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.

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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

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

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 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

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

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.

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.

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.

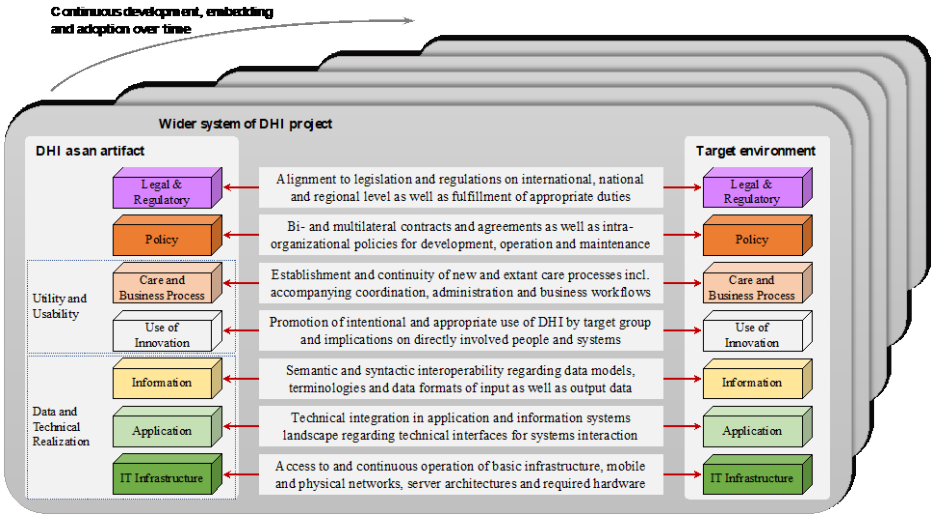

Figure 3: Digital Health Innovation Interoperability Framework

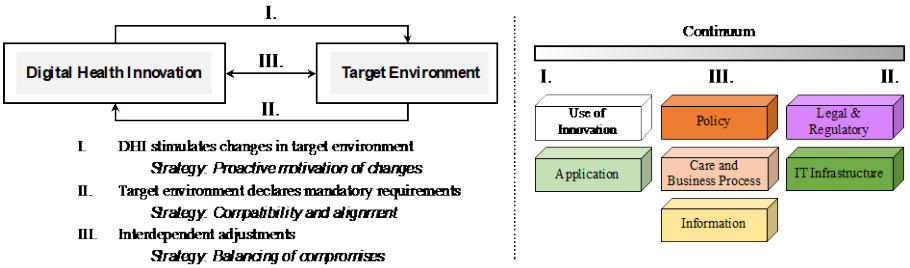

Figure 4: Dominance in Interoperability and indications on ensuring strategies

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.

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