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

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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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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.

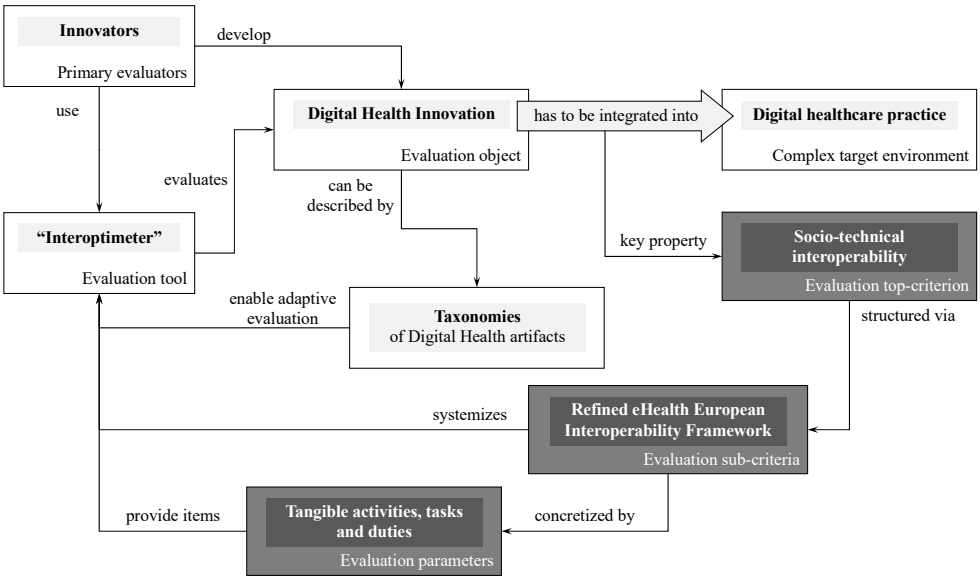

Figure 1: Paper's focus (dark gray) within concept of the "Interoptimeter" evaluation tool.

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

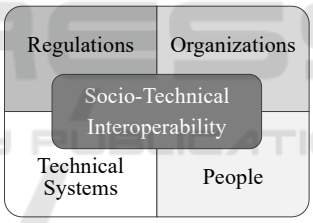

Figure 2: Construct of socio-technical interoperability.

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.

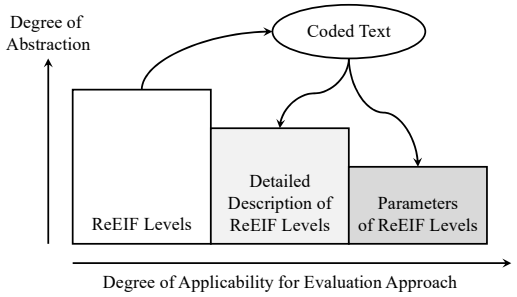

Figure 4: Objectives of QCA.

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.

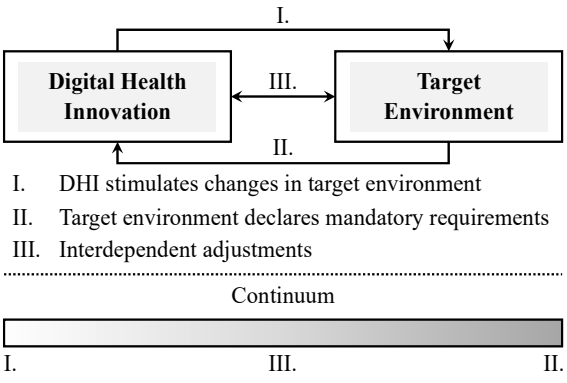

Figure 5: Principles of Dominance in Interoperability.

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

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