptions. Among others, such alignments or reorganizations aim to ensure: quality of care; accuracy and disease specificity; continuity; validity; safety and security; usability, user-friendliness, acceptance and satisfaction of patients and professionals as well as customizability and individualization. Innovators may support these efforts by confirmation of effects like: clinical effectiveness and outcomes; patient-related outcomes; efficiency and/or quality benefits; process measures; treatment or medication adherence. They therefore should consider or provide: comprehensive description of DHI functionality; guidelines and standards of health practice; deviation in regular practice; patient engagement, user empowerment or education initiatives.

Summing up, the demand for interoperability at the care process level entails a large number of aspects that innovators should address. Based on the concrete needs from care practice, the core process for which a DHI offers a solution must be analyzed intensively. Of particular interest are the questions: How do apply which users the DHI and which people are directly affected by it and how? How does the DHI change the existing core process? Furthermore, dependencies or the influence on accompanying care, administration or business processes must be taken into account. Innovators need to balance whether a DHI should be designed to be compatible with established processes or the design of a DHI and its value proposition requires changes of the status quo.

4.4 Information

The "Information" level comprises aspects of semantic and syntactic interoperability, esp. data types, formats and structures; data flows; and the use of terminologies and standards. Considered data and information sets typically consist of general health information, clinical data, information about decisions, system-generated data as well as timestamps or log files. Innovators may generally align with existing standards or participate in standardization initiatives to ensure: accuracy; comparability; completeness; comprehensiveness; consistency; relevance and value; confidentiality; reliability as well as integrity.

Ensuring interoperability on the "Information" level requires on the innovator's site the balancing task of: identification and alignment with data models, structures and formats that are determined by the target environment of a DHI; harmonization of those (eventually heterogenous) compatibility requirements with own development; identification and re-use of consented interoperability standards provided by relevant institutions, e.g., HL7 or IHE; and the promotion of standard adoption or initiating standardization processes of new specifications. Reflecting these subtasks, interoperability on "information" level seems to be primarily ensured by compatibility activities especially towards existing semantic and syntactic standards. Nevertheless, a DHI that offers a new solution for an existing problem will probably hit a spot where the state of practice does not offer a health information standard. Here, innovators are able to fill this gap with self-defined specifications and might contribute their achievements to the synergetic community.

4.5 Application

The "Application" level comprises agreements and their realization according to interconnectivity of distinguished (information and) application systems, esp. in terms of: interconnection services and data exchange; use of communication standards and unified terminologies to ensure robustness of technical interfaces, sustainability as well as usability of technical interfaces. This generally technical dominated interoperability level does also include human-centered aspects like end-user satisfaction and user acceptance but with a focus on the interconnection of a DHI with other application systems. While the "Care Process" level addresses usability of a DHI itself – simplified as its use without involvement of any other technical system – this level considers usability aspects of DHI within an interconnected, synergetic HIS landscape. For instance, a professional documentation tool for a specific indication can be autonomously usable, intuitive and, thus, valuable but if data exchange with central Electronic Health Record systems is not ensured then double documentation might occur and will decrease user acceptance.

Increasing interoperability on the "Application" level requires knowledge about (potentially) mandatory communication scenarios of a DHI with existing or future application systems. Definition and prioritization of these scenarios are key tasks for innovators before technical interface solutions can be derived and realized. Thereby, innovators are not exclusively responsible on the required realization efforts as changes of the target environment could also foster interoperability, e.g., by supporting communication standards like HL7 FHIR.

4.6 IT-Infrastructure

Interoperability on "IT-Infrastructure" level includes considerations of specific properties, e.g., availability, performance, capacity, scalability, reliability, stability as well as safety and security of infrastructural components, like basic infrastructure of electricity, physical and mobile communication networks, required hardware, distributed server architectures and physical databases as well as storage units. Activities that may be considered to fulfill interoperability on this level are, among others, the use of technical infrastructure standards and protocols, the establishment of infrastructural data protection measures and validation mechanisms as well as maintenance and failure prevention activities.

Depending on the specific characteristics of a DHI, innovators need to consider infrastructural aspects on international, national, regional or local level. As infrastructures do not change rapidly, innovators shall search for a DHI design that is compatible with existing infrastructures. Thus, specifying the access to required server structures or networks, clarifying how continuity of operations can be ensured and implementing mechanisms to prevent or handle potential failure as well as IT attacks are main tasks.

5 DISCUSSION

5.1 Relevance

The extent of aspects for the given descriptions of the ReEIF levels as well as for potential parameters for the presented evaluation approach motivates the relevance question for each item. At the highest level of abstraction (ReEIF levels), no differentiation of relevance can be stated in general as neglecting each level makes the failure of a DHI integration likely. Although the detailed descriptions are formulated generically, the characteristics of a specific DHI, its usage context, and the DHI project's organizational circumstances may assign a single aspect more or less relevant. These three influencing factors require an individual assessment of relevance at the level of the formulated parameters, which cannot be provided in a blanket manner within this paper. In order to take this sensitivity into account, the presented approach comprises a selection of relevant parameters for a concrete evaluation instance based on a previous DHI characterization (Figure 1).

5.2 Critique on ReEIF

Generally, the ReEIF suited the task of systemizing interoperability from a socio-technical HIS point of view. Nevertheless, from the author's perspective, two themes could be assigned within the ReEIF but do not match a level's intention perfectly and, thus, should be highlighted more explicitly.

As the ReEIF is originally focused on interoperability between organization, the usage of a DHI or the user itself is not prominently represented. Especially findings regarding usability have to be assigned to the "Care Process" level, as a DHI generally intends to support healthcare activities, or to the "Application" level, as data exchange within interconnected HIS components might be crucial for usability to ensure continuity of information flow. Considering the extent of the "Care Process" level presented here, it might be valuable to distinguish user-centered topics ("Use of DHI") from process-centered topics. Other authors promote a similar separation of a DHI's usage without any communication scenario to other technical systems from the alignment and continuity of process landscapes in a target environment of connected HIS (van Mens et al., 2020).

Another vagueness occurs while placing aspects about required data for a DHI's functionality into the right ReEIF levels. Especially in the light of data-centered DHI and the progress of AI application in healthcare, valid access to required data sources becomes a central topic for innovators. Thereby, "required data" rather combines all three technical ReEIF levels than perfectly fit into a single one. Even though the interplay of syntax and semantics (Information), technical system interfaces and communication standards (Application) as well as appropriate connection to networks, server architectures and databases is implicated, it shall be highlighted for future data-centered DHI.

5.3 Dominance in Interoperability

Interoperability, in its technical and non-technical manner, is a property that targets two or more systems as a unit, not as single parts. Ensuring interoperability in the context of this paper depends therefore on the constitution of both the DHI (as an artifact) and the target environment. Reflecting the findings against this background, it might be valuable for innovators to differentiate the way of how they should act to ensure interoperability: by alignment and providing compatibility or by declaration of requirements on the target environment's site. Simplified, when a DHI takes its place within an existing target environment, three principles of dominance in interoperability might occur (Figure 5): I. Dominance of DHI – the DHI stimulates changes in the target environment which ensure interoperability; II. Dominance of target environment – the target environment declares mandatory requirements that have to be aligned with; and III. Interdependent adjustments – interoperability ensured by coordinated changes on both sites.

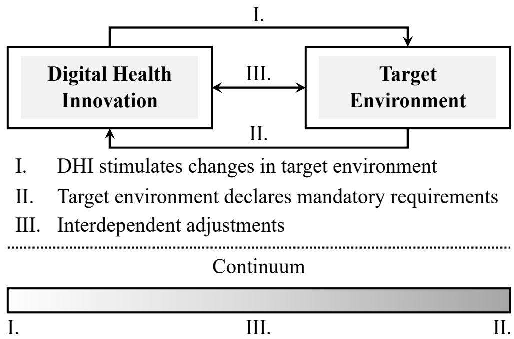

Figure 5: Principles of Dominance in Interoperability.

The findings as well as the dependency on a specific DHI indicate that these principles should not be seen as absolute categories. Rather, it shall be understood as a continuum within interoperability efforts can be assessed from an innovator's perspective. Regarding the findings, an innovators opportunity to ensure interoperability on "Legal & Regulatory" aspects as well as in existing "IT-infrastructures" tend to compatibility activities to the status quo (II). On the other hand, DHI that provide new solutions for healthcare practice and new beneficial value propositions will influence the way how healthcare is delivered and how "Care Processes" are conducted (I). "Policy", "Information" and "Application" level require a balance of activities striving to changes within established structures and the alignment with mandatory conditions (III).

5.4 Limitations

The scope and quality of the presented results have to be assessed under consideration of some limitations. In particular, inherent constraints on objectivity due to the qualitative, interpretive research approach result in three aspects that are stated here and motivate future research.

Degree of Abstraction. The chosen differentiation of two types of analytical findings (detailed descriptive aspects vs. potential evaluation parameters) as well as the high rate of subsumption (4500 initial markings to 300 finally used descriptive aspects and evaluation items) point to one issue: the definition and application of a common degree of abstraction as a coding guideline. Despite the fact that the coding rules were adjusted for comprehension within the material run, a relatively high variance had to be handled during the interpretation cycles. The decision whether an "actionable" evaluation item was detected could not be made for all markings without doubt. In front of this circumstance, the two types of findings were defined. The created detailed descriptions of the ReEIF levels could be used as a starting point for argumentative-deductive derivation of further actionable evaluation items to improve completeness and fit for different DHI types.

Suitability. One of the guiding motivations of this work is making knowledge about DHI integration into healthcare practice accessible and actionable for innovators. For this purpose, no restrictions were made with regard to DHI types, neither in the design of the evaluation approach nor during the parameterization of socio-technical interoperability. No artifact classes were explicitly excluded or prioritized. The scope of detected aspects achieved in this way was purchased with an initial lack of general fit of the individual item. For example, the question about confirmation of positive effects on patient self-management (CP-13) is irrelevant for DHI without patient involvement. Other items, such as the question about mechanisms to prevent system overload (ITI-02), may have universal relevance. Against this background, the detected items are to be assessed in terms of fit for different DHI types along established taxonomies in order to correspond to the adaptive character of the underlying evaluation approach (Figure 1).

Fuzziness. The method-related limitation of objectivity as well as the interrelation of detected aspects causes a certain fuzziness between separately listed evaluation items or gives the impression of redundancy in certain cases. For example, the items CP-10 ("Is continuity of care ensured?") and CP-34 ("Are seamless transitions between tasks of care ensured?") differ only slightly in their different perspectives (patient-centered vs. professional-centered) on continuous, trouble-free care processes. Despite this limitation, the results presented benefit from the diversity of perspectives gained as well as from the breadth of detected aspects. Further investigations could contribute to an improved distinction of the evaluation items, for example, by using a matrix structure.

Additionally, the limited **topicality** of this work has also to be named. This analysis started in 2020 and included only articles published until 2019. Due to the Covid-19-Pandemie and other circumstances, conduction, documentation and publishing of this work were delayed. Therefore, chosen literature data bases have been checked for additional resources, but the extent of articles matching the inclusion criteria is scarce. Nevertheless, three articles are mentioned here for completeness that generally confirm motivation and presented findings (Bashi et al., 2020; Guo et al., 2020; Villumsen et al., 2020). Bashi et al. reviewed science articles about the development of DH frameworks for chronic healthcare scenarios and recommend the re-use of frameworks for evidence-based DHI processes including evaluation activities. Guo et al. see the need of more pragmatic DHI and evaluation approaches to face the "no evidence, no implementation – no implementation, no evidence" paradox in DH. They highlight the awareness of socio-technical requirements faced by different stakeholders and call for new approaches to facilitate responsible growth of the DH domain. Villumsen et

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al. provide “an overview of the predominant approaches and methodological recommendations to national and regional monitoring and evaluation of eHealth”. Even though their main perspective addresses policy makers and appropriate initiatives, they recommend continuous, transparent monitoring and evaluation to facilitate learnings and implementation progress.

5.6 Further Research

The given results are currently being accompanied by an ongoing expert study. In 1-to-1 interview sessions, the experiences of experts from various professions (science, medicine, management and IT) are being collected in order to investigate the following questions, among other: How should differences in ReEIF levels in terms of relevance and criticality be assessed for definable DHI types? How shall interdependencies between ReEIF levels as well as between items taken into account? How can evaluation parameters be linked to action items and their termination within typical innovation phases?

6 CONCLUSION

This research paper addresses the challenge of innovators to fulfill the complex, interdisciplinary web of requirements for a successful integration of a DHI into modern healthcare practice. It presents an evaluation approach based on the key property of interoperability in a socio-technical manner. Along six interoperability levels defined by the ReEIF, this paper explores potential evaluation parameters for a self-assessment tool and provide detailed descriptions of ReEIF levels. While the organizational intended ReEIF generally suits the scenario of integrating a DHI into healthcare practice, the framework could benefit from little adjustments by a sound distinguishment of usability facets and the consideration of dominance in interoperability. The findings enrich both further research and practice to support innovators handling the complexity of domain specific target environments and, thus, to increase successful integration rates of future DHI.

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APPENDIX

All appendices are available via the following link: https://cloudstore.zih.tu-dresden.de/index.php/s/kSsiZwNXdd24XKF

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12 Paper P8

Table 17: Key information on paper P8 and declaration of authorship

Publication P6	
Title	**Holistic Interoperability From A Dogital Health Innovator's Perspective: An Interview Study**
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HOLISTIC INTEROPERABILITY FROM A DIGITAL HEALTH INNOVATOR'S PERSPECTIVE: AN INTERVIEW STUDY

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Abstract Current discussions on ensuring inter-organizational care and inter-sectoral collaboration in digital health increasingly prioritize interoperability as a target property. Previous conceptualization either prioritize a technological scope or focus on socio-technical interoperability between organizations. In doing so, the potential to draw on a holistic understanding to support innovators to increase the diffusion of digital health innovations (DHI) into healthcare practice remains untapped to date. This work addresses this gap. An expert study with 29 participants was conducted to explore whether and how the Refined eHealth European Interoperability Framework (ReEIF) can be used to manage DHI processes. The interviews provide insights regarding relevant interoperability aspects from an innovator perspective and opportunities to address these within DHI processes. On this basis, we propose a Digital Health Innovation Interoperability Framework (DHIIF), which is intended to help practitioners achieve more interoperability while improving the diffusion probability of their DHI.

Keywords:
Digtial Health,
Innovation,
Interoperability,
Interview Study,
Framework.

1 Introduction

Successful diffusion of Digital Health Innovations (DHI) into practice remains a tough challenge. Unfortunately, DHI projects still have a high failure rate, especially when a DHI project's ambition reaches a high-level (Cresswell and Sheikh, 2013; Mair et al., 2012; Standing et al., 2018). Research on Health Information Systems (HIS) already investigated the realm of reasons for failure and generally conceptualized what DH adoption requires. But practice-oriented research lacks in supporting DH innovators in ensuring the later integration of a DHI artifact into health systems and their HIS landscapes. The challenge becomes even more difficult when DHI's complexity and/or novelty increases due to inter-organizational care scenarios, application of new technologies, or new paradigms of healthcare delivery (e.g., value-based healthcare).

For this background, we defined our overall research goal as the derivation of a management framework for DHI processes to promote interoperability. We were thereby guided by three principles: 1. Interoperability is a key property of DHI and crucial for diffusion success; 2. Interoperability is a socio-technical property and requires a holistic conceptualization; 3. Ensuring interoperability is a high-priority goal of DHI processes and requires active management.

We selected the Refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2015) as a starting point for our investigation. It suits the stated principles and provides a European consented structurization of interoperability in DH. But its applicability to the context of DHI dissemination is somewhat vague, as it originally focuses on interoperability between organizations. Therefore, we question: How shall the ReEIF be adapted to suit the perspective of DH innovators and support them in DHI processes?

2 Foundations

2.1 Conceptualization of socio-technical interoperability

Interoperability is basically defined as the ability of two or more applications or information systems to effectively and efficiently perform tasks together (HIMSS, 2020; HL7 International, 2021; Zeinali et al., 2016). Technical properties, e.g., semantics and syntax, are at the focal point of discussion to ensure communication scenarios between technical systems. National and international committees (e.g., HL7 and IHE) strive to increase standardization and reduce inconsistencies in information flows.

Following the socio-technical understanding of HIS research, interoperability is understood in a broader sense as a construct of technical and organizational dimensions (da Silva Serapião Leal et al., 2019; Kuziemsky and Weber-Jahnke, 2009). Considering the multitude of non-technical aspects that determine a DHI's adoption (Hobeck et al., 2021; Kowatsch et al., 2019), the socio-technical interpretation gains relevance. This is underpinned by a recent article postulating the value of interoperability and ensuring mechanisms in the era of digital innovations (Hodapp and Hanelt, 2022). Thus, we initially conceptualized interoperability as the ability of a DHI and the status quo of a target environment to perform commonly. Thereby, the target environment in which a DHI will be integrated defines four general perspectives:

- Technical Systems collaborating directly or indirectly with a DHI
- People using a DHI or being affected by it (professionals and patients)
- Organizations that manage a DHI's operation as part of a HIS landscape
- Regulations that define duties and limits of a DHI usage

2.2 Refined eHealth European Interoperability Framework (ReEIF)

In 2015, the European Commission's Working Group "eHealth Network" published the ReEIF (eHealth Network, 2015). This framework is intended to support activities in the context of interoperability and standardization challenges. It provides a consented language and supports communication and decision-making processes. It distinguishes technical (Information, Application, IT-Infrastructure) and non-technical levels of interoperability (Legal and Regulatory, Policy, Care Process). Despite some vagueness for the context of integrating a DHI as an artifact into healthcare practice, we chose the ReEIF as initial delineation aid as its intention suits the background of DHI towards inter-organizational healthcare delivery or inter-sectoral collaborations.

From a top-down perspective, the ReEIF is already part of international recommendations. The WHO endorses its member states its adoption within their eHealth strategies to support all involved stakeholders from innovation to implementation (Peterson et al., 2016). The eStandard initiative built on the ReEIF and provided the "Interoperability guideline for eHealth deployment projects" as well as a "Roadmap for a sustainable and collaborative standard development" (eStandards, 2017a, 2017b). The research community also applied the ReEIF in selected contributions, e.g., to derive a framework for the digital transformation of the Greece health system (Kouroubali and Katehakis, 2019) or to propose a reference architecture for future digital ecosystems for primary care (d'Hollosy et al., 2018). In a prior literature study (Scheplitz, 2022), we assigned diffusion-critical aspects to the ReEIF levels and derived detailed descriptions of each level from an innovator's perspective.

2.3 Prior research on diffusion and adoption of DHI

Previous findings from HIS Research and related disciplines demonstrate the extent and complexity of what it takes to ensure the success of DHI. Multiple articles provide comprehensive lists of barriers and facilitators of planning and integrating DHI (Kowatsch et al., 2019; Schreiweis et al., 2019). With a practice-oriented motivation, Hobeck et al. provide a questionnaire based on selected diffusion critical barriers allowing innovators to self-assess a DHI process and align their findings with the ReEIF (Hobeck et al., 2021).

Other scientists faced insufficient DHI diffusion success issues from a top-down perspective. Our work is mainly influenced by two of them. First, in their Clinical Adoption Framework (CAF), Lau et al. provide a holistic, socio-technical evaluation framework for eHealth evaluation (Lau and Price, 2017). Van Mens et al. applied CAF for patient access to EHRs and enhanced it by 43 CAF categories, making it more tangible for other DH evaluation objects (van Mens et al., 2020). But in the end, CAF is primarily suiting rather DHI evaluation than DHI process management. Second, the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework defines pertinent, conceptual domains and highlights their interplay within a wider (institutional and societal) context determining sustainable DH adaptation over time (Greenhalgh et al., 2017). This framework is focused on DHI's path from the integration phase to its post-market usage and evolution.

All in all, several contributions discuss the adoption of the ReEIF for practice or consolidate relevant aspects of DH diffusion. They differ in detail but confirm each other in their socio-technical realm. Even though these articles promote awareness for better requirements engineering, the guidance for innovators on DHI process management is limited.

3 Method

A qualitative research approach was chosen to meet the research goal via an interview-based expert study. Experts from research and practice were acquired to discuss in 1-on-1 online interviews aspects of socio-technical interoperability, its criticality, and how innovators can ensure it.

3.1 Study Design

Interview studies have been a valuable qualitative research approach for Information Systems Research for decades (Myers and Newman, 2007; Schultze and Avital, 2011). For this purpose, a semi-formal interview guide was derived. It consists of open and closed questions and is structured in 4 thematic blocks.[1].

- Basic understanding interoperability; Ad hoc evaluation of ReEIF
- Previous DHI experiences; Transition to the study's generic objective in the third block; Description of one recent DHI project
- Change to a prospective, generic perspective; Topics and activities particularly critical to a DHI's diffusion success regarding ReEIF; Innovator's influence on ensuring interoperability DHI processes
- Characterization of participants (background, experience, expertise)

3.2 Data Sample

The participants were mainly recruited via email using German digital health expert networks from research and practice. Further experts were motivated to participate via the snowball principle. In total, 29 experts participated in the 1-on-1 interviews between September and November 2021. In terms of experience, professional background, and core expertise, the participant set is heterogeneous and covers the range of perspectives sought (see Appendix).

3.3 Details of Analysis

All recordings were independently analyzed by two researchers and one research assistant. Responses to closed-ended questions were documented directly for quantifying analyses. Responses to open-ended questions were converted to summarizing paraphrases. After a complete run through the material, all results

[1] The complete interview guideline can be found in Appendix - https://tud.link/7ua4

were consolidated, statements with the same intent were subsumed, and conflicting interpretations were discussed in group sessions by the analysts. Conflicts were resolved into adequate paraphrases under re-screening of recording sequences. The final set of paraphrases was interpreted according to the research question. All analysis activities were oriented towards the recommendations of summarizing, qualitative content analysis (Mayring, 2014).

4 Findings

Our ambitious research goal lead us to a sophisticating extent of paraphrased statements. A selection of those statements is consolidated in the following.[2]

4.1 Critique on ReEIF from an innovator's perspective

Participants were invited to assess the ReEIF from an innovator's perspective regarding critical aspects for the integration of a DHI into practice. The general feedback was positive. However, with a view to comprehensiveness, some participants perceived the following uncovered topics:

Distinguishment of user-centered and process-centered issues. The view of users and how they use a DHI is a prominent factor but underrepresented if positioned within Care Process level.

Highlighting the interplay of technical interoperability levels. Some participants asked how the required data for the functionality of a DHI is covered within ReEIF. Here, they assume that the technical levels of ReEIF (Information, Application, IT-Infrastructure) address this in symbiosis but also doubt if innovators would recognize this interplay easily.

Highlighting the business perspective. The definition of appropriate business models as a solid base for activities on the policy level should be presented more popular, since those efforts should not be underestimated, especially for DHI with revolutionary value propositions.

Considering cultural influences. On a macro-level (e.g., the inertia of medico-legal conditions) and on a micro-level (e.g., managing interdisciplinary collaboration), cultural factors influence ensuring interoperability.

Enhance ReEIF in a way that offers implications on DHI process management since it currently does not provide a processual perspective, especially when perceiving a DHI as a dynamic process.

[2] All paraphrases are document incl. interview IDs within Appendix - https://tud.link/7ua4

The participants were asked which ReEIF level requires the most attention. Here, answers often tried to balance efforts and relevance. As most experts stated, all levels are equally relevant in general because unawareness of each level could lead to a failure of a whole DHI project. However, 20 experts mentioned that the care process level requires the most attention and reasoned it by i) the high need for communication and analysis resources and ii) a dominating impact of this level.

4.2 Crucial aspects of interoperability

In further questions, we stepped into detailed discussions about the crucial aspects of interoperability. We strove to identify aspects and their alignment to ReEIF levels. However, some participants stated generic aspects. The majority (n=22) highlighted the need for interdisciplinarity to integrate all relevant stakeholders and competencies required by each level. Even though reaching interdisciplinarity requires efforts in organization and communication, the benefits of internal and external commitment to a DHI process and acceptance of a DHI artifact are worth it. More than half of the participants (n=16) mentioned user-centeredness as a maxim and expressed its positive influence on usability and utility (Care Process) and positive follow-on effects on all interoperability levels by the high commitment of users and stakeholders. Some participants switched to a processual perspective and suggested an early, systematic, and exhaustive requirements analysis that allows a precise definition of a DHI's vision. Other interviewees argued that this definition step should balance the overall ambitions and conclude with a minimal valuable product that promotes communication and development. A few participants suggested early piloting and field trials as close to healthcare practice as possible fostering advantages on technical and Care Process levels and mentioned further benefits in identifying legal and policy hurdles that might otherwise remain hidden.

At the Legal and Regulatory level, the awareness of medico-legal conditions and the fulfillment of regulatory duties have been highlighted, especially regarding ethical approval, intellectual property, technical and medical liability, certification processes, and the medical evaluation for proof of evidence. For the latter one, the systemic issue of a locked-in cycle was mentioned where a missing evaluation hinders a regulatory approval so that field trials can not be conducted and no real-world data is gathered, which reasons the absent evaluation. At the Policy level, the participants named internal, bi-, or multilateral agreements and contracts as central objects. Some participants highlighted here an economic view and stated appropriate business models with sustainable remuneration models as crucial. At the Care Process level, an in-depth understanding of existing care and accompanying processes of coordination and administration plus intended and unintended effects of a DHI's integration was frequently named and shall be ensured by multiple observations of daily practice with and without a DHI.

Some Participants described aspects of technical interoperability levels (Information, Application, IT-Infrastructure) commonly due to their symbiotic interrelation. These aspects follow the principle of reusing existing solutions, standards, or generic specifications. These participants suggested evaluating the state of practice within the target environment, comparing it with the general state of standardization for the specific use case, and claiming consulting services from appropriate associations (e.g., HL7, IHE). Here, a conflictual gap might occur between standardization knowledge vs. the state of its implementation. Some interviewees named this a reason for present and future proprietary interfaces, when the status quo refers to deprecated systems and innovators are forced to provide compatibility. Thus, breaking through this cycle requires legal acts for the mandatory use of modern standards. Furthermore, interoperability on these three levels could be promoted by innovators by a sound definition of a minimal valuable product, including specifications of required data exchange scenarios. These definitions support negotiation and communication activities as well as early prototyping and testing. It suits interoperability, especially on the Information level that comprises the definition of domain knowledge, its coding, and the use of standards or initiating standardization.

4.3 Ensuring interoperability within DHI processes

Besides the question of "what" are relevant aspects of interoperability, we also asked for the "how" they should be addressed. We distinguished these questions within our interview guidelines. However, as presented in the previous section, the participants frequently reflected on both commonly. We now consolidate fundamental findings of an innovator's influence on ensuring interoperability and how related tasks fit into typical process models.

4.3.1 Proactive vs. reactive influence

All interviewees agreed that ensuring interoperability is a task that innovators are responsible for, even though systemic issues, e.g., legal acts for mandatory use of

IT standards, are related to public institutions or official committees. Innovators always have an influence but the way how they force it differs. There are generally two strategies: I. via a proactive influence on the target environment to change the status quo or II. via a reactive influence by compatibility to the target environment. These strategies should rather be seen as ends of a continuum than a binary differentiation. The participants reflected that there might be tendencies of advantageousness but innovators mostly have to balance these strategies.

We discussed such tendencies in more detail. Our first approach investigated if tendencies are related to different ReEIF levels. Here, the participants mentioned that striving for compatibility (strategy II.) leads DHI activities related to Legal and Regulatory and IT-Infrastructure. On these levels, the innovator's potential to achieve changes within a short period in mostly inflexible structures is marginal. The other levels offer more room for proactive initiatives. For Care Process and Information, the participants argued for balancing the strategies. On the one hand, they articulated the inherent change due to a DHI's integration. On the other hand, the ability and motivation to change established processes in practice are limited. Especially physicians, caregivers, and IT departments might be overcharged with additional changes and are looking for stability. Regarding the Application level, the participants tend to see the potential of motivating changes proactively and benefiting from newly created interfaces. However, these tendencies may vary due to the specific characteristics of a DHI or its context. The participants reflected thereby a DHI's degree of novelty (innovation as evolution or revolution), the general state of standardization for the particular use case, and the extent of involved stakeholders within the DHI project.

4.3.2 Agility vs. stringency

While discussing the innovator's opportunities in ensuring interoperability, the participants reflected on both agile process models (e.g., SCRUM) and more stringent approaches (e.g., V-Model or waterfall model). Agility and iterative development-test cycles fostering user-centeredness and awareness of interwoven care processes and accompanying processes were seen as a maxim.

Overall, the interviewees favored agile approaches explicitly on Care Process, Information, and Application level. Rather stringency than agility is needed on the Legal & Regulatory, Policy, IT-Infrastructure level. Even though these levels would probably benefit from more agility, innovators mostly have to follow mandatory, formally defined processes, are thereby confronted with sequentially required duties, and face time-intensive negotiations. Consequently, DHI processes forcing socio-technical interoperability need to harmonize agile development approaches with top-down required, sequential processes Some interviewees recommended a top-level sequential DHI process, starting with an exhaustive analysis phase to clearly define a DHI's vision and a minimal valuable product. Agile development and testing cycles shall build on this sound basis and will end up again in stringent phases of final evaluation and certification stages. This slightly trivial combination of stringency and agility varies due to DHI project conditions (e.g., private-funded vs. public-funded, internal vs. inter-organizational consortium) and the characteristics of the DHI artifact (e.g., degree of novelty or closeness of DHI's effects on the patient).

5 Discussion

5.1 Digital Health Innovation Interoperability Framework

We reflected our findings against domain-specific diffusion theory (Greenhalgh et al., 2017; Lau and Price, 2017; van Mens et al., 2020) for an adaption of the ReEIF and propose a Digital Health Innovation Interoperability Framework (DHIIF). The DHIIF primarily supports managing interoperability from an innovator's perspective with the overall aim to achieve interoperability holistically and improve the diffusion probability of a single DHI. The DHIIF's center presents seven interoperability levels as enrichment of the six ReEIF levels that describe the relevant topics within DHI processes (Figure 3). Looking through a technical lens, we underline the symbiotic interrelation of Information, Application, and IT-Infrastructure level to fulfill requirements of data exchange that become even more relevant in the light of rising data-centered DHI and AI applications. We further introduce the distinguishment of interoperability from a user-centered and a process-centered perspective. Even though they are interrelated and commonly determine a DHI's utility and usability, innovators should concentrate on both levels separately. Our findings confirm and specify prior results from a literature study (Scheplitz, 2022) that started the adoption of ReEIF for innovators. We further align with adoption theory highlighted in NASSS (Greenhalgh et al., 2017), which describes the influence of the wider system of a DHI project (e.g., its organizational background, conditions of the specific target environment, cultural influences) and longitudinal dynamics on the "how" innovators shall promote interoperability on each level.

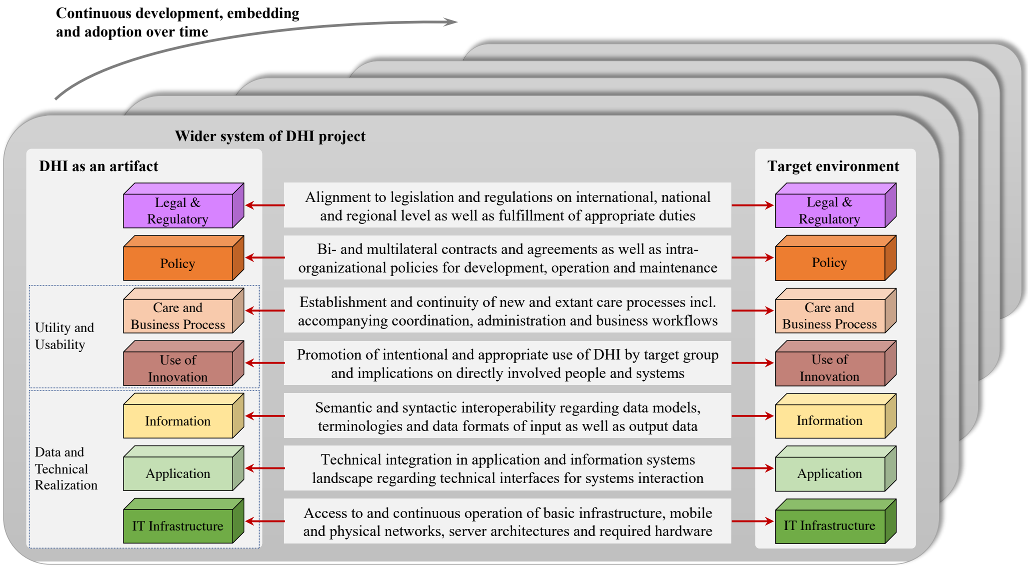

Figure 3: Digital Health Innovation Interoperability Framework

Interoperability is a property that targets two or more systems as a unit, not as single parts. Therefore, it depends on the constitution of both the DHI (as an artifact) and the target environment. Strategies to ensure interoperability may differ due to specific conditions but also to characteristics of each interoperability level. We confirmed prior indications (Scheplitz, 2022) about three general principles of dominance in interoperability and related strategies (Figure 4). We derived indications of which strategies should be pursued on each interoperability level of DHIIF. However, we argue that these principles and strategies should not be understood as discrete categories. Instead, they unfold a continuum that allows innovators to define their strategies and activities for a specific DHI process.

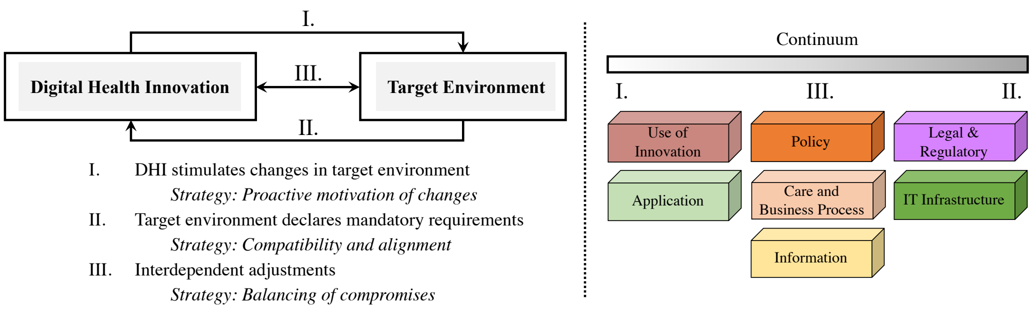

Figure 4: Dominance in Interoperability and indications on ensuring strategies

5.2 Limitations

The results of this study should be evaluated considering a few limitations. A first limitation was indicated by some participants. They described difficulties in making general assessments and motivated differentiation due to the specific DHI context. In this regard, interviewees described three interdependent sensitivity dimensions: 1. the DHI as an artifact including its value proposition, technological approach, and its degree of novelty on each ReEIF level; 2. the wider DHI project context comprising the specific target environment (status quo of technological, organizational, and legal conditions) as well as organizational project background (e.g., the innovator's status, the structure of consortia or funding conditions); 3. the DHI as a process with a longitudinal view on how a DHI project is conducted to develop and integrate the intended DHI artifact and how resilient this process is on dynamics in the first two dimensions.

Some methodological limitations also influence the validity of our work. As typical for qualitative research approaches, our results are limited in objectivity. We tackled this issue by including a multitude of professional backgrounds and expertise. However, with 29 participants we only conducted a mid-scale study. Furthermore, our results are subject to a national bias, as we almost exclusively interviewed German experts. The amount of internationally operating experts, as well as the rigid orientation of this study along with a European consented framework, strengthen the generalizability of this contribution.

6 Conclusion

With this expert study, we stepped towards more guidance on DHI process management strictly focused on socio-technical interoperability. We gathered knowledge from domain-specific diffusion theory, a prominent interoperability framework, and experienced practitioners to propose a Digital Health Innovation Interoperability Framework that provides structurization and processual implications for ensuring interoperability and increasing diffusion probability.

Acknowledgments

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13 Paper P9

Table 18: Key information on paper P9 and declaration of authorship

Publication P6	
Title	**Demonstration and Evaluation of the Digital Health Innovation Interoperability Framework**
Author(s)	Tim Scheplitz (TS)
Publication	submitted and under review as contribution to 11th International Conference on Health and Social Care Information Systems and Technologies (HCist), Lisboa, Portugal, 2022
Author's contribution[13]	Conception: TS 100% Data processing, evaluation and interpretation: TS 100% Formulation of the manuscript: TS 100%
Additional materials	-

[13] The contributions of the author(s) are structured according to the authorship criteria of the German Research Foundation for good scientific practice (DFG, 2013).

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Demonstration and Evaluation of the Digital Health Innovation Interoperability Framework

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Abstract

The relevance and role of interoperability currently change due to the unique characteristics of Digital Health Innovations (DHI) and the ongoing demand for defragmentation in Health Information Systems (HIS) landscapes. Efforts towards novel data-centered value propositions, inter-organizational care scenarios, and inter-sectoral collaborations force innovators to parallelly manage to realize the innovative idea and pave the path to seamless integration into complex target environments. Thus, the construct of interoperability shifts from a technical requirement's position to a socio-technical concept that provides guidance for DHI management. This research contributes to the discourse about the reconceptualization of interoperability for DHI. It builds upon a recently proposed Digital Health Innovation Interoperability Framework (DHIIF) and presents, first, a demonstration of its use within an ongoing DHI project on Digital Phenotyping and, second, a small-scale evaluation via an online expert survey. This paper provides the DHIIF's justification and confirms its utility as a conceptual fundament for DHI practice and HIS research.
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Peer-review under responsibility of the scientific committee of the HCist - International Conference on Health and Social Care Information Systems and Technologies 2022
Keywords: Digital Health Innovation, Health Information Systems, Interoperability, Framework

1. Introduction

Discovering Digital Health Innovations (DHI) and their integration into healthcare practice remains a tough challenge. Unfortunately, DHI projects still have a high failure rate, especially when a DHI project's ambition reaches a high-level [1], [2]. Research on Health Information Systems (HIS) has already investigated the broad realm of reasons for failure and generally conceptualized what DH adoption requires [3], [4]. But practice-oriented research

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lacks in supporting DH innovators in ensuring the later integration into health systems and their HIS landscapes. The challenge becomes even more complicated when DHI's complexity and novelty increase due to inter-organizational care scenarios, new technologies, or new healthcare delivery paradigms (e.g., value-based healthcare).

Through an even more generic lens: the nature of digital innovations challenges our understanding of how they are created, how they provide new value propositions, and how socio-technical ecosystems pave the way to a sustainably beneficial, innovation-friendly environment [5], [6]. In healthcare, the digital innovations' unique characteristic of combinatorial, distributed, and open-ended value chains [7] meets transforming HIS landscapes that – so far – rather strive for more interoperability than impress with a sufficient degree of interoperability. Besides required efforts from a systemic point of view, this paper argues that prioritization of and alignment with interoperability goals improves the diffusion rate of single DHI and the overall healthcare system as an effective, innovation-friendly domain. For this background, this research is motivated by a need for conceptualization and contextualization of interoperability for improving DHI management as recommended by Hodapp and Hanelt. They recently highlighted the increasing relevance of interoperability and ensuring mechanisms [8].

Thus, the overall goal of this research is the conceptualization and contextualization of interoperability for DHI and, consequently, the provision of DHI management support. Recent contributions derived the Digital Health Innovation Interoperability Framework (DHIIF) as a structuring and orientation aid for DHI projects [9], [10]. This paper enriches prior results and presents their evaluation due to a demonstration and a utility assessment by experts. Analogous to the previous studies, it follows three fundamental assumptions briefly introduced here (see Fig. 1): 1. Two interrelated fields of action characterize future DHI: Creating novel value propositions and ensuring interoperability with the intended target environment (scope of paper); 2. Interoperability appears in a dualistic manner as a key requirement crucial for diffusion success on the one hand and as a guiding construct for DHI management on the other; 3. Interoperability is a socio-technical property requiring a holistic conceptualization and a proactive management approach.

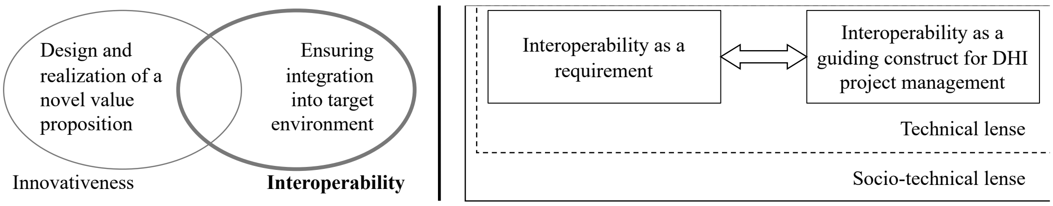

Fig. 1. Left: Interplay of Innovativeness and Interoperability. Right: Dualistic role of interoperability for DHI

2. Method

This work is part of an overall Design Science Research approach [11]–[13] that seeks to conceptualize and contextualize interoperability for DHI. Here, the central design artifact is intended to moderate interoperability between the micro perspective of digital health innovators (design, realization, and integration of DHI) and the macro perspective of complex target environments (socio-technical HIS landscapes). In previous analyses and design stages, the DHIIF was developed based on literature- and expert-based methods [9], [10] to support structuring and guidance for future DHI projects. The evaluation of the DHIIF is the subject of this paper, which thus represents another step within the overarching DSR framework [12], [14].

For this purpose, a two-part approach is taken to demonstrate the DHIIF's applicability for particular DHI projects and present results of small-scale evaluation by DHI experts. For demonstration, the DHI is applied to structure and determine strategies required in a current DHI project on Digital Phenotyping to ensure interoperability holistically. Complementary results of a small-scale online expert survey are presented that differentially evaluate the usefulness of DHIIF (ex-post assessment).

In April and May 2022, digital health experts were invited to assess the DHIIF via an online survey. Experts were acquired via several channels, including presentations in expert networks (German "Interoperabilitätsforum"; Special Interest Group Digital Health of German Association of Informatics) and online via websites, social media, and mailing lists. In addition, participants of a previous interview study [9] were also asked to provide evaluative support for the research project. In total, 12 experts participated. The online survey included three main blocks: A brief introduction explaining the intention and extent of DHIIF; 2. Assessment and critique of suitability by use cases and target group; 3. Utility to address current research topics of interoperability stated by Hodapp and Hanelt [8].

3. Prior Research

3.1. Foundations of Interoperability for DHI

Interoperability is defined as the ability of two or more applications or information systems to effectively and efficiently perform tasks together [15], [16]. Technical properties, e.g., semantics and syntax, are at the focal point of discussion to ensure communication between technical systems. National and international committees (e.g., HL7 and IHE) strive to increase standardization and reduce inconsistencies in information flows. Interoperability is also understood in a broader sense as a construct of technical and organizational dimensions [17], [18]. Considering the multitude of non-technical aspects that determine a DHI's adoption [3], [19], this socio-technical interpretation gains relevance. At the beginning of our exploration of interoperability from a DH innovators perspective, we described this construct as the ability of a DHI and the status quo of a target environment to perform commonly in four general dimensions: Technical systems collaborating directly or indirectly with a DHI; People using a DHI or being affected by it (professionals and patients); Organizations that manage a DHI's operation as part of a HIS landscape; and Regulations that define duties and limits of a DHI usage.

In 2015, the European Commission's Working Group "eHealth Network" published the "Refined eHealth European Interoperability Framework (ReEIF) to support activities in the context of interoperability and standardization challenges [20]. It provides a consented language and distinguishes technical (Information, Application, IT-Infrastructure) and non-technical levels of interoperability (Legal and Regulatory, Policy, Care Process). But some vagueness in terms of appropriateness for integrating a DHI as an artifact into healthcare practice remains due to its scope of interoperability between different healthcare organizations. We decided to use the ReEIF as initial delineation aid as its intention aligns with the background of DHI towards inter-organizational healthcare delivery or inter-sectoral collaborations. Based on a literature analysis [10] and an interview study with DH experts [9], we were able to adapt the ReEIF and propose the DHIIF (see Fig. 2).

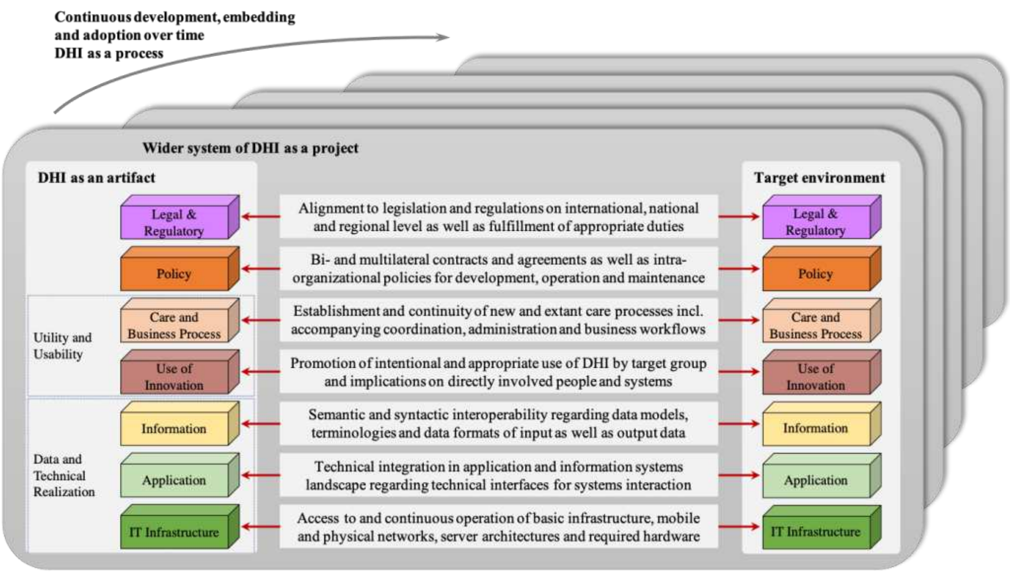

Fig. 2. Digital Health Innovation Interoperability Framework [9]

3.2. Proposing the Digital Health Innovation Interoperability Framework (DHIIF)

The DHIIF understands DHI from three perspectives: as a novel artifact (or composition) providing a specific value proposition that will be integrated into an existing HIS landscape; as a design and development process realizing this artifact; and as a project that declares the specificity of the target environment, organizational project conditions, and the wider system of politics, regulations, and socio-cultural circumstances [21]. From the central artifact perspective, we adapted the ReEIF as mentioned above and derived redefinitions of each interoperability level through the lens of the DH innovator. We added the level of "use of innovation" as user-centered requirements were only indirectly described in ReEIF but strongly influence the diffusion of a DHI into practice. We further broadened the level of "care and business processes" to highlight the interrelation of care processes intentionally influenced by a DHI artifact and further care, coordination, administration, and business processes. In the end, seven interoperability levels structure the holistic framework (see Fig. 2). They get specified for particular DHI projects and are longitudinally influenced by dynamics within a DHI process which shape extent as well as strategies and measures of ensuring interoperability.

The distinguishment of different interoperability levels provokes the question of if and how DH innovators can contribute to ensuring each facet. We postulated that they are responsible for this task, even though systemic issues might limit their influence. Innovators always have an influence but the way how they force it differs. There are generally two strategies: I. via a proactive influence on the target environment to change the status quo, or II. via a reactive influence by compatibility to the target environment [9]. Both contrasting strategies are concretized for all DHIIF levels in Table 1. These strategies should be seen as ends of a continuum than as a binary differentiation (see Fig. 3). They are therefore meant as entry points for defining the strategies of a specific DHI.

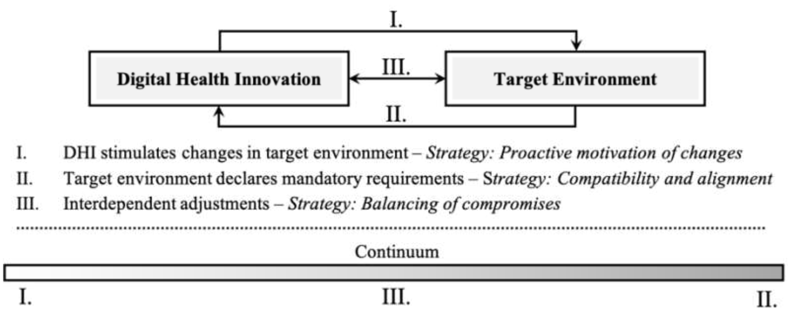

Fig. 3 Continuum of strategies on ensuring interoperability [10]

4. Demonstration of DHIIF's Application for Management of Distinct DHI Project

In a current research project, we used the DHIIF to structure interoperability efforts and strategies for improving diffusion capability. The project's primary goal is to develop an inclusive HIS landscape to enhance precision medicine for multiple sclerosis (MS) care. In detail, the project merges synergetic benefits of a) a quality-oriented patient pathway approach for inter-organizational care, b) machine learning technologies to evaluate and adjust individual pathways as well as pathway templates, and c) a strengthened patient involvement via a patient portal and smart wearables for integrating patient-generated data. Prospectively, the consortium also aims at a Digital Phenotyping application to increase the required individualization of MS treatment. Simplified, multimodal datasets will be processed by machine learning techniques to digitally represent clinical biomarkers, enrich them with further progress and usage data, and thus gain insights into individual treatment and coping strategies. Through a technological lens, this DHI conglomerate needs to be embedded in a HIS landscape composed of a hospital information system, a professional application system for MS, a pathway system for planning and conducting integrated care pathways, a patient portal, and mobile devices at the patient's side.

For an initial structurization of required efforts, we contextualized the framework of mechanism for ensuring interoperability [8] with the DHIIF (see Fig. 4, left), which opened the potential range of interoperability-related tasks.

In group sessions of the project consortia (DH innovator), we explicitly reflected on each cluster, identified related aspects ("What"), and discussed strategies and tasks to address them ("How"). We followed six refinement steps: 1. Differentiate clusters by relevance for distinct DHI; 2. Identify subtopics within priority clusters; 3. Clarify the general state of standardization for each cluster; 4. Clarify the standard implementation state in each cluster's target environment; 5. Reflect DHI's novelty for each cluster; and 6. Determine ensuring strategy for each cluster. Within the last step, we explicitly considered both the continuum of ensuring strategies (see Fig. 3) and potential, more or less likely, dynamics within the target environment (see Fig. 2). Finally, this procedure allowed us to systematically clarify how interoperability will be addressed holistically within our ongoing DHI project. We could identify relevant tasks and determine ensuring strategies differentially on each DHIIF level (see Fig. 4, right, and Table 1). Furthermore, this DHIIF-based structurization supported our internal communication regarding establishing a consented understanding of detailed interoperability goals. Despite our observed advantages, this individual approach shall be interpreted as an exemplary demonstration of applying the DHIIF. It motivates the use of the DHIIF for other distinct DHI projects in similar ways but underlines the need for revision and adaptation.

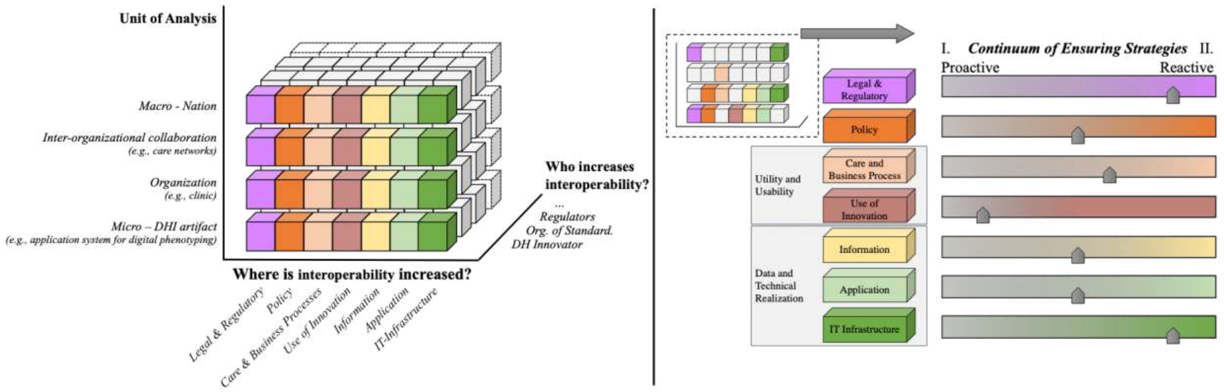

Fig. 4. Left: Framework of mechanism for ensuring interoperability [8] contextualized by DHIIF [9]; Right: Application for distinct DHI project

Table 1. General strategies for ensuring interoperability on each DHIIF Level and exemplary demonstration – Part 1

DHIIF Level	Strategy I – Proactive motivation of change (end of continuum)	Determined strategy for distinct DHI project (Digital Phenotyping MS)	Strategy II – Reactive alignment and compatibility (end of continuum)
Legal & Regulatory	Identification, negotiation and resolving of legal or regulatory conflicts; Involvement in political decision making and lobbying	Macro: Compatibility dominated (e.g., ethical approval, data privacy and security laws, duties of medical device certification process); Micro: Proactive negotiation of specific patient-related, data-centered value proposition	Identification of and alignment with appropriate laws and regulations; Fulfillment of duties and potential DHI redesign;
Policy	Definition of revolutionary business model and bi- or multilateral negotiations as well as contracting with small room for compromises	Low priority – Organization & Micro: Balanced strategy regarding preparations and negotiations of business model, terms of conditions and business collaborations with compatibility to hospital policies	Embedding in or enhancement of existing policy structures; Alignment with established and standardized remuneration models; Passive policy negotiations
Care & Business Processes	Reconfiguration of existing or definition and implementation of new processes (care, administration, business, coordination) due to DHI's integration in specific setting	(Inter-)Organizational: Balanced strategy where high-level care processes and routines are improved by pathway adaption via machine learning techniques and phenotyping	Identification of and alignment with existing care processes and accompanying procedures; prioritizing continuity of status quo and avoiding processual changes

Table 1. General strategies for ensuring interoperability on each DHIIF Level and exemplary demonstration – Part 2

DHIIF Level	Strategy I – Proactive motivation of change	Applied strategy on Digital Phenotyping Project	Strategy II – Compatibility and reactive alignment
Use of DHI	Realization of new human-technology-interaction scenarios and promotion of intentional and appropriate use by target users	Low priority – Micro: Result representation via existing professional systems and patient portal; Application of explainable AI guides	Design and realization of human-technology-interaction scenarios that are well known by target users
Information	Reuse of standards (data models, formats, terminologies); Definition and application of specifications; Standardization activities	Organization & Micro: Balanced strategy with compatibility to (prospectively) implemented information standards (HL7/MII) in hospital information system and proactive inquiry of sufficient standard implementation in MS system	Identification and reuse of as well as alignment with data models, terminologies and formats applied in target environment
Application	Reuse of communication standards and protocols; Definition and application of new specifications; Standardization activities	Organization & Micro: Balanced strategy with compatibility to (prospectively) implemented communication standards (HL7/MII) in hospital information system and proactive inquiry of sufficient standard implementation in MS system	Identification of and compatibility to technical interface definitions and communication standards applied in target environment
IT-Infrastructure	Identification, negotiation and resolving of infrastructural conflicts (e.g., lack of accessibility or hindering requirements)	Organization & Macro: Compatibility dominated (IT infrastructure of university hospital, nationwide telematic infrastructure and connectivity to research data infrastructure)	Embedding in existing infrastructures; Adjustments of DHI due to given restrictions (opportunities and requirements)

5. Evaluation of DHIIF by Online Survey

Overall, the participants of this small-scale online survey (n=12) confirmed the DHIIF's design and extent. All experts agreed (n=6) or strongly agreed (n=6) with the holistic conceptualization approach for interoperability for DHI. However, the participants assessed the DHIIF's usefulness differentially regarding intended use cases of DHI practice, potential target groups, and its contribution to related research questions (see Table 2). In terms of specific use cases, the DHIIF suits best for describing and structuring interoperability and for providing orientation for DHI project and process management. In contrast, the participants were only moderately convinced of the DHIIF's value in reducing DHI's complexity or project failure rates. Regarding different user groups, the participants underlined that the DHIIF offers valuable support, especially for academia, business professionals responsible for DHI management, domain-specific associations, and standard-setting organizations. For other professions or disciplines (e.g., healthcare providers, insurance, or decision-makers of public health), the DHIIF suit less but might also offer assistance if appropriate explanations are provided or if other target groups are involved within the use of DHIIF. In line with the utility for research-related scenarios and target groups, there are current research questions about interoperability in the era of DHI [8] to which the DHIIF particularly contributes. The participants highlighted gains for the ongoing discourse about the co-evolution of interoperability and strategic rationales in DHI, the determination of a theoretical foundation for studying interoperability in DHI, and its influence on domain issues due to fragmentation.

In additional qualitative feedback, a few participants underlined the DHIIF's benefits of a comprehensive, structured explanation including the consideration of dynamics in adaption and continuous, evolutionary improvement. Here, these persons also criticized the DHIIF's theoretical, complex, and generic nature, so its use for distinct DHI projects might be challenging. Further stakeholder-oriented material, e.g., application guidelines or manuals, was recommended to address the gap between a generic validity of a framework and its utilization in DHI practice. Such material shall also discuss the interrelations of DHIIF components in more detail.

To sum up, this survey confirmed the DHIIF's contribution on both the scientific and the DHI practice side. While the latter requires more nuanced and actionable material, HIS research might directly profit from the proposed socio-technical understanding of interoperability to investigate its impact on increasing success rates of DHI projects and how ensuring mechanisms cause advantages from multiple perspectives.

Table 2. Selected results of a small-scale expert online survey assessing the DHIIF (n=12); * at least one participant did not assess the item

Category Scale	Assessment task / question	Results Avg. [Distribution]
Usefulness for specific use cases (5-level Likert; from "do not agree" – 1 to "fully agree" – 5)	The DHIIF is useful to …	
	… structure interoperability for DHI.	4,42 [0,0,2,3,7]
	… describe the realm of interoperability.	4,42 [0,0,1,5,6]
	… reduce complexity for DHI support.	3,42 [0,3,4,2,3]
	… support the conduction of DHI projects.	4,42 [0,1,2,5,5]
	… manage DHI processes.	4,08 [0,0,3,5,4]
	… reduce failure rate of DHI projects.	3,58 [0,2,3,5,2]
Usefulness for target groups (5-level Likert; from "do not agree" – 1 to "fully agree" – 5)	The DHIIF usefully supports …	
	… medical professionals.	3,42 [0,3,2,6,1]
	… clinical and care management.	3,58 [0,2,3,5,2]
	… economy, esp. medical technology and health IT.	4,08 [0,1,2,4,5]
	… innovation hubs, incubators, and project management.	4,25 [0,1,0,6,5]
	… associations and standard-setting organizations.	4,08 [0,0,3,5,4]
	… public health.	3,36 [0,1,5,5,0]*
	… insurance and other payors.	2,92 [0,3,7,2,0]
	… legal and regulatory.	3,58 [0,2,3,5,2]
	… science.	4,67 [0,0,1,2,9]
Contribution to research questions (3-level Likert; "not all" – 1; "slightly" – 3; "very" – 5)	How does the DHIIF contribute to current research questions [8] of	
	… how does interoperability co-evolve with strategic rationales in DHI?	4,67 [0,2,10]
	… how can interoperability counteract increasing fragmentation?	4,27 [0,4,7]*
	… how does interoperability holistically influence digital business ecosystems underlying DHI?	4,09 [0,5,6]*
	… how can we foster interoperability and DHI while mitigating potential negative effects?	3,00 [2,7,2]*
	… what is the appropriate theoretical foundation for studying interoperability in DHI?	4,40 [0,3,7]*

6. Discussion

6.1. Limitations

The presented results should be interpreted in light of certain limitations. First, this paper only demonstrates one possible way to apply the DHIIF for DHI management support. Here, we observed several advantages for structuring, orientation, and internal communication but the realm of application variations is broad. The contexts of other DHI projects and dynamics within intended target environments require verification of how the DHIIF can be used to support the planning and execution of interoperability tasks in the best possible manner. Therefore, this demonstration shall serve as a reference point for applying the DHIIF as a conceptual basis for diverse DHI projects, manifesting a holistic understanding, and determining adequate strategies and measures to ensure interoperability. Consequently, this paper invites the use of the DHIIF as an aid for DHI management similar to the demonstration above or creatively for other usage scenarios of practice and research. For instance, the DHIIF can be used as a fundament for a self-assessment tool allowing DH innovators to continuously evaluate a DHI's integration capability [10].

Concerning the online survey, the findings shall be interpreted only as indications of a small-scale evaluation due to the number of participants. The DHIIF was introduced in detail by a 30min life or recorded presentation and a written description within the online survey. The participants were thereby comprehensively empowered to assess the DHIIF. However, as presented in this paper, a demonstration of its application was not part of the survey's preparation. A combined evaluation (DHIIF's demonstration, a trial application of DHIIF by participants, and a final assessment of how they used the DHIIF and how they experienced it) is part of future research. It will evaluate the utility and usability of the DHIIF in detail. Nevertheless, the results presented here confirm the study's motivation, intention, and contribution, especially for scientific use and discourse. Additionally, it should be noted that this survey is subject to a German bias, which only slightly affects the study's validity due to its degree of abstraction.

6.2. Conclusion

The relevance and role of interoperability currently change due to the unique characteristics of Digital (Health) Innovations and the ongoing demand for defragmentation in HIS landscapes. Rising streams of data-centricity, inter-organizational care, and inter-sectoral collaborations challenge DH innovators to ensure the DHI's capability to integrate seamlessly into complex target environments. Interoperability transitions to a holistic construct that can guide future DHI projects. This work contributes to related research questions that seek to conceptualize and contextualize interoperability for DHI. It reflects a recently developed framework (the DHIIF), demonstrates its application for structuring and orientation in modern DHI projects, and presents confirming results of a small-scale evaluation conducted via an online survey. Besides the potential for future enrichments of DHIIF to increase suitability for different target groups, the DHIIF provides a valuable conceptual fundament for science and DHI practice.

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Part III
Appendices

Appendix A Complete List of Publications

In Table 19, a list of all publications by the author is provided. The publications are ranked both according to the VHB-JOURQUAL3[14] ranking and the WKWI[15] ranking. If relevant, the impact factor is annotated additionally.

Table 19: Complete list of author's publications.

Publication	Ranking
2022	
H. Schlieter, M. Susky, P. Richter, E. Hickmann, **T. Scheplitz**, M. Burwitz, T. Ziemssen: Die Generation Alpha der Digital Health Innovationen - Eine Fallstudie aus der Versorgung von Multiple Sklerose PatientInnen, In: *HMD Praxis der Wirtschaftsinformatik*, 2022. [accepted]	VHB JQ3: D WKWI: B
T. Scheplitz: Demonstration and Evaluation of the Digital Health Innovation Interoperability Framework, In: Proceedings of *11th International Conference on Health and Social Care Information Systems and Technologies (HCist)*, Lisboa, Portugal, 2022. [acceppted]	–
T. Weimann, **T. Scheplitz**: The PathwAI Framework – Derivation and Demonstration of a Design and Development Aid for Coupling AI and Pathway-based Health Information Systems, In: *Special Issue on Knowledge Representation and Reasoning for Healthcare Processes in Journal of Artificial Intelligence in Medicine*, 2022. [submitted and under review]	– (Impact factor 5,326)
T. Scheplitz, M. Neubauer: Holistic Interoperability From A Dogital Health Innovator‘s Perspective: An Interview Study, In: Proceedings of *35th Bled eConference*, Bled, Slovenia, 2022.	VHB JQ3: – WKWI: C
T. Scheplitz, T. Weimann, und M. Burwitz: PathwAI Systems in Healthcare – a Framework for Coupling AI and Pathway-based Health Information Systems, In Proceedings of *55th Hawaii International Conference on System Sciences (HICSS 2022)*, Jan. 2022. [Online]. `https://hdl.handle.net/10125/79838`.	VHB JQ3: C WKWI: B

[14]JQ3: VHB-JOURQUAL3 (2015):
`https://vhbonline.org/en/vhb4you/vhb-jourqual/vhb-jourqual-3/complete-list`

[15]WKWI: “WI-Orientierungsliste der WKWI” (2008):
`http://www.kaifischbach.net/wkwi/orientierungslisten.pdf`

Table 19: Complete list of author's publications *(continued)*.

Publication	Ranking
T. Scheplitz: Ensuring Socio-technical Interoperability in Digital Health Innovation Processes: An Evaluation Approach, In: Proceedings of the *15th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2022)*, Volume 5: HEALTHINF, Online Streaming, 2022, S. 264–275. doi: 10.5220/0011009800003123.	–
L. Otto, L. Kosmol, **T. Scheplitz**, und H. Schlieter: Be Aware! Indications for Intercultural Awareness for Digital Health Innovations and Innovation Capability, In: Proceedings of the *15th International Joint Conference on Biomedical Engineering Systems and Technologies*, Volume 6: Scale-IT-Up, Online Streaming, 2022, S. 801–811. doi: 10.5220/0011009900003123.	–
2021	
T. Scheplitz: Pathway–Supporting Health Information Systems: A Review, In: *Proceedings of 16th Annual Conference on Health Informatics meets Digital Health (dHealth 2021)*, Published in: Studies in Health Technology and Informatics, D. Hayn, G. Schreier, und M. Baumgartner, Hrsg. IOS Press, 2021. doi: 10.3233/SHTI210093.	–
T. Scheplitz: Pathway Supporting Health Information Systems: Interdisciplinary Goal Integration – A Review, In: *Innovation Through Information Systems*, Cham, 2021, S. 79–87. doi: 10.1007/978-3-030-86790-4_6. [Republished Version in English Language of Pfadunterstützende Health Information Systems: Interdisziplinäre Zielintegration – ein Review]	–
T. Scheplitz: Pfadunterstützende Health Information Systems: Interdisziplinäre Zielintegration – ein Review, In: Proceedings of the *16th International Conference on Wirtschaftsinformatik (WI 2021)*, Feb. 2021, [Online], https://aisel.aisnet.org/wi2021/WCreating/Track04/11.	VHB JQ3: C WKWI: A
R. Hobeck, H. Schlieter, und **T. Scheplitz**: Overcoming Diffusion Barriers of Digital Health Innovations Conception of an Assessment Method, In: *Proceedings of 54th Hawaii International Conference on System Sciences (HICSS 2021)*, 2021, doi: 10.24251/HICSS.2021.443.	JQ3: C WKWI: B
2020	
I. Voigt, M. Benedict, M. Susky, **T. Scheplitz**, S. Frankowitz, R. Kern, O. Müller, H. Schlieter, T. Ziemssen: A digital patient portal for patients with multiple sclerosis, In: *Frontiers in Neurology*, Bd. 11, S. 400, 2020.	– (Impact factor 4,086)

Table 19: Complete list of author's publications *(continued)*.

Publication	Ranking
T. Scheplitz, M. Benedict, H. Schlieter, S. Kaczmarek, und M. Susky: Forschung in Digitalen Innovationsprojekten – zwischen Praxistauglichkeit und wissenschaftlicher Relevanz, In: *HMD Praxis der Wirtschaftsinformatik*, 57(2), 257–273., Feb. 2020, doi: 10.1365/s40702-020-00601-2.	VHB JQ3: D WKWI: B
2019	
T. Scheplitz, S. Kaczmarek, und M. Benedict: The Critical Role of Hospital Information Systems in Digital Health Innovation Projects, In: Proceedings of *IEEE 21st Conference on Business Informatics (CBI)*, Moscow, Russia, Juli 2019, S. 512–521, doi: 10.1109/CBI.2019.00066.	VHB JQ3: – WKWI: B
R. Haase, M. Dominik, M., Benedict, I. Voigt, **T. Scheplitz**, D. Schriefer, R. Kern, M. Susky, M. Wunderlich, K. Akguen, K., others: User-centered development of an integrated disease management portal for patients with multiple sclerosis: results of patient and physician surveys, In: Multiple Sclerosis Journal, London, England, 2019, pp. 350-351.	– (Impact factor 5,855)
M. Benedict, H. Schlieter, M. Burwitz, **T. Scheplitz**, M. Susky, P. Richter, T. Ziemssen: Patientenintegration durch Pfadsysteme. In: T. Ludwig, V. Pipek (eds.), In: Proceedings of the 14th *International Conference on Wirtschaftsinformatik (WI 2019)*, Siegen, Germany: Universitätsverlag Siegen, 2019, pp. 927–941.	VHB JQ3: C WKWI: B
M. Benedict, H. Schlieter, M. Burwitz, **T. Scheplitz**, M. Susky, P. Richter: A Reference Architecture Approach for Pathway-Based Patient Integration. In: Proceedings of the 23rd IEEE *International Enterprise Distributed Object Computing Conference (EDOC 2019)*, Paris, France, 2019, pp. 58–66., doi: 10.1109/EDOC.2019.00017.	VHB JQ3: – WKWI: B
2018	
T. Scheplitz, M. Benedict, und W. Esswein: Patientenkompetenz durch Online-Portale - Eine Funktionsanalyse, In: Proceedings of *Multikonferenz Wirtschaftsinformatik 2018 (MKWI2018)*, Lüneburg, 2018.	VHB JQ3: D WKWI: C

Appendix B Complete List of Conference Presentations

Table 20: Complete list of author's conference presentations.

Presentation title, conference, venue	Date
Demonstration and Evaluation of the Digital Health Innovation Interoperability Framework, *11th International Conference on Health and Social Care Information Systems and Technologies*, Lissabon, Portugal, 2022.	09.06. – 11.11.2022
Holistic Interoperability From A Dogital Health Innovator's Perspective: An Interview Study, *35th Bled eConference*, Bled, Slovenia, 2022.	26.06. – 29.06.2022
Be Aware! Indications for Intercultural Awareness for Digital Health Innovations and Innovation Capability, *15th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2022), Workshop: Scale-IT-Up*, Online.	09.02. – 11.02.2022
Ensuring Socio-technical Interoperability in Digital Health Innovation Processes: An Evaluation Approach, *15th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2022), Sub-Conference: HEALTHINF*, Online.	09.02. – 11.02.2022
PathwAI Systems in Healthcare – a Framework for Coupling AI and Pathway-based Health Information Systems, *55th Hawaii International Conference on System Sciences (HICSS 2022)*, Online.	03.01. – 06.01.2022
Pathway-Supporting Health Information Systems: A Review, *16th Annual Conference on Health Informatics meets Digital Health (dHealth 2021)*, Online.	24.05. – 25.05.2021
Pfadunterstützende Health Information Systems: interdisziplinäre Zielintegration – ein Review, *16th International Conference on Wirtschaftsinformatik (WI 2021)*, Online.	09.03. – 11.03.2021
Overcoming Diffusion Barriers of Digital Health Innovations Conception of an Assessment Method, *54th Hawaii International Conference on System Sciences (HICSS 2021)*, Online.	05.01. – 08.01.2021
The Critical Role of Hospital Information Systems in Digital Health Innovation Projects, *IEEE 21st Conference on Business Informatics (CBI 2019)*, Moscow, Russia.	15.07. – 17.07.2019
Patientenkompetenz durch Online-Portale – Eine Funktionsanalyse *Multikonferenz Wirtschaftsinformatik, (MKWI 2018)*, Lüneburg, Germany	06.03. – 09.03.2018

Appendix C Explanations of ReEIF Levels

Table 21: Description of ReEIF Levels by eHealth Network (2015)

Refined eHealth European Interoperability Framework (ReEIF)	
Legal & Regulatory	On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region.
Policy	On this level, contracts and agreements between organizations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organizations are formalized on the Policy level. In governance documents the governance of collaboration is anchored.
Care Process	After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver the integrated care.
Information	This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.
Applications	On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import using these communication standards. Another aspect in this level is the integration and processing of exchanged information in user-friendly applications.
IT Infrastructure	The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the "generic" interoperability standards and protocols.

Appendix D Legal acts on interoperability in Germany

Table 22: Overview of recent political changes fostering interoperability in Germany

Date	Name and link to reference	Key aspects related to interoperability goals on macro level
Oct 2021	Health-IT-Interoperability-Governance-Regulation (§394a SGB V; GIGV; Gesundheits-IT-Interoperabilitäts-Governance-Verordnung) https://www.bgbl.de	Establishment of coordination agency, expert panel, and situational tasks forces for distinct subjects Enhancement of a national, independent knowledge platform to organize and transparently inform about technical standards, interoperability specifications (e.g., profiles and guidelines), digital applications and telemedical projects
Oct 2021	Health-IT-Interoperability-Regulation (BGBl. I S. 4739; GIV; Gesundheits-IT Interoperabilitäts-Verordnung) https://www.gesetze-im-internet.de/giv/BJNR473900021.html	Mandatory implementation of appropriate interfaces in IT systems of healthcare practitioners, dental care practitioners and clinics to ensure data exchange to personal health records and electronic prescription
Jun 2021	Digital-Healthcare-And-Nursing-Modernization-Act (BGBl. I S. 1309; DVPMG; Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz) http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl121s1309.pdf	Integration of digital nursing applications as prescriptive health interventions Refinement of earlier regulations on prescriptive DH applications strengthening requirements on interoperability Legal preparation of subsequent Health-IT-Interoperability-Governance-Regulation
Oct 2020	Hospital-Futures-Act (KHZG; Krankenhauszukunftsgesetz) https://khzg.de/	Public investment program to promote modernization of hospitals with special focus on emergency capacity, digitalization, and IT-security Funding requires international standards (technological, syntactic, semantic) to ensure internal and external interoperability of digital services
April 2020	Digital-Health-Application-Regulation (BGBl. I S. 768; DIGAV; Digitale-Gesundheitsanwendungen-Verordnung) https://www.gesetze-im-internet.de/digav/BJNR076800020.html	Integration of DH applications as prescriptive health interventions Mandatory statements on standardized specifications to ensure semantic and technical interoperability Definition of a mandatory certification procedure requiring a self-disclosure of DH application provider including items on interoperability Promotion of interoperability principles and provision of references on central interoperability registers, standards and profiles
Dec 2019	Digital-Care-Act (DGV; Digitale-Versorgung-Gesetz) https://www.bundesgesundheitsministerium.de/digitale-versorgung-gesetz.html	Empowerment of Federal Ministry of Health to promote interoperability on legal and regulatory level by: Procedures to determine specifications regarding open and standardized interfaces of healthcare IT systems; Mandatory deadline to their integration and advancement; Definition of to be considered standards, profiles, and guidelines

Appendix E Comparison of foundations of complexity and evolutionary economics and the author's positioning

The Network for Pluralist Economics (German Netzwerk Plurale Ökonomik e.V.,) provide an open-access and bottom-up e-learning platform called "Exploring Economics" (see website via https://www.exploring-economics.org/). Here an international team of scientists, editors, students, and lecturers promote pluralism and innovation in economics for teaching and studying the economic problems of the present. For structuring and comparison reasons, the network refers to three central categories (ontology, epistemology, and axoiology) and selected sub-aspects. With greatest thanks to all contributors, the economic-philosophical positioning of this thesis follows these proposed central questions and aligns generally with fundamentals of complexity and evolutionary economics. The following tables 23, 24, and 25 explain in more detail how the author of this thesis reasons the suitability of the selected economic perspectives for the DH domain and its pursuit of interoperability.

Table 23: Influence of Complexity and Evolutionary Economics on ontological position

Complexity and Evolutionary Economics (Network for Pluralist Economics, 2022)	***Positioning and assumptions of the doctoral thesis related to economical profile***
Central Problem of economy	
Scarcity of (natural) resources; **Uncertainty** of future and fallibility of knowledge; **Change** and dynamics of constantly evolving economic organizations	Scarcity of resources (time, competencies, knowledge, technology etc.) needed for DHI projects; Uncertainty HIS landscapes and fallibility of socio-technological knowledge about design, development, use, and management of DHI; Dynamical transformation of healthcare due to progress in medicine, public health, technology, and business
Focal point for knowledge acquisition	
Meso perspective: Groups and institutions of **economic agents**. Their interactions are shaped by the decisions of other agents as well as institutions such as the rule of law, culture, and markets. Macro perspective: Together, institutions and individuals form a **complex system**. At the same time, the system shapes the institutional structure and human decisions. These elements on their own cannot explain economic phenomena.	Interdisciplinary teams for DHI projects interacting with stakeholders (e.g., healthcare organizations, healthcare professionals, patients, technologists, IT-provider, policy makers, bodies of law and regulations, insurances etc.); Complex target environment for DHI of institutions, organizations, individuals, and existing HIS landscapes
Fundamental assumption about human beings	
Economic subjects (agents) act in a "**boundedly rational**" way. Their rationality is limited by the tractability of the decision problem, the cognitive limitations of their minds, and the time available to make the decision.	Bounded rationality is mainly reasoned by the interdisciplinary complexity of the domain, especially for DHI that inherently strive for novelty in healthcare practice
Dependency on context	
Moderate Contextual: Actors exist as independent entities. Yet there are mechanisms at the context level which influence these actors and their interactions. Interactions are shaped by decisions of other agents as well as institutions and are bounded by environmental constraints.	Agents and interactions related to DHI projects are influenced by other directly involved agents (stakeholders) and contextual circumstances (e.g., political will, changing regulations, culture, infrastructural progress, progress in technology, dynamics in HIS market, pandemical crises)
Understanding of time	
Dynamic: Time is a continuous process and not reversible. There is constant change and no convergence to a fixed point. The present and past states of economic systems rely on its past. The economy becomes a system that evolves procedurally.	Constant change of healthcare system shaped by medical, technological, organizational, societal, and environmental changes as well as their interrelations; Digital Health domain evolves continuously; Specific DHI projects rely on past of related agents

Table 24: Epistemological position influenced by Complexity and Evolutionary Economics

Complexity and Evolutionary Economics (Network for Pluralist Economics, 2022)	***Positioning and assumptions of the doctoral thesis related to economical profile***
Relation of knowledge and object	
Whether strict realistic nor constructivist; There is a "real" world, but also a discursive world in which scientific access to the real world takes place; True complexity as the property of a real-world system means that no model is able to adequately capture all its properties; The assumption of fundamental uncertainty entails that knowledge is hypothetical.	Foundations and contributions of doctoral thesis do not claim absolute and undeniable truth. Instead, acquired knowledge and further contributions provide a reliable but hypothetical model of the DHI reality that captures its relevant properties for the stated scope of this thesis.
Perspective-driven vs. object-driven	
Evolutionary Economics: The objects of inquiry are processes of change, e.g. economic development, innovation, technological or institutional change. Complexity Economics: A certain mode of thought, viewing the world as a complex system, is applied to all sorts of economic problems.	Synergetic balance of both perspective- and objective-driven position; DHI processes and their management as central objects of inquiry; Existing complex, socio-technical HIS landscapes of current and future healthcare reality motivate selected mode of thought.

Table 25: Axiology and values influenced by Complexity and Evolutionary Economics

Complexity and Evolutionary Economics (Network for Pluralist Economics, 2022)	***Positioning and assumptions of the doctoral thesis related to economical profile***
Selected Axioms	
Continuous innovation and adaption; Evolution; Complex systems; Emergence; Path dependency; Heterogeneous agents and population; Uncertainty; Dynamics of imbalance	Complex healthcare systems determine the target environment for and, thus, influence DHI; Healthcare domain is holistically characterized by continuous innovation, adaption, and evolution; Emergence and path dependency apply as phenomena and systematically reason uncertainty and dynamics of imbalance
Inherent Values	
Complexity Economics: Resilience and Transparency of information Evolutionary Economics: Prepare the economy for innovation and change; Enhance research and technology	Contribution of doctoral thesis seeks to prepare agents of healthcare systems, especially innovators, for the complex challenge of DHI; Resulting enhancement of technology-related research increases the transparency of knowledge and promotes resilience of the domain

Appendix F List of Analyzed Literature in P7

Appendix 1 of "Parameters of Socio-technical Interoperability for Digital Health Innovations: An Evaluation Approach"

LIST OF ANALYZED LITERATURE

1. J. Zelmer, K. van Hoof, M. Notarianni, T. van Mierlo, M. Schellenberg, und C. Tannenbaum, „An Assessment Framework for e-Mental Health Apps in Canada: Results of a Modified Delphi Process", *JMIR Mhealth Uhealth*, Bd. 6, Nr. 7, S. e10016, Juli 2018, doi: 10.2196/10016.
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Appendix G Detailed Description of ReEIF-Level for DHI Derived in P7

Appendix 2 of "Parameters of Socio-technical Interoperability for Digital Health Innovations: An Evaluation Approach"

ASPECTS FOR DETAILED DESCRIPTION OF REEIF LEVELS

1 ReEIF Level "Legal & Regulatory"

Input:

"On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region." – original explanation by eHealth Network 2015

Detected Aspects:

Fundamental as well as domain-specific public regulations and laws at regional, national or international level with regard to:

1. Equity
2. Equality
3. Justice
4. Security
5. Liability
6. Privacy
7. Confidentiality
8. Ethics

Derived detailed description:

This level describes fundamental as well as domain-specific public regulations and laws at regional, national or international level with regard to certain rights and values, esp. equity, equality, justice, security, liability, privacy, confidentiality and ethics. They regulate and ensure, among other things, personal rights, medical procedural rules, public structures of healthcare delivery, and data processing conditions. To ensure interoperability in this dimension, DH innovators can take action by identifying relevant regulations and guidelines, ensuring compliance to them, and/or requesting of specific consulting services and advisory.
Ensuring interoperability on the "Legal & Regulatory" level is mostly understood from the innovator's perspective of a specific DHI as being aware of and comply with the current and/or future legal circumstances. Unlinked from a specific DHI project, there might be also opportunities for innovators to participate in design or reformation processes on a legal level depending on an innovator's influence, position and possibilities to invest the required amount of time.

2 ReEIF Level "Policy"

Input:

"On this level, contracts and agreements between organizations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organizations are formalized on the Policy level. In governance documents the governance of collaboration is anchored." – original explanation by eHealth Network 2015

Detected Aspects:

Basic as well as specific guidelines, their manifestation within agreements or contracts and their compliance (governance) regarding …

9. Organizational compatibility 10. Public (national) policies and programs (besides laws and legislative restrictions) 11. liability 12. Sustainability 13. Safety, security & privacy 14. Competencies 15. Quality assurance & management 16. Value presentation 17. Business model 18. Financial/economic efficiency 19. Payment & funding 20. Technical Support	21. Operations and maintenance 22. Working collaborations / cooperation 23. Education & training 24. Licenses 25. Accreditations 26. Change management 27. Stakeholder involvement & management 28. Resistance / willingness 29. Communication

Derived detailed description:

This interoperability level includes basic as well as specific policies or guidelines between organizations, esp. between the organizational background of innovators and contractually involved parties (Clinicians, IT businesses, funding agencies and individuals (e.g., Patient) and their compliance (governance). Also, intraorganizational policies (for instance of single hospitals) are of interest for innovators, as they eventually ensure or inhibit the adoption of a DHI within clinical practice. Those policies need to be clarified, negotiated, documented, communicated and fulfilled by innovators and appropriate parties regarding aspects like: organizational compatibility; liability; sustainability; safety, security and privacy; competencies; quality assurance & management; value propositions; business principles; technical support; operations and maintenance; working collaborations and cooperation; education and training as well as licenses and accreditations.

Ensuring interoperability on the "Policy" level requires, trivially speaking, the negotiation and confirmation of agreements between all involved stakeholders of a DHI. Depending on the specific DHI, its usage context and its innovational degree, this task becomes more or less complex. As policy activities refer to a broad variety of aspects that are also part of other interoperability levels and due to the unknown balance between compatibility to existing policies and the need for new agreements, the required efforts shall be rather over- than underestimated.

3 ReEIF Level "Care Process"

Input:

"After the organizations have agreed to work together, specific care processes are analyzed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver the integrated care." – original explanation by eHealth Network 2015

Detected Aspects:

Subject areas - Change and reorganization of ...	… including definitions and statements about …
30. Workflows 31. Business and care processes 32. Administrative management 33. Care structure 34. Care models 35. Health care programs 36. Care plans 37. Personal interactions 38. Professional communication 39. Behavior (professional, patient) 40. Social interaction	41. Error prevention 42. Liability of practice 43. Competences 44. Cooperation 45. Coordination 46. Risk description
… to ensure properties, esp. …	… and to confirm effects according to …
47. Quality of care 48. Acceptance 49. Accuracy 50. Continuity 51. Appropriateness 52. Validity 53. Timeliness 54. Safety & security 55. Usability, user-friendliness 56. Satisfaction of professionals (user, client) 57. Patient satisfaction (user, client) 58. Patient safety 59. Patient centeredness 60. Customizability 61. Disease specificity 62. Individualization (appropriate and convenient care pathways)	63. Clinical effectiveness and outcome 64. Patient-related outcomes 65. Efficiency and/or quality 66. Process measures 67. Treatment adherence 68. Medication adherence … with inclusion or consideration of 69. Comprehensive description of functionality 70. Needs of primary clients 71. Guidelines of medical practice 72. Relation to regular practice 73. Standards of health practice 74. Effort expectancy 75. Patient engagement 76. User empowerment 77. Education 78. Endorsement

Derived detailed description:

This interoperability level addresses the alignment or reorganization of: workflows of care delivery; business and administrative processes; healthcare models and programs; care plans and pathways as well as personal interaction and communication. This includes (re)definitions and statements about: cooperation; coordination; competences and responsibilities; liability of practice as well as error prevention and risk descriptions. Among others, such alignments or reorganizations aim to ensure: quality of care; accuracy and disease specificity; continuity; validity; safety and security; usability, user-friendliness, acceptance and satisfaction of patients and professionals as well as customizability and individualization. Innovators may support these efforts by confirmation of effects like: clinical effectiveness and outcomes; patient-related outcomes; efficiency and/or quality benefits; process measures; treatment or medication adherence. They therefore should consider or provide: comprehensive description of DHI functionality; guidelines and standards of health practice; deviation in regular practice; patient engagement, user empowerment or education initiatives.
Summing up, the demand for interoperability at the care process level entails a large number of aspects that innovators should address. Based on the concrete needs from care practice, the core process for which a DHI offers a solution must be analyzed intensively. Of particular interest are the questions: How do apply which users the DHI and which people are directly affected by it and how? How does the DHI change the existing core process? Furthermore, dependencies or the influence on accompanying care, administration or business processes must be taken into account. Innovators need to balance whether a DHI should be designed to be compatible with established processes or the design of a DHI and its value proposition requires changes of the status quo.

4 ReEIF Level "Information"

Input:

"This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements." – original explanation by eHealth Network 2015

Detected Aspects:

Aspects of semantic and syntactic interoperability, esp. … 79. Types of data / information 80. Formats of data / information 81. Data structure 82. Data flow 83. Data organization 84. Structured data collection 85. Terminologies 86. Standards … for data and information sets, among others, consisting of … 87. Clinical data 88. Information about decisions 89. System-generated data 90. Timestamp	… to ensure the following characteristics and quality features: 91. Accuracy 92. Comparability 93. Completeness and comprehensiveness 94. Consistency 95. Relevance and value 96. Confidentiality 97. Reliability 98. Integrity

Derived detailed description:

The "Information" level comprises aspects of semantic and syntactic interoperability, esp. data types, formats and structures; data flows; and the use of terminologies and standards. Considered data and information sets typically consist of general health information, clinical data, information about decisions, system-generated data as well as timestamps or log files. Innovators may generally align with existing standards or participate in standardization initiatives to ensure: accuracy; comparability; completeness; comprehensiveness; consistency; relevance and value; confidentiality; reliability as well as integrity.

Ensuring interoperability on the "Information" level requires on the innovator's site the balancing task of: identification and alignment with data models, structures and formats that are determined by the target environment of a DHI; harmonization of those (eventually heterogenous) compatibility requirements with own development; identification and re-use of consented interoperability standards provided by relevant institutions, e.g., HL7 or IHE; and the promotion of standard adoption or initiating standardization processes of new specifications. Reflecting these subtasks, interoperability on "information" level seems to be primarily ensured by compatibility activities especially towards existing semantic and syntactic standards. Nevertheless, a DHI that offers a new solution for an existing problem will probably hit a spot where the state of practice does not offer a health information standard. Here, innovators are able to fill this gap with self-defined specifications and might contribute their achievements to the synergetic community.

5 ReEIF Level "Application"

Input:

"On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import using these communication standards. Another aspect in this level is the integration and processing of exchanged information in user-friendly applications." – original explanation by eHealth Network 2015

Detected Aspects:

Agreements and guarantee of subsequent aspects for interconnectivity of distinguished (information and) application systems:

99. Connection services, data exchange (import/ export)
100. Communication standards
101. Unified Terminologies
102. Robustness
103. Sustainability
104. Usability, end-user satisfaction, user acceptance
105. Documentation

Derived detailed description:

The "Application" level comprises agreements and their realization according to interconnectivity of distinguished (information and) application systems, esp. in terms of: interconnection services and data exchange; use of communication standards and unified terminologies to ensure robustness of technical interfaces, sustainability as well as usability of technical interfaces. This generally technical dominated interoperability level does also include human-centered aspects like end-user satisfaction and user acceptance but with a focus on the interconnection of a DHI with other application systems. While the "Care Process" level addresses usability of a DHI itself – simplified as its use without involvement of any other technical system – this level considers usability aspects of DHI within an interconnected, synergetic HIS landscape. For instance, a professional documentation tool for a specific indication can be autonomously usable, intuitive and, thus, valuable but if data exchange with central Electronic Health Record systems is not ensured then double documentation might occur and will decrease user acceptance.

Increasing interoperability on the "Application" level requires knowledge about (potentially) mandatory communication scenarios of a DHI with existing or future application systems. Definition and prioritization of these scenarios are key tasks for innovators before technical interface solutions can be derived and realized. Thereby, innovators are not exclusively responsible on the required realization efforts as changes of the target environment could also foster interoperability, e.g., by supporting communication standards like HL7 FHIR.

6 ReEIF Level "IT Infrastructure"

Input:

"The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the "generic" interoperability standards and protocols." – original explanation by eHealth Network 2015

Detected Aspects:

This Level Includes consideration of the following properties, components, and activities.

Properties:	Components:
106. Availability 107. Capability, Performance 108. Capacity 109. Scalability 110. Reliability 111. Stability 112. Physical safety & security	113. Basic infrastructure (electricity, physical & mobile network etc.)) 114. Hardware (static, mobile) 115. Access and Connection to required Server/ Backend and databases (medical, national etc.) 116. Storage systems 117. Compatible equipement
Activities: 118. Use of technical infrastructure standards and protocols 119. Data protection 120. Validation 121. Failure prevention 122. Maintanance	

Derived detailed description:

Interoperability on "IT-Infrastructure" level includes considerations of specific properties, e.g., availability, performance, capacity, scalability, reliability, stability as well as safety and security of infrastructural components, like basic infrastructure of electricity, physical and mobile communication networks, required hardware, distributed server architectures and physical databases as well as storage units. Activities that may be considered to fulfill interoperability on this level are, among others, the use of technical infrastructure standards and protocols, the establishment of infrastructural data protection measures and validation mechanisms as well as maintenance and failure prevention activities.
Depending on the specific characteristics of a DHI, innovators need to consider infrastructural aspects on international, national, regional or local level. As infrastructures do not change rapidly, innovators shall search for a DHI design that is compatible with existing infrastructures. Thus, specifying the access to required server structures or networks, clarifying how continuity of operations can be ensured and implementing mechanisms to prevent or handle potential failure as well as IT attacks are main tasks.

Appendix H Complete List of Potential Parameters Identified in P7

Appendix 3 of "Parameters of Socio-technical Interoperability for Digital Health Innovations: An Evaluation Approach"

COMPLETE LIST OF POTENTIAL EVALUATION PARAMETERS SORTED BY REEIF LEVEL

1 ReEIF Level "Legal & Regulatory"

Table 1. Complete List of Evaluation Items - ReEIF Level "Legal & Regulatory"

ID	Evaluation Item
LR-01	Have the legal conditions been explicitly determined, have appropriate guidelines been followed, or have specific consulting services been obtained in this regard?
LR-02	Are security guidelines and standards adhered to or specific consulting services obtained in this regard?
LR-03	Is adequate access to information guaranteed?
LR-04	Have relevant accreditation procedures been performed?
LR-05	Is the management of consents implemented?
LR-06	Are legal requirements regarding data standards taken into account?
LR-07	Are national data protection and standardization requirements taken into account?
LR-08	Have the necessary licensing and certification procedures been performed for the deployment?
LR-09	Are guidelines regarding risk-benefit relations adhered to?
LR-10	Are provisions regarding professional accountability defined?
LR-11	Are legal requirements regarding data storage and hosting adhered to?
LR-12	Are legal requirements regarding privacy and data protection adhered to?
LR-13	Is there a potentially necessary affirmative ethical approval?

2 ReEIF Level "Policy"

Table 2. Complete List of Evaluation Items - ReEIF Level "Policy" – Part 1

ID	Evaluation Item
POL-01	Are mutual accountability obligations defined?
POL-02	Has an activity plan been created and adhered to in order to achieve overarching goals?
POL-03	Is the alignment to industry standards ensured?
POL-04	Are client level outcomes (health service delivery) articulated?
POL-05	Are scaling goals articulated or a collaborative scaling up plan defined?
POL-06	Are necessary assumptions and data sources explicitly defined?
POL-07	Is the availability of hardware and software defined and guaranteed?
POL-08	Is the availability of necessary infrastructure defined and guaranteed?
POL-09	Has a benefit-cost analysis been performed?
POL-10	Is the business continuity guaranteed?
POL-11	Has a business model or business plan been defined?
POL-12	Has a change management plan been defined?
POL-13	Has alignment along partner priorities been communicated?
POL-14	Are customer service availability and performance defined?
POL-15	Are business partners and value chains defined?
POL-16	Are delivery mechanisms for training defined?
POL-17	Is transparency of development activities ensured?
POL-18	Are device security policies specified?
POL-19	Are early and iterative technology assessments made by different decision makers?
POL-20	Does a cost declaration exist for the end user?
POL-21	Are payers engaged in the innovation process?
POL-22	Are regulations specified for the use and maintenance of necessary equipment?
POL-23	Have goal statements been agreed upon and communicated?
POL-24	Are guidelines for economic evaluation taken into account?
POL-25	Are health systems-level outcomes articulated?
POL-26	Are the necessary personnel and organizational resources defined and planned?
POL-27	Has an implementation plan been defined?
POL-28	Are interaction scenarios described?
POL-29	Are joint decision-making processes formalized?
POL-30	Are delivery limits defined in terms of scaling up?

Table 3. Complete List of Evaluation Items - ReEIF Level "Policy" – Part 2

ID	Evaluation Item
POL-31	Is technical first level support provided at the local level?
POL-32	Are limitations due to local health system characteristics taken into account?
POL-33	Are local, sociocultural norms taken into account?
POL-34	Is a marketing plan defined?
POL-35	Are mechanisms established to gather partner feedback?
POL-36	Are scaling metrics defined?
POL-37	Are mechanisms established to monitor quality and costs?
POL-38	Have needs of external partnership been determined?
POL-39	Are negotiation plans with partners defined?
POL-40	Are operationalization plans defined?
POL-41	Are partnership relationships defined?
POL-42	Have payers analyses been performed at different levels of the value chain?
POL-43	Is a payment model defined?
POL-44	Is a performance monitoring plan defined?
POL-45	Are measures defined to prevent loss and theft of devices?
POL-46	Are measures defined to prevent misuse?
POL-47	Are procurement activities of software as well as hardware defined?
POL-48	Are cost prognoses prepared in relation to different implementation phases?
POL-49	Has a proof of acceptability been performed?
POL-50	Are protocols in place to address non-compliance and ensure accountability?
POL-51	Are tools/ processes/ platforms offered that allow organizations to conduct self-assessments and build their own capacity for successful change?
POL-52	Are quality agreements with vendors specified?
POL-53	Are regular follow-ups and supportive supervision planned?
POL-54	Are reimbursement policies specified and communicated?
POL-55	Are remuneration policies specified or remuneration alternatives defined?
POL-56	Are mechanisms for replacing lost or damaged devices defined?
POL-57	Are role models defined?
POL-58	Are service level agreements with vendors specified?
POL-59	Are shared assessment models defined and communicated?
POL-60	Are technical support regulations defined?
POL-61	Have potential third-party agreements been determined?
POL-62	Are advanced trainings and peer group trainings planned?
POL-63	Is a training strategy defined?
POL-64	Has a transition plan been drawn up with regard to changes in payers?
POL-65	Is the transparency of information security documented and communicated?
POL-66	Have value chains been analyzed with regard to the key interests of potential payers?

3 ReEIF Level “Care Process”

Table 4. Complete List of Evaluation Items - ReEIF Level "Care Process" – Part 1

ID	Evaluation Item
CP-01	Is adequate access to the (digital) health service guaranteed?
CP-02	Is access or use guaranteed even during downtimes?
CP-03	Are changes accounted for in assistance processes and decision making?
CP-04	Are changes in health indicators taken into account? (Indicator and/or value)
CP-05	Is clinical safety ensured for patients as well as healthcare providers?
CP-06	Are co-operations between primary and secondary care considered?
CP-07	Are necessary competencies for use ensured?
CP-08	Is compliance to established processes ensured?
CP-09	Are patient pathways / patient journeys / treatment sequences taken into account?
CP-10	Is continuity of care ensured?
CP-11	Are benefits directly embedded in work routines?
CP-12	Is the diversity of skills of users adequately taken into account?
CP-13	Have effects on patient self-management been considered and/or demonstrated?
CP-14	Are effects on clinical outcomes and/or patient behavior considered and/or demonstrated?
CP-15	Are participation mechanisms (empowerment) implemented?
CP-16	Is evidence considered or confirmed for DHI benefits?
CP-17	Are changes in health status attributable to the use of the DHI?
CP-18	Are changes in human resource allocation taken into account?
CP-19	Is DHI functionality warranted for the variety of individual care pathways?
CP-20	Are interfaces to non-healthcare (public) services supported?
CP-21	Are interfaces to other care services supported?
CP-22	Are participatory decision-making processes considered in use scenarios?
CP-23	Have mentoring programs been implemented?
CP-24	Has expectation management been implemented?
CP-25	Are outcome measures considered and implemented?
CP-26	Have patient empowerment measures been implemented?
CP-27	Has consideration been given to how DHI can become routine elements?
CP-28	Were privacy assessments of involved stakeholders taken into account?
CP-29	Is professional collaboration defined across different levels of health care?
CP-30	Is professional access to information adequately guaranteed?

Table 5. Complete List of Evaluation Items - ReEIF Level "Care Process" – Part 2

ID	Evaluation Item
CP-31	Are quality of life measures implemented?
CP-32	Are benefits demonstrated under real-life conditions?
CP-33	Are scientific findings sufficiently referenced and considered?
CP-34	Are seamless transitions between tasks of care ensured?
CP-35	Are security mechanisms implemented for the use of DHI?
CP-36	Is sufficient, actionable information provided for medical as well as organizational decision making?
CP-37	Have any changes in the distribution of tasks been taken into account?
CP-38	Are mechanisms for updating and synchronizing clinical values adequately implemented?
CP-39	Are user engagement measures taken into account and implemented?

4 ReEIF Level "Information"

Table 6. Complete List of Evaluation Items - ReEIF Level "Information"

ID	Evaluation Item
INF-01	Is the provision and/or receiving of actionable information ensured?
INF-02	Is controlled medical vocabulary used and are standards of clinical terminologies adhered to?
INF-03	Has a data accuracy check been implemented?
INF-04	Is data collected and analyzed to audit data flow processes?
INF-05	Has a data assessment and/or validation been implemented?
INF-06	Are requirements data standards and/or standardized data dictionaries implemented?
INF-07	Are data cleaning mechanisms implemented?
INF-08	Are appropriate and sufficient data collection methods (quantitative and/or qualitative) implemented?
INF-09	Is there documentation of data management?
INF-10	Do collected data ensure functionalities of evaluation and reporting?
INF-11	Are further agreements on variables and formats for data exchange adhered to?

5 ReEIF Level “Application”

Table 7. Complete List of Evaluation Items - ReEIF Level "Application" – Part 1

ID	Evaluation Item
APP-01	Is access to intraorganizational electronic medical records ensured?
APP-02	Is access or use guaranteed even during downtimes?
APP-03	Are administrative system interactions implemented?
APP-04	Has a guide to system adoption been created or considered?
APP-05	Is a backup functionality adequately implemented?
APP-06	Are electronic data exchange standards adhered to?
APP-07	Has a conflict check of the system interactions been performed?
APP-08	Are alternatives with mobile clients considered?
APP-09	Are consistent software updates guaranteed?
APP-10	Are scenarios of data sharing across multiple data sources and diverse care settings considered?
APP-11	Are authentication mechanisms of the data origin implemented?
APP-12	Have measures been implemented to ensure data quality?
APP-13	Is the functionality ensured with different operating systems?
APP-14	Is the functionality for different types of devices ensured?
APP-15	Are helpdesk services realized?
APP-16	Is it ensured that information is only transferred to required personnel?
APP-17	Have interfaces for public health services been implemented?
APP-18	Has a documentation of the necessary system interactions been created (system landscape esp. system types)?
APP-19	Has documentation of ideal system interactions been created (system landscape esp. application types and functionalities)?
APP-20	Have logic tests been performed?
APP-21	Are mechanisms implemented to reduce errors and misinterpretations?
APP-22	Are frequencies of synchronization implemented appropriately?
APP-23	Are modification options for local developers taken into account?
APP-24	Are data extraction and export functionalities adequately implemented for the end user?
APP-25	Have existing services been appropriately reused?
APP-26	Are mechanisms for real-time processing adequately implemented?
APP-27	Has role-based access control been implemented?
APP-28	Are security measures implemented for data access?
APP-29	Is evidence of effectiveness confirmed?
APP-30	Are store-and-forward mechanisms adequately implemented
APP-31	Have stress tests been performed and confirmed?
APP-32	Are data and information transfers appropriately timed?

6 ReEIF Level "IT Infrastructure"

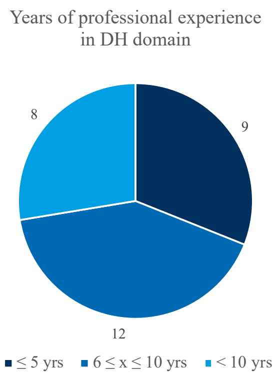
Table 8. Complete List of Evaluation Items - ReEIF Level "IT Infrastructure"

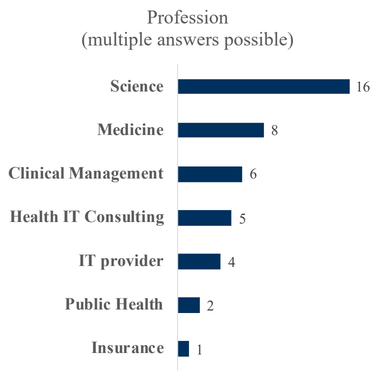
ID	Evaluation Item
ITI-01	Have assessments been made regarding network coverage and electricity security?
ITI-02	Are structures or mechanisms implemented to prevent system overloads?
ITI-03	Are necessary bandwidths determined and guaranteed?
ITI-04	Is the operation of necessary communication network ensured?
ITI-05	Have potential connection and transmission problems to the required networks been considered?
ITI-06	Is it ensured that latency periods do not exceed a reasonable duration?
ITI-07	Are archiving mechanisms guaranteed infrastructurally?
ITI-08	Are protection and security systems (hacking) implemented?
ITI-09	Is the network performance sufficiently ensured?
ITI-10	Are mechanisms for offline data storage implemented?
ITI-11	Are mechanisms of offline synchronization implemented?
ITI-12	Are open interfaces implemented infrastructurally?
ITI-13	Are the processing capacities sufficiently ensured?
ITI-14	Are provision, setup and maintenance of necessary servers ensured?
ITI-15	Are reference architectures considered or adapted?
ITI-16	Is the security of documentation and data storage guaranteed?
ITI-17	Are security plans, procedures and/or protocols defined for infrastructural aspects?
ITI-18	Are infrastructural standards met?
ITI-19	Are safety and transmission standards considered and implemented?
ITI-20	Are technical architectures described, documented and communicated?

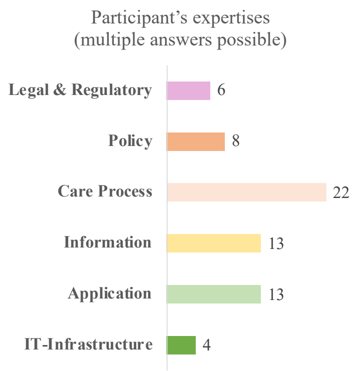
Appendix I Details of Data Sample and Interview Guide of P8

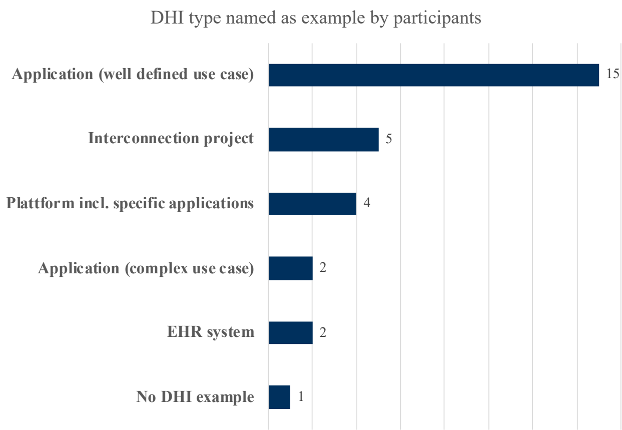
APPENDIX - HOLISTIC INTEROPERABILITY FROM A DIGITAL HEALTH INNOVATOR'S PERSPECTIVE: AN INTERVIEW STUDY

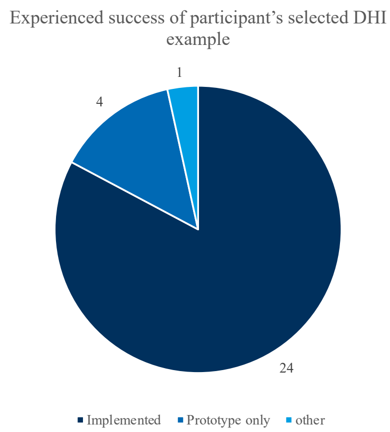
1 Data Sample Details











2 Interview Guideline

ID	Question	Intention and Expectations
0. Introduction		
0.1	No Questions	Welcoming; short presentation of research interest, motivation, few definitions and information about procedure of interview;
0.2	What do you understand by the term "interoperability"?	Participant's understanding of interoperability without influence by interviewer; socio-technical or technical interpretation
0.3	No Question	Initial definition of interoperability, Initial introduction of ReEIF
0.4	How well does this structure encompass the activities of innovation processes in digital health?	Participant's first impression about utility of ReEIF for structuring Digital Health Innovation activities; overall assessment and critique
0.5	Which of the levels depicted here should receive the most attention within an innovation process?	Participant's first thoughts about which level needs most intention; assumption: all levels are relevant but differ in required efforts
1. Experience		
1.1	Please describe a digital health innovation briefly for which you have played a key role in the past. (Care context; Value proposition(s); novel component)	Switch from an abstract level of discussion to a specific example; make participant comfortable by talking about own experience; What kind of DHI is participant familiar with
1.2	How do you assess the success of this innovation process? a) Was it possible to realize the innovation? b) Could the innovation be integrated into healthcare practice?	Increasing awareness about differentiation of successful development and successful translation into practice; indication if participant speaks about positive or negative experiences
1.3	When you think about the development process of the innovation you just described, which activities do you think were most critical to success?	Mentioning critical activities for successful translation into practice of selected example (negative or positive); Interviewer makes notes to provide named activities in further question
2. Advices for future projects		
2.1	Which activities are or will be most critical to ensure the success of integrating a Digital Health Innovation into healthcare practice?	Switch back to generic point of view for future projects (maybe circumstances changed); Mentioning critical activities for successful translation of a DHI into practice Interviewer makes notes to provide named activities in further question
2.2	What recommendations can you make regarding process models or the scheduling of the activities mentioned for successful digital health innovation processes?	Switch to processual perspective; termination of named activities or tasks related to the introduced levels of ReEIF; thoughts about sequential or agile innovation processes in the domain
2.3	In your opinion, where are the critical success factors for integrating a digital health innovation into healthcare practice? (Scale from 1 "technical only" to 10 "non-technical only")	Simplified scale for provoking the participant to decide whether he/she sees the crucial activities in technical or non-technical aspects; indication of need for useful support
2.4	No Question	Presentation of ReEIF Framework in more Detail; definition and intention of each ReEIF level; highlighting organizational perspective of ReEIF but assumed adaptability for DHI integration
2.5	We have just talked about challenges or tasks that are critical to success: To which levels would you assign them?	Assigning named activities (1.3; 2.1); show slides of Level definition if needed; no corrections by interviewer except requested by participant

2.6	Would you like to name any other tasks (or challenges) that are critical to success?	Additions to prior questions after recent discussion; assigning to ReEIF Level if possible
2.7	What actions can or should innovators take to ensure interoperability on these levels?	Switch to tangible action that innovators can do for ensuring interoperability – answer so far may tend to be more abstract
2.8	How good or bad do you rate the measures just mentioned in terms of their feasibility from an innovator's perspective?	If tangible actions can be named by the participant the may also have an idea about how easy or tough these activities can be conducted by innovators; need for support
2.9	How challenging a measure is perceived may be related to the power of influence on the innovator side. How do you assess the power of innovators to influence interoperability per level?	Influence in general on ensuring interoperability; Discussion about Dominance of innovator's influence – Do the target environment dictate requirements that have to be fulfilled by DHI or does DHI motivate changes in target environment; do the participants see differences in these thoughts between ReEIF levels?
2.10	How well does this structure (ReEIF) encompass the activities of innovation processes in digital health?	Same question as 0.4; did participant changed its view on it due to interview? Participant's impression about utility of ReEIF for structuring Digital Health Innovation activies; overall assessment and critique
2.11	Which of the levels depicted here should receive the most attention within an innovation process?	Same question as 0.5; did participant changed its view on it due to interview? Participant's first thoughts about which level needs most intention; assumption: all levels are relevant but differ in required efforts
3. Participant Characteristics		
3.1	How long have you been professionally involved in digital health?	Data for data sample characterization; potentially used for combination analysis
3.2	Which actor group (role) would you most likely assign yourself to today? (a) Science; b) IT practice; c) Health IT Consulting; d) Medicine / Responsible for clinical IT-Innovation; e) Health system Manager / Clinical CEO or CIO; f) Decision maker / representative of the public; g) Decision makers of insurances or other payer organizations; h) other)	Data for data sample characterization; potentially used for combination analysis
3.3	In which of the interoperability levels discussed do you see your main competencies and areas of responsibility? (Legal & Regulatory; Policy; Care Process; Information; Applications; IT-Infrastructure)	Data for data sample characterization; potentially used for combination analysis
Farewell and Feedback		

Declaration of Authorship

I hereby certify that this thesis has been composed by me and is based on my own work, unless stated otherwise. No other person's work has been used without due acknowledgement in this thesis. All references and verbatim extracts have been quoted, and all sources of information, including graphs and data sets, have been specifically acknowledged.

Dresden, the 23rd March 2023