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LET'S GET PHYSIC(AI)L – TRANSFORMING AI-REQUIREMENTS OF HEALTHCARE INTO DESIGN PRINCIPLES

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Research in Progress

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Abstract

As healthcare's digitization advances, artificial intelligence (AI) techniques offer opportunities to improve medical care. In addition to the much-discussed potential in diagnostics, AI-based systems can further support processes in clinics or comparable healthcare facilities, helping to improve medical, organizational, and administrative processes. Nevertheless, apart from single use-cases, AI in healthcare is still not unleashing its full potential. To empower the technology and provide a guideline for developers but also other entities such as medical institutions, we derive and plan to validate design principles guiding the design of AI-based systems specifically operating in clinics and healthcare facilities. In this research in progress study, we conduct the first two phases of the DSR approach by identifying requirements in literature and transforming these into design principles. By doing so, we provide a collection of literature-based design principles that need to be considered when implementing AI-based systems into healthcare contexts.

Keywords: Healthcare, AI-based Systems, Requirements, Design Principles

1 Introduction

During the last decade, artificial intelligence (AI) and specifically machine learning (ML) resurged as innovative technologies (Yu et al., 2018) and are expected to transform landscapes of tasks that are considered suitable for this technology (Brynjolfsson and Mitchell, 2017). While the term AI remains an abstract concept, the techniques behind AI, such as ML, natural language processing (NLP), and computer vision, are diverse and embedded into all kinds of contexts. The potential benefits of AI-based systems are investigated, for example, in healthcare (Hamet and Tremblay, 2017), where deep learning networks are employed for computer vision in areas such as cardiology or pathology (Esteva et al., 2021).

Nevertheless, the context of healthcare remains a challenging environment for AI. Supportive for AI implementations is the emergence and increase in health data, which can be used to train AI technologies. This is due to the ongoing digitalization in this domain (Belle et al., 2015; Adibuzzaman et al., 2018), especially the adoption of Electronic Health Records (EHR) (Wang et al., 2018). Due to the nature of AI and its reliance on statistical methods, most applications will likely never achieve an accuracy of 100% (Brynjolfsson and Mitchell, 2017). Thus, AI regularly produces errors (Amershi et al., 2019) that are often unpredictable for humans (Yang et al., 2020). This is critical for the domain of healthcare because it is a tangled environment where highly critical information is processed, and decisions based on incorrect information can cause a direct impact on a patient's health (Holzinger et al., 2007). Hence, for a successful and safe implementation of AI-based systems in healthcare, we argue that developers must consider a wide range of requirements from different sources such as medical staff or regulations from legal institutions (e.g., laws). For instance, in the European Union, AI-based systems in healthcare are required to implement a human-in-the-loop approach to ensure correct system behavior by the General Data Protection Regulation (GDPR) (Schneeberger et al., 2020). While this is a non-negotiable requirement, there are also soft requirements such as establishing users' trust in the AI-based system to ensure their acceptance (Petitgand et al., 2020; Wang et al., 2020; Lockey et al., 2021). Furthermore, research suggests that the sole indicator of the accuracy of AI algorithms is probably not an ideal metric to evaluate clinical AI-based systems (Kelly et al., 2019).

Drawing on the tension between the emerging requirements of AI and the special requirements of healthcare on information, we argue that an overview of critical requirements and their possible design solutions for AI-based systems in healthcare is strongly needed. Aside from the practical relevance for developers, this overview also helps future researchers to match their research to the overall topics of AI in healthcare.

To better understand the requirements that AI-based systems in healthcare face and how these requirements can be instantiated, we apply the design science research methodology (Gregor and Hevner, 2013; Gregor et al., 2020; Peffers et al., 2020). We derive and validate design principles to provide a guideline for future developers. With this research in progress, we aim to contribute towards two different goals. First, we investigate what requirements AI-based systems in the context of healthcare need to be considered. Second, we transform these requirements into applicable design principles to specify and formulate design knowledge for practical application. Hence, this paper aims to answer the following research questions:

> ***RQ1:*** *Which requirements need to be considered when implementing AI-based systems in healthcare?*
>
> ***RQ2:*** *What are design principles for an AI-based system in healthcare that help to comply with existing requirements?*

Our research process can be described as a DSR approach and is split into different phases. First, a literature review is conducted to derive the requirements discussed in the previous research. Then, these requirements are transformed into concrete design principles, utilizing the design principle anatomy of Gregor et al. (2020). Last, we aim to validate these design principles in multiple cycles with experts in healthcare and present our findings. This paper is structured as follows: the relevant theoretical background is examined in section 2. The concrete methodology, including the research process, is presented in section 3. This is followed by the preliminary (and shortened) findings of the conducted literature review and the transformation into design principles in section 4. The last section outlines subsequent steps and possible limitations of our work once completed.

2 AI-based Systems in Healthcare

There is broad discussion and inconsistency for defining the concept of 'AI'. Focusing on the aspect of 'intelligence,' AI can be described as an entity that can interpret, learn and adapt from data, i.e., from information (Kaplan and Haenlein, 2019; Davenport et al., 2020) and tries to imitate the cognitive processes of humans (Syam and Sharma, 2018). In general, AI is associated with the ability to perform tasks that were usually solved by humans (Wang, 2008). During the last few years, AI proved to perform better in certain tasks than humans, and its various advantages have been acknowledged by scientific research (Asan et al., 2020; Lai et al., 2021). Meanwhile, AI is considered a general-purpose technology, underpinning its importance as an innovation driver, and is increasingly embedded into different tasks that are considered suitable for AI (Brynjolfsson and Mitchell, 2017).

To achieve this, AI comprises building blocks that are applied depending on the task. Some of these are based on ML techniques, natural language processing, computer vision, deep learning, robotics, and rule-based expert systems (Vemuri, 2020). Nevertheless, ML is one of the major techniques of AI (Jiang et al., 2017; Meskó et al., 2018; Davenport and Kalakota, 2019) and, in contrast to 'traditional systems,' ML algorithms learn from data and detect reoccurring patterns in it (Meskó et al., 2018; He et al., 2019). Mitchell (1997) provides the following definition for ML, "A computer program is said to learn from experience E with respect to some class of tasks T and performance measure P, if its performance at tasks in T, as measured by P, improves with experience E" (Mitchell, 1997, p. 2). Using the provided definitions, we define an AI-based system as a system where one of the techniques of AI is used as the main components of the system.

AI-based systems in healthcare are typically associated with the application area of disease detection, where it is employed in various forms to detect diseases in images or free texts and support medical experts at decision making (Yu et al., 2018; Davenport and Kalakota, 2019). Apart from this application area, they identify patient engagement and the capability of AI to deliver individualized treatments and patient care as another promising use case. Finally, AI could be used in administrative applications to automate tasks such as clinical documentation or medical treatment management (Davenport and Kalakota, 2019). To the best of our knowledge, previous research of human-AI collaboration in healthcare focused on visual disease detection (e.g., Calisto et al., 2020, 2021),

3 Methodology

In this study, we propose a five-phase DSR-approach (see Figure 1) by following the proposed DSR process of Peffers (2020). A systematic literature review (Webster and Watson, 2002) is carried out to identify the problem (requirements) for AI-based systems in healthcare. Moreover, we supplement this process by replacing the second phase of Peffers (define objectives of solution) with the proposed formulation of design principles from Gregor et al. (2020). We follow the approach of Gregor et al. (2020) due to their innovative approach for formulating design principles and addressing different entities such as implementers, enactors, or users. Building on this, we aim to instantiate these design principles in an AI-based system for information extraction based in NLP. Such systems can, for example, support clinical administrative processes by recognizing relevant information out of texts (e.g., medical records). Focus groups will be used to gather feedback and incorporate it into the designs (Phase 3). Phase 4 aims to evaluate the design principles (to validate their relevance and correctness) and their instantiation in the form of concrete designs (design of phase 3). Phase 5 aims to derive level two contributions (i.e., design principles) (Gregor and Hevner, 2013) to create AI-based systems in healthcare.

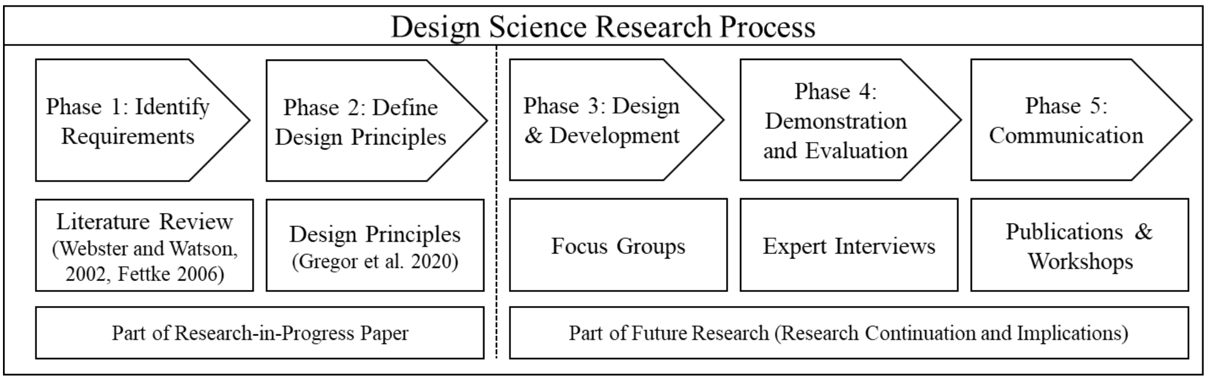

Figure 1. Research Process, based on Peffers et al. (2020).

3.1 Literature Review

The literature review is conducted based on the proposed methodology of Webster and Watson (2002). According to the authors, the primary goal of a literature review is to observe a specified research field and synthesize its current state and findings. Thereby, literature reviews contribute to consolidating the current state of a research field and identifying future research directions (Webster and Watson, 2002). Moreover, we focus our research on representative works and conduct a non-exhaustive literature review which can be one selection strategy according to Fettke et al. (2006). We argue that it is sufficient to identify the central requirements. Last but not least, we plan to iteratively create categories for the requirements that emerge by synthesizing the reviewed literature.

3.2 Design Principles

Gregor et al. (2020) provide a framework for defining so-called design principles for artifacts. These design principles aim to make requirements accessible by formulating them in a specific pattern and simplifying the creation of artifacts (Gregor et al., 2020). The first section of a design principle describes the aim, the implementer, and the user who shall achieve the aim. The second section (context) refers to the environmental boundaries, which can be “conditions, implementation setting, further user characteristics” (Gregor et al., 2020, p. 1633), and narrow down the use case. Then, mechanisms are employed; these are mainly actions and manipulation of artifacts necessary to achieve the described aim. These mechanisms are performed by enactors that are connected to them. In the end, a rationale shall be described, which supports the requirement and explain why the design principle was employed on a theoretical or empirical basis. Moreover, the framework allows design principles to have subordinate design principles upon which to build.

3.3 Validation of Design Principles

We suggest conducting two phases to validate the design principles and their instantiations. First, a focus group discussion (Morgan, 1997) will be employed with medical staff to gather relevant requirements and match them with the literature-based requirements. Afterward, we discuss the literature-based requirements and the resulting design principles.

Second, expert interviews will be carried out. The method of an expert interview was specifically chosen because it allows us to get detailed feedback for the formulated design principles and the instantiated designs (Bogner et al., 2009). An expert can be defined as a person who has more knowledge than others in the field of interest (Meuser and Nagel, 2009). In our context, medical staff is considered experts because they work in the field of interest (healthcare) and are potential users. We plan to interview physicians as well as nurses and administrative personnel. We plan to apply the qualitative content analysis following Mayring (2015) to process the interviews further, allowing us to assort information gathered from the expert interviews into categories. In general, information is encoded to unify statements and group them according to their content. The gained insights from this proceeding are then used to validate or adapt the design principles. The validation part is not covered in this research in progress and will be carried out at the beginning of 2022.

4 Preliminary Findings

4.1 Literature-based Requirements

Studies concerning the application of AI in healthcare are scattered across different disciplines and keywords. Hence, it was decided to use the following databases: The Association for Information Systems, which includes some of the most valued journals and conferences in the information systems community; PubMed, which was specifically selected since it is the largest database for healthcare-related research; Web of Science which is a meta-database that comprises a plethora of databases to minimize the risk of missing relevant works.

The titles of the initially found 3,303 articles were screened (see Table 1), and 127 articles were considered suitable for full-text screening. This low number of suitable titles can be explained by the high number of articles that focus on the performance of AI algorithms (which we explicitly exclude from our literature review). During the full-text screening, 16 relevant articles were found for this research. Moreover, three articles were added by conducting a forward and backward search. Thus, 19 articles are included in this literature review, aiming to identify reoccurring requirements covered by multiple articles.

Database	Search strings	Initial hits
Association for Information Systems	abstract:(Artificial Intelligence OR AI) AND (Healthcare OR Medicine)	181
PubMed	((AI[Title/Abstract]) OR (Artificial Intelligence [Title/Abstract])) AND ((Healthcare[Title/Abstract]) OR (Medicine[Title/Abstract]))	1,340
Web of Science	(TS=(Artificial Intelligence OR AI)) AND TS=(Medicine OR Healthcare)	1,782

Table 1. Databases and Search Strings of the Literature Review.

Our literature review indicates that AI-based systems in healthcare need to consider nine requirements in total, which can be grouped into three categories. The identified categories will be described in a shortened version. The applied concept matrix (Webster and Watson, 2002) shows the identified requirements and their respective categories.

Articles	Requirements								
	Reliability			**Functionality**			**Laws and Ethics**		
	AI-Performance	Explain-ability	Trust	Control	Usability	Interoperability	Liability	Security & Privacy	Ethical behavior
Pétitgand et al. 2020	X		X		X	X			
Holzinger et al., 2017		X		X			X	X	
Lockey et al., 2021		X		X					
Fotopoulos et al., 2021		X							
Reddy et al. 2020		X					X		
Roski et al., 2021			X						
Amann et al. 2020	X	X					X	X	X
Davenport and Kalakota 2019		X			X	X			
Longo et al. 2020		X		X				X	
Schneeberger et al. 2020		X		X				X	
Asan et al. 2020			X						
Velupillai et al., 2018	X				X				
Longoni et al. 2021	X		X	X					
Kelly et al. 2019		X		X					X
Challen et al. 2019				X					X
Longoni et al., 2019		X						X	X
Yu et al. 2018		X		X		X		X	
Reddy et al. 2019		X	X				X		X
Gerke et al., 2020	X	X					X	X	X

Table 2. Concept Matrix Structuring Analyzed Literature.

The first category, *reliability*, includes requirements that need to be fulfilled to enable human-AI collaboration. AI-Performance is important for medical staff to rely on and trust the AI-based system (**R1**) (Wang et al., 2020). Moreover, explainability is crucial to investigate the reliability of the system and important for medical staff to be able to comprehend the results of the system and to be able to detect possible errors caused by the AI (**R2**) (Amann et al., 2020; Reddy et al., 2020; Lockey et al., 2021). The reviewed literature also indicates that explainability and performance are contradictory requirements, as the least explainable and transparent models tend to perform best (Lockey et al., 2021). Lastly, trust is added to this category because it influences the interaction of humans and AI. Additionally, trust is relevant for AI in healthcare on an individual level and an organizational level (Roski et al., 2021). Literature suggests that a certain level of trust is needed to implement an AI-based system in healthcare (R3) successfully. Nevertheless, trust can also have negative impacts if it is too low (non-usage of the AI-based system) or too high (overly relying on the AI-based system) (Asan et al., 2020; Petitgand et al., 2020).

The second category, *functionality,* comprises requirements that are functions and characteristics an AI-based system needs in the context of healthcare. The first requirement is control (**R4**), which demands the ability of humans to be able to intervene in the workings of the AI-based system (Holzinger et al., 2017; Lockey et al., 2021). This is also implicated by articles investigating risk assessments of AI-based systems (Challen et al., 2019). One central aspect of control is integrating a human-in-the-loop approach (Kieseberg et al., 2016; Schneeberger et al., 2020) which is a prerequisite for deploying AI-based systems in healthcare. The requirement of usability (**R5**) is demanded to enable medical staff to use the system in production and be able to understand presented information by the system (Velupillai et al., 2018; Petitgand et al., 2020). Last but not least, interoperability (**R6**) is needed to successfully integrate the AI-based system into the existing IT landscape of the medical institution (Yu et al., 2018; Davenport and Kalakota, 2019; Petitgand et al., 2020). Petitgand et al. (2020) describe a case study where missing interoperability between a health information system and an AI-based system reduced physicians' usage because the AI-based system was not properly integrated into the workflow.

The third category, *laws and ethics,* includes regulations and moral behavior with which the solutions must comply. The first requirement in this category, liability (**R7**), describes the issue that it has to be declared who is responsible for the results of the machine (Gerke et al., 2020; Reddy et al., 2020). Different actors qualify for this: the application's creators, the supervising medical staff, or the hospital director. However, Schneeberger et al. (2020) emphasize the duality of liability, including the possible non-use of AI. This implies that if AI gains superiority (in terms of performance) in certain tasks, then healthcare providers would also be liable for not using AI (Amann et al., 2020). Additionally, AI-based systems must ensure patient information privacy and data security (**R8**). This is a general requirement for information systems in the context of healthcare (Palvia et al., 2012) and is not specific to AI. According to the GDPR, the processing system must cover and protect patients' privacy (Schneeberger et al., 2020). The GDPR also restricts the usage of black-box models to those where mechanisms can be employed to explain why a specific result was produced by the AI-enabled system (Holzinger et al., 2017). Apart from laws that regulate patients' privacy, a lack of privacy can also contribute to users' distrust (Reddy et al., 2020). Last, ethical behavior (**R9**) strives for an unbiased and not discriminating AI algorithm (Kelly et al., 2019; Reddy et al., 2020; Wang et al., 2020). For example, AI algorithms can be biased by the data they are trained on if the data only covers a specific population (Schneeberger et al., 2020).

4.2 Transformation into Design Principles

Following the proposed methodology of Gregor et al. (2020), the next phase transforms the literature-based requirements into design principles. In total, we generated six design principles from the requirements. The lower number of design principles can be explained by the fact that some requirements point towards the same design solution but from different perspectives (e.g., legal and medical staff perspectives) (see Figure 2). The design principles are confirmed through initial expert interviews with medical experts.

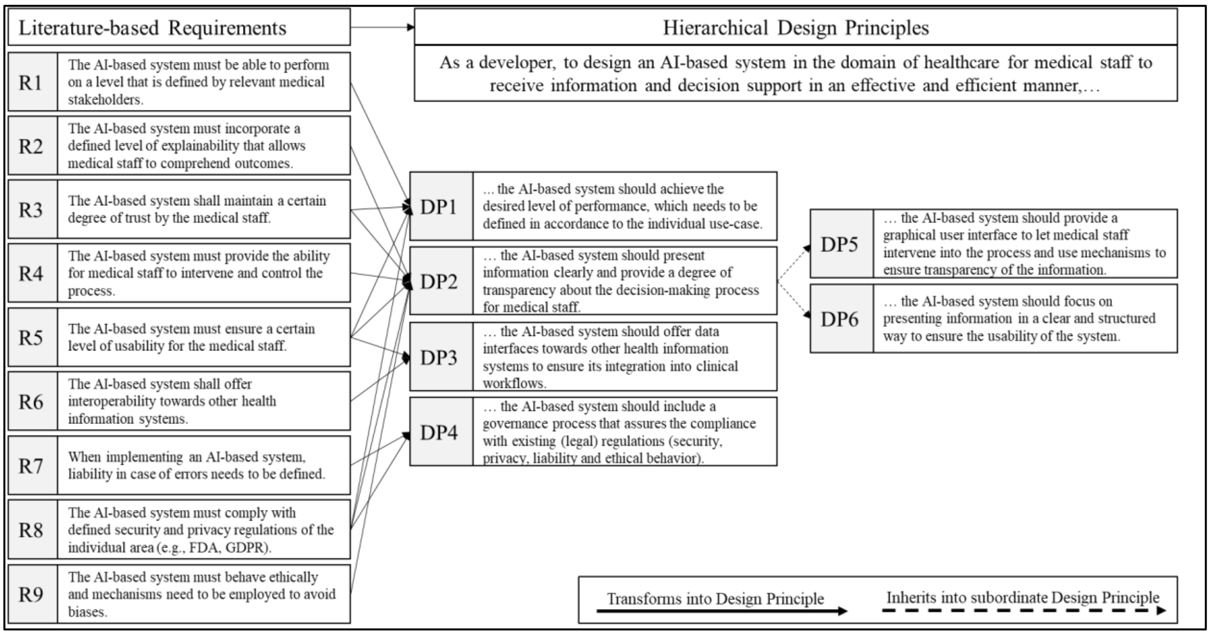

Figure 2. Transformation of Literature-based Requirements into Hierarchical Design Principles.

The first design principle (**DP1**) is based on the requirements R1, R3, and R5. The reviewed literature indicates that a certain level of performance is needed for AI-based systems to be accepted as useful by medical staff (Petitgand et al., 2020). Moreover, trust itself cannot be established but is partially introduced by the high performance of the AI-based system. Thus, DP1 defines that an AI-based system needs to achieve an appropriate and predefined level of performance (depending on the use case). The second design principle (**DP2**) states that the AI-based system should provide transparency about the decision-making process to ensure the comprehensibility of the results and is based on R2, R3, R5, R8, and R9. The DP2 has subordinate design principles that need to be fulfilled in order to be able to realize DP2. First, a graphical user interface is a prerequisite (for most applications) to increase the transparency of the AI-based system (**DP5**). Moreover, information should be communicated clearly and structured to medical staff (**DP6**). Additionally, AI-based systems in healthcare need to provide the ability for medical staff to control the process and intervene if needed (DP5). This is a direct requirement (R4) due to the mentioned critical impact on patients' health if decisions are based on incorrect information. R8 also demands the ability to control the process due to legal regulations (e.g., GDPR). The next design principle (**DP3**) states that an AI-based system must be able to be integrated into the clinical workflow and thus offer interoperability (R6) through interfaces to other health information systems. Moreover, the literature provides evidence that an (AI-based) system needs to be integrated into the clinical workflow to be considered usable by medical staff (R5). The last design principle (**DP4**) demands that a governance model should be implemented into the AI-based system to monitor its compliance with regulations such as security or privacy laws (e.g., FDA, GDPR) (R8). In addition, a governance model is needed to define superior concepts such as liability (R7).

5 Research Continuation and Implications

Our study aims to derive design principles for AI-based systems in healthcare. The found requirements and derived DPs are not completely new; however, current literature lacks clear and applicable guidelines for developers of AI-based systems. Our preliminary results contribute to this research gap by providing design principles that can be used as a guideline to design AI-based systems. By conducting the literature review, we can answer our first research question, "*Which requirements need to be considered when implementing AI-based systems in healthcare?*" and suggest that developers of

AI-based systems need to be aware of a wide range of requirements from different sources. While all named requirements play a significant role in the successful implementation of AI-based systems in healthcare, especially the requirement of explainability (R2) was mentioned very often and is demanded (according to the reviewed literature) by several stakeholders (e.g., medical staff and laws). Moreover, our results indicate that it is not solely the high performance of the AI that is important for successful implementation into healthcare. Additionally, the literature review revealed dependencies and interactions between the requirements (e.g., explainability and performance) that need to be considered when implementing AI-based systems. The application areas of AI in healthcare are highly diverse. Nevertheless, we argue that the derived design principles need to be considered, regardless of in which specific use-case an AI-based system shall be employed. By transforming the design principles into design features, they are generalizable for all AI-based systems in healthcare.

We follow the proposed research process to validate the derived general design principles. The general design principles are transformed into design features to implement them into an artifact in the next step. This artifact will then be validated in two cycles. First, the method of focus groups will be applied to gather feedback. Second, in-depth interviews will be conducted to validate the design features and design principles. Using this validation phase, we will be able to verify or neglect the general design principles. Once the research process is completed, we can answer the second research question, "*What are design principles for an AI-based system in healthcare that help to comply with existing requirements?"* and deliver validated design principles (second level contribution according to Gregor and Hevner, (2013)) that should be followed when implementing AI-based systems in healthcare.

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