Master Thesis

Is Germany ready for the European Health Data Space?
An analysis of challenges and potential improvements to patient care and the healthcare system from the perspective of expert groups

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Abstract

In Germany, great potential to improve healthcare through digitalization and better use of data remains untapped. With its proposal for a European Health Data Space (EHDS), the European Commission has elaborated an ambitious foundation that can potentially help to advance healthcare. Many publications have addressed the opportunities of digitalization in healthcare and problems regarding the hesitant implementation in Germany. However, what is missing so far is a current qualitative study of how different key stakeholder groups frame the respective problems and what they expect from the EHDS. To investigate and compare different angles and fill this gap, I conducted expert interviews among five stakeholder groups in Germany. My study included Patient Representatives, Statutory Health Insurance, Policy Makers, Medical Doctors, and the Private Sector. I found that all experts generally favor digital progress in healthcare, provided that several fundamental principles are not compromised. All groups' expressions consistently corresponded to this study's three identified themes: Systemic Characteristics, Perspectives on Health Data, and People Related Themes. But the framing of their views and aims within those themes varies in part greatly.

According to my analysis, the high fragmentation of the health system, powerful self-governing structures, and a lack of political implementation power resulted in a lack of infrastructure. Therefore, the coordination of data collection, storage, and use remains behind its capabilities. Data security and protection were deemed essential by all groups but were also seen as overregulated and a frequent excuse for lack of progress. All stakeholder groups emphasized the importance of patient benefit and patient-centeredness, which Patient Representatives most clearly expressed. The interviewees agreed that time plays a significant role and that set deadlines for the EHDS will not be feasible in Germany. My study shows similarities and differences between and within the groups regarding retrospective problem framing and a future outlook on the EHDS. The findings are consistent with other studies that have looked at digitalization in the German healthcare system and the implementation dynamics of governance approaches in complex systems.

(Keywords: digitalization in healthcare; European Health Data Space; EHDS; health data use; digital health)

List of Abbreviations

BDI	Federation of German Industries
BMG	Federal Ministry of Health
EHDS	European Health Data Space
ePA	Electronic Patient Record
EU	European Union
EXPH	Expert Panel on Effective Ways of Investing in Health
FAIR	Findable, Accessible, Interoperable, Reusable
FDP	Free Democratic Party
FHML	Faculty of Health, Medical and Life Sciences
GDPR	General Data Protection Regulation
GKV-SV	National Association of Statutory Health Insurance Funds
IT	Information Technology
MD	Medical Doctor
MS	Member States
OECD	Organization for Economic Co-operation and Development
PKV	Private health insurance
RKI	Robert Koch Institute
SDGs	Sustainable Development Goals
SHI	Statutory Health Insurance
SPD	Social Democratic Party of Germany
TAPIC	Transparency, Accountability, Participation, Integrity, Capacity
TÜV	Technical inspection associations
UM	Maastricht University
UN	United Nations
WHO	World Health Organization

1 Introduction

Digitalization and the use of health data have enormous potential to enhance patient care and health systems (Pastorino et al., 2019). They offer the possibility to improve prevention and early detection of diseases, treatment, and aftercare of patients (Gopal et al., 2019). Although the German government already laid the initial legal foundation in 2003, digitalization in the healthcare sector has been proceeding slowly in recent years compared to other countries and other sectors (Brandl & Hornuf, 2020; Lemmen, Simic & Stock, 2021). In 2018, Germany was ranked second to last in the Bertelsmann Foundation's digital health index, which assesses the degree of digitalization in the health systems of 17 states of the European Union (EU) and the Organization for Economic Co-operation and Development (OECD) (Thiel et al., 2018). According to a survey on health data infrastructure and governance by the OECD among their members, Germany came last in the area "of key national health datasets available and regularly linked for monitoring and research" (Oderkirk, 2021). Despite the dramatic recent increase in usable health data, efficient use has yet to be achieved (Gopal et al., 2019).

In the legislative period from 2018 to 2021, several legal cornerstones were laid for digital progress in healthcare (Bratan et al., 2022). Nevertheless, their realization is proceeding only hesitantly, and still, numerous opportunities to better use existing health data to improve healthcare remain untapped (Bratan et al., 2022; Messal et al., 2022). The underlying factors for slow progress are manifold, among them the complexity of the German healthcare system (Thomas et al., 2020; Bratan et al., 2022). Although health care systems are generally complex, the German system is also shaped by a long history of federalism and self-governing bodies in health insurance and care, affecting progress (Nohl-Deryk et al., 2018; Federal Ministry of Health (BMG), 2020).

To address the issue of better health data use to a greater extent, the European Commission is pursuing a large-scale project to strengthen healthcare across the EU: The EHDS, which aims to advance the use of primary and secondary data in healthcare delivery, policy, and research (European Commission, 2022). The European Commission's initiative was widely recognized by different stakeholder groups, like the Federation of German Industries (BDI), recognizing the need and underlining the project's potential (BDI, 2021). Together with other European business associations, they highlighted the possibility of the EHDS to "unlock the potential of health data in Europe" (BDI, 2021). Germany's National Association of Statutory Health Insurance Funds (GKV-SV) has already called for expanding European collaboration in 2019 in a position statement (GKV-SV, 2019). However, in the most recent

coalition agreement of the German government concluded at the end of 2021, the EHDS is merely mentioned in a half-sentence in the section on Europe but not at all in the section on "Care and Health" (Social Democratic Party of Germany (SPD), Bündnis 90/Die Grünen, & Free Democratic Party (FDP), 2021). Germany is also not participating in the preceding pilot of the project within the eHealth Digital Service Infrastructure entitled "MyHealth@EU," which is already in operation in many member states (MS) (European Commission, n.d.).

Examining the German healthcare system as a complex system that already faces significant internal challenges, integrating it into the EHDS becomes all the more challenging. The problem examined here thus consists of two components: on the one hand, the untapped potential in Germany in using existing health data and, on the other hand, its integration into the EHDS, another complex system.

Scientific Context

Numerous studies have already been conducted on digitalization in the German healthcare system. Baierlein (2017), for example, identified reasons for slow progress and existing challenges already five years ago. These relate, in particular, to the high fragmentation of the healthcare system in terms of processes and actors, as well as data protection issues (Baierlein, 2017). Nohl-Deryk et al. (2018) identified a lack of readiness and organizational structure for digitalization among self-governing bodies in Germany and the medical workforce. They highlighted insufficient evidence and interoperability as problematic issues (Nohl-Deryk et al., 2018). A study by Lemmen et al. (2021) on systems medicine showed a general openness among German patients to better data use in healthcare. At the same time, concerns about data privacy, reducing individuals to their data, and potential dehumanization were identified (Lemmen et al., 2021). Low data quality can be a risk to the efficient and safe use of digitalization in healthcare, and sophisticated technologies may be susceptible to misuse (Matusiewicz, Pittelkau, & Elmer, 2018). Brönneke and Debatin (2022) have only recently addressed the quality of care connected with digitalization and concluded that respective improvements are generally possible. Bratan et al. (2022) studied development prospects for e-health in Germany and drew comparisons with other countries. Their report resulted in recommendations for action, for example, regarding strengthening interoperability, IT security, and digital health literacy among patients and health professionals (Bratan et al. 2022).

On the European level, Pastorino et al. (2019) found in their exploration of best practice examples that different projects show great potential to strengthen healthcare through better use of data. Previous workshops and studies, moreover, have already addressed the governance of

the EHDS and the prevailing regulations on health data among the MS concerning the General Data Protection Regulation (GDPR) (European Commission, 2021). Accordingly, a system of data unity in Germany is already being developed at the national level (European Commission, 2021). However, to my knowledge, no study has yet examined the status quo of the German healthcare system concerning the EHDS from the prospect of experts from different domains. This gap raises the issue of how, from the perspective of key stakeholder groups, the German healthcare system could be successfully integrated into the EHDS to strengthen patient care and the healthcare system through better use of data.

Research Objective and Questions

This study addresses the knowledge gap raised above. Therefore, I provide early insights into a current matter of social and political importance that concerns all EU citizens. My underlying hypothesis is that the attitudes and motivations of the expert groups towards digitalization in healthcare follow different motives, which I investigated with the first research question of this study. I assume that interrogating the problem framing from different perspectives will significantly help determine what still needs to be done to implement the proposed EHDS successfully. At the same time, the second and third research questions are aimed explicitly at the proposal of the EHDS. The research questions read as follows:

1. How do experts frame the prevailing problem(s) with digitalization in the German healthcare system?
2. What challenges and hurdles do they envision with the implementation of the EHDS?
3. How can patient care and the healthcare system be improved through enhanced data use in the context of the EHDS in Germany?

By interviewing ten experts in the healthcare sector from five different domains, the topic is studied in a multi-faceted manner using qualitative methods. This will be supported by systems thinking, and health systems governance approaches, which can contribute to overcoming complexity (Brinkerhoff & Bossert, 2008). The study's primary purpose is to identify areas of agreement and divergence among the different expert groups to identify and name any internal hurdles of the healthcare system in the context of involvement in the EHDS at an early stage. Therefore, recommendations for action for the groups involved and the European Commission are derived from the findings. This study aims to contribute to the successful preparation and implementation of the EHDS so that patients individually and society as a whole can benefit from its assembly. Therefore, the societal perspective is deliberately included in this study through the inclusion of Patient Representatives. The four

other groups are Statutory Health Insurance (SHI), Policy Makers, Private Sector, and Medical Doctors (MD). Targeting the Sustainable Development Goals of the United Nations (UN), the research project can be assigned to the two goals “3 - Ensure healthy lives and promote well-being for all at all ages” and “9 - Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation” (UN General Assembly, 2015). It is intended to contribute to the development of a reliable, high-quality, sustainable, and resilient cross-border infrastructure (Goal 9) for the promotion of human well-being and the strengthening of the healthcare system (Goal 2) (UN General Assembly, 2015). Therefore, it aims to promote innovation and open up and use new opportunities.

2 Background

2.1 Digitalization in Germany's Healthcare System

Germany is generally known as a pioneer and innovation driver in digitalization in many sectors, such as digital payments and the manufacturing industry, sometimes serving as a role model (Bogner et al., 2016; Brandl & Hornuf, 2020). However, progress in the digitalization of the healthcare system is proceeding relatively slowly (Messal et al., 2022). A brief insight into important specifics, various perspectives, and previous research is given below for a general understanding of its status quo.

In 2003, the Act on the "Modernization of Statutory Health Insurance" in Germany laid the foundation for a forward-looking orientation of the healthcare system; an electronic patient file was already envisaged (Bratan et al., 2022). Today's Gematik[1] was founded in 2005 (Thiel et al., 2018). Back then, its focus was on introducing an electronic health card, but now it encompasses the digitalization of the healthcare system as a whole (Bratan et al., 2022). However, the legislative periods up to 2018 were characterized by too little will to implement and insufficient enforcement (Ex & Amelung, 2018; Nohl-Deryk, 2019). At the same time, digital progress in healthcare in Germany is also highly dependent on the vote of powerful self-governing bodies (Thiel et al., 2018). These power dynamics have also been reflected in the decision-making processes and competencies of Gematik (Bratan et al., 2022). Besides the BMG, the GKV-SV, the German Medical Association, the German Dental Association, the German Hospital Association, the German Pharmacists Association, the National Association of Statutory Health Insurance Physicians, the National Association of Statutory Health Insurance Dentists, and the Association of Private Health Insurers (PKV) are shareholders of the agency (Gematik, 2022). In the legislative period from 2018 to 2021, four new crucial digitalization laws were enacted due to these developments (Bratan et al., 2022). In addition, the federal government acquired a majority stake of 51 percent in Gematik in 2019 to be able to make majority decisions on its own (Bratan et al., 2022).

From the patient's point of view, there is now a considerable range of digital health applications (Federal Institute for Drugs and Medical Devices (BfArM), n.d.). Since October 2020, following approval as a medical device, certain apps can be prescribed on demand according to the "Digital Healthcare Act" (BfArM, n.d.; Bratan et al., 2022). Currently, 33 of these applications are available in the directory of the competent authority (BfArM, n.d.).

[1] Germany's National Agency for Digital Medicine.

Furthermore, the electronic patient record (ePA) was introduced in January 2021, although the usage rate is relatively low (Dönisch, 2022). A study on digital health literacy showed that a high value is attached to it but that there is hardly any substantive discussion of the topic (Samerski & Müller, 2019). An expansion of it, both among patients and organizations, must be strengthened to release more benefits of digitalization (Samerski & Müller, 2019). The innovative power of the Private Sector and the start-up landscape in Germany regarding digitalization in healthcare are considered immense (Bratan et al., 2022). They are promoted by numerous public and private initiatives (Bratan et al., 2022). Manufacturers, industries, and SHIs are identified among the players that tend to drive digitalization (Bratan et al., 2022). In contrast, service providers, practitioners, and patient advocacy groups play a more restraining role (Bratan et al., 2022).

2.2 The European Health Data Space

The European Commission has developed a legal proposal on the EHDS, intended to serve as a legal framework for future health data use across the EU (European Commission, 2022). It aims to improve primary and secondary health data use for prevention, healthcare delivery, policy, and research (European Commission, 2022). The project is intended to encompass all MS to make the EU more capable of action and more resilient to crises (Hendolin, 2021). The proposal published on May 3rd, 2022, is now available for discussion and debate in the Council and the European Parliament (European Commission, 2022). The development process included an impact assessment and public consultation in 2021 (European Commission, 2022).

Primary data is mainly used in patient care and clinical settings to enhance health services (European Commission, 2022). Thus, the EHDS aims to strengthen the rights of all citizens with regard to the availability of and control over their electronic health data (European Commission, 2022). It also provides for a mandatory cross-border infrastructure to enable EU-wide primary use of electronic health data (European Commission, 2022). Secondary data refers primarily to re-using the data for other purposes, such as research, innovation, and policy (European Commission, 2022). Therefore, the proposal specifies establishing rules and mechanisms to support the use of secondary health data (European Commission, 2022). It also seeks to develop a mandatory cross-border infrastructure for secondary data use (European Commission, 2022). Thus, “Health Data Access Bodies” must be established in all MS (European Commission, 2022). So far, national borders and regulations have impeded the cross-border movement of digital health applications (e.g., telemedicine) (European Commission,

2022). There is also limited data on developments and applications of artificial intelligence in healthcare in the EU, which is being addressed by the EHDS (European Commission, 2022).

Regarding data use, the EHDS follows the FAIR principle, which states that data should be findable, accessible, interoperable, and reusable (Wilkinson et al., 2016; European Commission, 2022). These challenges can only be met by adhering to citizens' rights, data protection, and security mechanisms (European Commission, 2022). The pilot project "MyHealth@EU" is already operational in some MS, with patient overviews and electronic prescriptions being exchanged where necessary (European Commission, 2021). The project builds on transparency; here, the patient can see all the data exchanged and with whom (European Commission, 2021). It serves as a precursor to the EHDS and provides valuable insight (European Commission, 2022). Since the EHDS is a project of great magnitude and objective, it is characterized by numerous interrelated challenges and potentials that I will question from the German perspective in this study.

2.3 Theoretical Considerations

Healthcare Systems – Complex Systems

Definitions of complex systems vary depending on the context and application area (Kannampallil et al., 2011). According to Meadows (2008), a complex system always consists of elements, interconnections, and a function or purpose. Kannampallil et al. (2011) speak, on the other hand, of the interrelatedness of components, meaning the influence between them. Concerning healthcare, Plsek and Greenhalgh (2001) refer to complex adaptive systems as collections of individual actors who have the freedom to operate in a way that is not always entirely foreseeable and whose actions are interconnected so that the actions of one actor change the context for other actors.

System thinking can contribute to health system strengthening, with intervention and evaluation playing a major role (Savigny et al., 2009). However, systems thinking itself does not answer the question of what needs to be done to overcome a challenge (Meadows, 2008). Instead, it helps to understand complex interconnections and can thus support the development of appropriate strategies (Meadows, 2008). Accordingly, challenges in complex systems can be seen as opportunities by anticipating them and changing their structure (Meadows, 2008). Reformulating goals or mitigating, reinforcing, or changing feedback loops can help achieve the desired results (Meadows, 2008). Therefore, qualitative analysis of systems can be applied to better understand the core causes of problems and address their complexity (Kiekens, Dierckx de Casterlé & Vandamme, 2022).

Healthcare systems typically involve a great variety of actors, including insurance, multiple professions, public authorities, governments at different levels, and the private sector (Greer, Wismar & Figueras, 2015). Unifying all these actors with an approach, moving them in a common direction, and ensuring that their efforts are aligned despite differing interests is a significant challenge that can be encountered with governance (Greer, Wismar & Figueras, 2015). Thus, governance approaches are one way to face and manage the complexity of such systems and align to a common goal (Greer, Wismar & Figueras, 2015).

Governance for Digitalization in Healthcare

A governance framework widely used for health systems that considers accountability relationships among Policy Makers, providers, and people was introduced by the World Bank as early as 2003 (World Bank, 2003). The concept has subsequently been adapted and developed several times for different research purposes, whereby, for example, group internal relationships have been added (Brinkerhoff & Bossert, 2008; Bigdeli et al., 2020). An alternative concept from the World Health Organization (WHO) is the so-called six building blocks, incorporating service delivery, health workforce, information systems, access to essential medicines, financing, and governance, whereby governance was placed at the center of the other five themes here as well (WHO, 2007).

Alongside countless publications on governance and health system strengthening, researchers and organizations have increasingly looked at the governance of digitalization in healthcare in recent years. Digital transformation, according to Carnicero and Serra (2020), calls for governance that addresses the rights and regulations, as well as the responsibilities and risks, of health data use and the deployment of information systems. According to Marcelo et al. (2018), the ultimate goal of digital health governance is to enable a health system to embrace digitalization to maximize health, as defined in a country's national health strategies and plans, as well as global goals such as the health-related Sustainable Development Goals (SDGs). The independent Expert Panel on Effective Ways of Investing in Health (EXPH), established by the European Commission, argues that it is first necessary to assess whether digital health services contribute optimally to the goals of a health system (Ricciardi et al., 2019). Their paper illustrates the intangible complexity of digital transformation in healthcare and states that governance should be designed to adequately capture all relevant changes (Ricciardi et al., 2019). Health systems need to be prepared for digitalization across the board, from training to finance and regulatory requirements to establishing monitoring to track the impact on the performance of the system (Ricciardi et al., 2019).

Regarding an appropriate method for organizing governance work, reference was made to the TAPIC[2] framework, which is considered robust and practicable (Ricciardi et al., 2019). Five key characteristics emerge from this framework put forward by Greer, Wismar, and Figueras (2015): transparency, accountability, stakeholder participation, integrity, and political capacity. Governance is understood here as "the structure of decision-making and policy implementation in a system" (Greer, Wismar & Figueras, 2015) shaped by patterns and routines more than by leadership.

The OECD identified in 2013 that member countries lacked health data governance, which is why a respective recommendation was developed (OECD, 2022). Its goal is to regulate the use and exchange of health data, ensure privacy, enable efficiencies, foster quality, and drive innovative research (OECD, 2022). The current report on implementing these recommendations shows that there is still a great need for action (OECD, 2022). I consider the EHDS in this study as a chance to further push for an EU-wide, unified governance approach to digitalization in healthcare.

2.4 Conceptual Framework

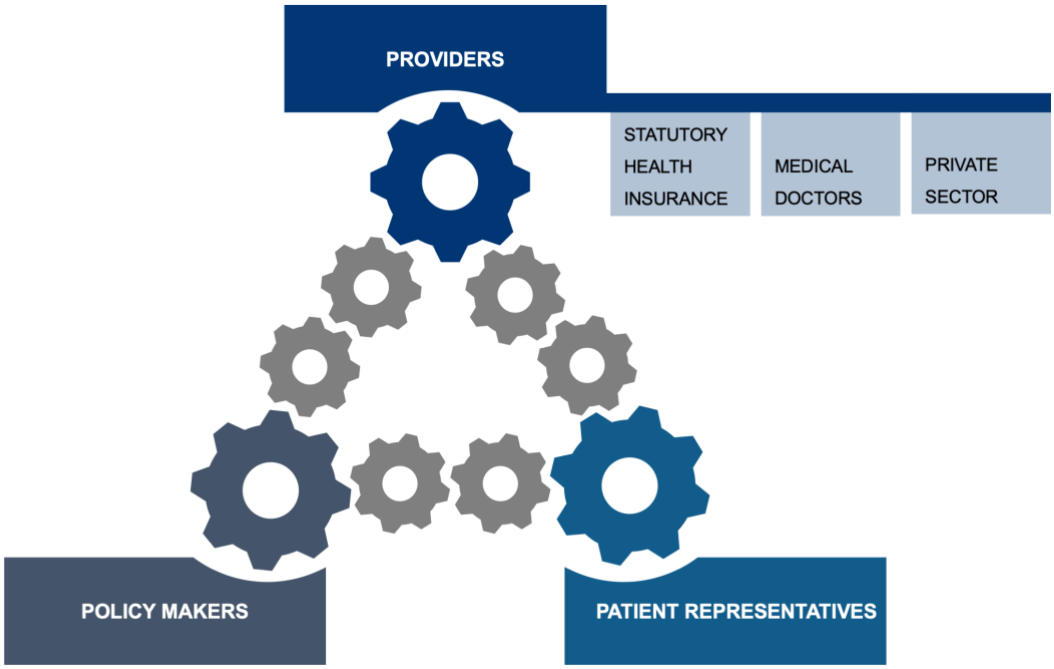
In this research, I understand the governance of digitalization in healthcare as a critical element to bringing about progress in strengthening the healthcare system and improving patient care. As a basis for the conceptual framework, I have chosen the Governance Triangle of the World Bank (2003), including the adaptations of Brinkerhoff and Bossert (2008) and Bigdeli et al. (2020). Besides Policy Makers and patients, represented here by Patient Representatives, I have differentiated among Providers, as shown in Figure 1. On the one hand, drawing on Kraus et al. (2021), I have given health insurance providers their own role. The choice of SHI rather than PKV was deliberate, as SHI insures a large majority of Germans (almost 90 percent) (Bratan et al., 2022). In addition, I have included MDs as treatment providers, and the Private Sector, as providers of healthcare products (Bratan et al., 2022).

I also use gears instead of arrows, as presented by Bigdeli et al. (2020), to better illustrate the dynamics and interrelationships of stakeholder groups in the system. Moreover, I will also consider six levels of relationships, three across the groups and within each group (Bigdeli et al., 2020). The within-group view is particularly appropriate for the German health care system because, for example, policymaking occurs at the federal and state levels (Bratan et al., 2022).

[2] Transparency, Accountability, Participation, Integrity, Capacity (Greer, Wismar & Figueras, 2015).

Figure 1.

Conceptual Framework Health Systems Governance Triangle.



Notes. Own representation, adapted from World Bank (2003) and Bigdeli et al. (2020).

This approach allows me to retrospectively interrogate intra- and intergroup narratives of their relationships to the status quo and a future-oriented expectation regarding the EHDS. Applying this assessment brings the complex composition of the German healthcare system to a highly simplified level of abstraction while still mapping five key stakeholder groups (Savigny et al., 2009, Bigdeli et al., 2020). The selection is based on my previous research for this project and includes five fields of interest and perspectives that seem most valuable for my research questions (Ex & Amelung, 2018; Nohl-Deryk et al., 2018; Samerski & Müller, 2019; Bratan et al., 2022).

3 Methodology

3.1 Research Design

In this study, qualitative research methods were used to interrogate the legal proposal of the EHDS in the context of the German healthcare system. Qualitative research aims to generate data saturation and in-depth information (Malterud, Siersma & Guassora, 2016). To analyze and categorize the problem with digitalization in the German healthcare system and the challenges and potentials of the EHDS, I conducted ten semi-structured interviews with five different groups of experts (Green & Thorogood, 2018). In-depth interviews provide unique insights into aggregated and often particular knowledge (Green & Thorogood, 2018). This format allowed for inquiries into participants' subjective perceptions and experiences on the specific topic (Saldaña, 2011). In addition, it provided an appropriate setting to address the theoretical assumptions drawn and to build on them according to the conceptual framework described (Green & Thorogood, 2018). This qualitative data collection method allowed participants to express their views in their own words and left room for explanation and opinion (Saldaña, 2011). The study took place from May to August 2022.

3.2 Setting and Participants

The study includes two participants from the five expert groups to present different narratives and perspectives (Malterud, Siersma & Guassora, 2016). The groups identified in Chapter 2.4 are described in more detail in Table 1 below. The number of interviewees was selected based on estimated data saturation. The sample provided valuable comparisons and subsequent theoretical considerations related to the conceptual framework (Malterud, Siersma & Guassora, 2016). Inclusion criteria were at least five years of professional experience in the German healthcare sector and being in a position responsible for digitalization and/or the EHDS in one of the five designated groups for at least three years. The contacting of potential interview participants took place in collaboration with the Representation of the European Commission in Germany from May 2022. Furthermore, I was able to use my own network and apply snowball sampling to gain access to the network of the participating persons as well (Green & Thorogood, 2018).

Table 1.

Expert groups and participants' overview.

Group	Domain	ID	Description
1	Patient Representatives	11	Advisor for health and social policy in patient advocacy
		12	Head of digital transformation at a patient counseling organization
2	Statutory Health Insurance	21	Professional advisor in corporate development (digital office)
		22	Head of data management
3	Policy Makers	31	Head of a ministry unit at the federal level
		32	Head of a ministry unit at the federal state level
4	Medical Doctors	41	Practitioner and head of digital health at a university hospital
		42	General practitioner in private practice
5	Private Sector	51	Director of business development in a company builder for founders and start-ups
		52	Digital transformation leader in a biotechnology company

Notes. All groups refer to the German healthcare system and experts and decision-makers in digitalization and/or the EHDS.

3.3 Data Collection

After completing all preparatory work, I started collecting data in mid-June 2022. The interviews followed a semi-structured interview guide (Annex 3) I created beforehand with a predefined set of open-ended questions (Green & Thorogood, 2018). After a brief introduction, the participants were asked to freely frame the problem of digitalization in the German healthcare system from their perspective. This was followed by an open description of the respective expert's personal experience with the problem stated. This served to reveal any differences in perception between and within the expert groups.

An elaboration on expected challenges and hurdles regarding Germany's participation in the EHDS by the participant followed. Finally, questions were asked about possible improvements. Comprehension questions were asked throughout the conversation to ensure that the presented content was understood correctly. The interview guide was developed based on the literature I reviewed during the development of the prior research proposal and incorporated critical components of the conceptual framework presented in Chapter 2.4 (Saldaña, 2011).

Before the actual use of the guide, I conducted a pretest with two experts independent of the study to test its content and comprehensibility. Subsequently, I made minor adjustments and included changes in perspective brought in when necessary. Based on this preparation, as an interviewer, I could direct the focus of the conversation to the questions in my study.

Eight interviews were conducted online via different videoconferencing systems. Mainly my official Zoom account at Maastricht University (UM) was used. At the participant's request, other systems (Microsoft Teams and Cisco Webex) were used in four cases to comply with the respective organizations' or companies' special data protection requirements. In addition, one interview was conducted in person and one via telephone. Each interview lasted about 45 minutes and was conducted in German. All interviews were recorded with an audio recorder after participant consent and transcribed verbatim to allow for subsequent thematic data analysis and translation into English (Saldaña, 2011).

3.4 Data Analysis

The data analysis was based on the preceding considerations regarding the conceptual framework and applied comparisons between and within groups of experts (Bigdeli et al., 2020). From the very beginning of the data collection phase, the interviews collected were transcribed verbatim. In addition, the scripts were read several times to become more familiar with the content (Saldaña, 2011). Thematic analysis and coding of the statements then followed, with the scripts first examined using deductive themes that were systemic in nature (complexity, power dynamics, and governance) (Saldaña, 2011). For this purpose, particular sentences were assigned labels to serve the subsequent interpretation of the content (Saldaña, 2011). The initial code tree was further developed based on the content using an inductive iterative approach. The final code tree includes three main themes and nine sub-themes, within which the research questions of this study can be answered in a multi-layered and thematically interpretive manner (Saldaña, 2011). The findings also led to the design of an extended interaction model that builds on the conceptual framework. The analysis was carried out using the MAXQDA software solution from VERBI GmbH. It was conducted entirely in German to preserve nuance; only the individual statements for the interpretative presentation of results were translated into English.

3.5 Ethical Considerations

Ethical considerations were made to ensure that any ethical concerns have been adequately addressed and excluded. The study received ethical clearance from the UM Ethics Committee

under the registration number FHML/GH_2022.008. Informed consent was obtained from all participants (Annex 1 and 2).

Participation in the study and consent to the use of the data was voluntary. The study followed all standards of the EU's GDPR. Therefore, the audio files are stored with anonymized labels on a protected server at UM and will be deleted at the end of the project on August 31st, 2022. The transcripts of the interviews stored on the protected UM server are also anonymized, i.e., without names and personal identifiers, so that no conclusions can be drawn about an individual. Furthermore, the study results will be made available to all participants in written form after completing the project.

4 Results

The thematic analysis of the transcripts of the interviews I conducted resulted in three important themes that I identified, namely (1) Systemic Characteristics, (2) Perspectives on Health Data, and (3) People Related Themes. More detailed subthemes were developed based on inductive, iterative coding, whereas some of those condition or influence others; these can be found in Figure 2. The findings in these subthemes are presented below, each placed in the context of the three research questions of this study if applicable. The representation does not follow any rating order but partly builds on each other. Moreover, the level of elaboration results from the density of the interview contents. Additional subheadings were used as needed, for example, if a lot was said about the EHDS in any subtheme. Exemplary data excerpts from the subthemes are selected and presented as quotations, underlining my interpretative descriptions.

Figure 2.

Themes and subthemes resulting from the analysis.

Notes. Own representation based on the analysis.

4.1 Systemic Characteristics

Fragmentation of the Healthcare System

The strong fragmentation of the German healthcare system, which is due to a multitude of actors, federal structures, and sectoral segregation, was expressed in nine out of ten interviews. In particular, fragmentation was mainly addressed in the problem framing with digitalization according to the first research question and in its impacts on other subthemes. One Patient Representative described the German healthcare system as “so incredibly complex and so fractionated that any changes that actually relate to the whole system are incredibly elaborate” (ID12). Its sectoral separation led to “breaks in care between outpatient and inpatient and so on” (ID12). Policy Makers share this view, whereas one stated:

> "We very often (…) fail to reach the sectoral boundaries, which are also divided into small parts." (ID31). "These are boundaries between outpatient and inpatient, but these are also sector boundaries between, between individual players in a hospital." (ID31)

Brought to the point by an MD who said, "many cooks spoil the broth" (ID42). At the same time, a clinical colleague added the resulting "high heterogeneity between the digitalization, or the type of digitalization in hospitals, in the private practice sector and with the patient" (ID41) to the problem framing. A federal state-level Policy Maker additionally described the obstructive effect of federalism in Germany in this context, which makes it onerous, for example, to conduct medical studies in multiple states (ID32). According to the Private Sector, all this has led to "so many particular interests also, what concerns data protection, or many strong initiatives, strong associations, which all somehow advance an own interest" (ID52). SHI experts also perceived the diversity of actors lacking a shared vision and being confronted with too many challenges (ID21; ID22). Whereas one of them also described widespread phlegmatic dynamics (ID22).

One deduction that can be made from the interviews regarding the challenges with the EHDS is to unite all stakeholders and ensure their cooperation. However, most interviewees perceived the legal proposal for the EHDS as an opportunity to form a suitable basis to face this challenge.

Power Dynamics

According to almost all interview participants, particular interests and resulting power dynamics play a significant role in (digital) developments of the German healthcare system. Within the fragmentation described above, the system is characterized by powerful self-governing bodies, which, according to several interviewees, significantly influence the progress and speed of digitalization. This subtheme again relates mainly to the problem framing according to the first research question of this thesis.

One of the MDs argued that the "healthcare system (is) strongly characterized by self-determination and free action" (ID41). A Private Sector expert stated, "we have self-governing bodies that do not actually work together at the top, but deliberately set themselves up against each other" (ID52). From this perspective, it was also noted that particular interests are legitimate, "only it must not go so far that this ultimately hinders progress" (ID51). Patient Representatives agreed that there is a lack of creative will and that it is always an arduous struggle to achieve progress within these structures (ID11; ID12).

> "I believe that the organizations that are endowed with a great deal of power, both in the area of payers and in the area of service providers, have had the opportunity for far too long to engage in such a power game and destructive struggle for every little bit of progress" (ID12).

Similar arguments were made from the SHI experts' perspective. It was perceived that it is more a matter of being right and a certain egoism put before the common good and sustainable progress (ID22).

> "One can say that for a long time the self-governing bodies, which have been entrusted with the implementation of the whole thing, have been obstructed, possibly group egoism has been considered more important than pursuing a common goal" (ID21).

Policy Makers had a similar view; many actors, particular interests, and participatory processes prevailing in Germany, with the involvement of self-government bodies, have led to the processes becoming very slow (ID31; ID32). "There was a real momentum only when then also the federal government took over the majority in Gematik" (ID31). A Patient Representative emphasized, "so what the BMG ultimately did, what Spahn did, should have been done ten years earlier, so to speak, namely transferring the majority of Gematik to the federal government" (ID12). A Policy Maker noted that "through the back door, that is a turning away from the principle of self-governance because, at the end of the day, the BMG decides, even if it doesn't bear the costs at all, but the GKV-SV still does" (ID32).

Summarizing the comments from the interviews, I note that, in retrospect, particular interests and prevailing power structures have had a slowing effect on the further development of the German healthcare system. In the case of the EHDS, the challenge in terms of interests and power will be to unite the stakeholders' goals and win them over to the idea of the project.

Political Framework

Given that a policy proposal is the subject of my study, participants' elaborations in this field were extensive, both in retrospect and concerning the EHDS. There was consensus in the Private Sector that transformation can only succeed if policymakers formulate what they want and set appropriate frameworks (ID51; ID52). However, the challenge of acting on time was also highlighted: "guidelines need about five years before they can be updated again. But medical knowledge doubles every 72 days" (ID51).

According to nine out of ten interview participants, these framework conditions for digitalization in the German healthcare system have not been set for too long. An expert from the Private Sector pointed out that it would have been possible and affordable to address the issue already ten years ago (ID51). One MD said, "there should have been guidelines or

directives earlier on that were at least followed" (ID41). In his perception, this lack led "to a conglomerate that, over the perhaps 20 years of digitalization in healthcare, has resulted in a strong diversification that is almost impossible to recapture" (ID41). According to one Policy Maker, the political courage to step on the toes of individual professions with progressive ideas has been lacking for too long (ID32).

Legislative Period 2018 - 2021

In contrast, the approaches from the last legislative period were appreciated by most interview participants. An expert from SHI said:

> "With the penultimate change of government, federal Minister of Health Jens Spahn took a different approach. He then unleashed a whole avalanche of digitalization laws - in the end, there were five of them" (ID21).

However, in his view, this also meant that overambitious implementation deadlines laid down in the law could not be met (ID21). Nevertheless, experts from all groups in this study praised the then Minister for having the necessary willpower, good stakeholder involvement, and solid ideas (ID12; ID21; ID22; ID31; ID32; ID42; ID51). SHI and Private Sector also valued the dynamics that senior ministry executives have brought to the topic of digitalization but who now in part work in the Private Sector (ID22; ID51).

Both Policy Makers agreed that the last legislative period has brought about a great deal of movement, which must now be implemented and reflected in the quality of care (ID31, ID32). Due to the fragmentation and power dynamics already described, it was also pointed out that "it's not so easy for politicians to dictate and say that's how it's done now" (ID31).

Legislative Period from 2021

From different groups, displeasure was expressed with the current legislative period; for example, an MD said, "this government and this minister loves not to give people any time. But just three minutes before, then suddenly decide something. And that's, that's detrimental" (ID41). Experts from the SHI and Private Sector expressed an impression that the current minister does not yet know how to take up the digitalization legacy of his predecessor (ID22; ID51). The Policy Maker from the state level confirmed:

> "We are now one, almost one year, almost one year into the new legislature. And it's actually other than falling flat on its face on the e-prescription and needing to get out of there somehow; nothing has really happened at all" (ID32).

The Policy Maker at the federal level stated that “it is already known that we are now intensively negotiating a digitalization strategy” starting after the summer break (ID31). A clear governance structure is needed to drive transformation forward (ID31). In that regard, one Patient Representative welcomed the fact that “the coalition agreement states that Gematik will be expanded into a large digital agency” (ID12). According to him, there needs to be more will to reform, and Gematik needs to act more autonomously to drive the whole thing forward innovatively (ID12).

EHDS

Several interview participants noted that current German legislation is incompatible with the EHDS (ID12; ID21; ID32; ID52). A Patient Representative commented, “between this proposal and the current status quo in Germany are simply worlds apart” (ID12). Nine respondents nevertheless saw the proposal as a positive move to foster medical progress and open new markets. One expert from the Private Sector expressed that there is considerable regulatory and legislative catching up to participate in the EHDS (ID52). He described further concerns about possible opening clauses, which are already being used excessively in Germany with the GDPR (ID52). Nevertheless, it is essential to take this step now because digital innovation is increasingly taking place outside Europe (ID52).

The proposal was largely welcomed by both Policy Makers interviewed and criticized in some places (ID31; ID32). Initially, they feel well prepared politically since some impulses from the German 2020 Council Presidency have been incorporated, the current coalition agreement contains three projects that fit well with the EHDS, and a health data utilization law is already in the works (ID31; ID32). However, what is missing from a Policy Maker’s perspective, in addition to the envisioned access bodies in the MS, is a corresponding access body from the EU, which also has much valuable health data (ID31). Furthermore, the question of how a data holder should provide data to a requester still needs to be clarified realistically (ID31). Another criticism lay in the question of the order of competencies, which, according to the EHDS proposal, would, in part, extend very much into the sovereignty of the MS (ID31; ID32). “There are an insane number of competencies that are supposed to go to the Commission, and at the same time, the Commission sees itself only as a processor” (ID31).

Also, it became clear in interviews with Patient Representatives, SHI, and MDs that the topic of EHDS has not yet sufficiently reached stakeholders (ID22; ID41; ID42). Furthermore, it was stated that it is formulated too abstractly for many groups and MS (ID12; ID32) and that the actual goal of the whole thing is not entirely clear (ID11; ID22). An MD reported, “This is a problem of the EU in general; the perception is close to zero” (ID42). One Policy Maker also

pointed out that “at the moment, the discussions are still rather restrained because most have problems with the complexity of the proposal” (ID32).

There was a great agreement in the perception that the envisioned implementation deadlines of the proposal are unrealistic and cannot be met (ID12; ID21; ID31; ID32; ID41). It should be given enough time, one physician said (ID41). One Policy Maker assumed that it could also take a long time until there is a decision in the EU trialogue on the EHDS and that the actual policy could look quite different (ID32). According to the second Policy Maker, the proposal's contents are also unrealistic in the context of the planned deadlines (ID31).

> “When I look at Article 33 with this huge list of data categories that have to be made available with Shell[3], preferably in three, in three years, I have to say that even the Finns won’t be able to manage that” (ID31).

He added that doable solutions must be found for the MS “because it cannot be in the Commission’s interest to overburden everybody now” (ID31). Moreover, some MS might have problems finding the financial means for implementation (ID31). Regarding the proposal, Policy Makers wished for the addition of a European Access Body (ID31), more realistic implementation deadlines (ID31; ID32), and perhaps even a unified electronic health record solution that would resolve “all these nagging interoperability issues” (ID32). One would also appreciate a Europe-wide opt-out solution to generate high user numbers, expecting great opportunities for research and governance (ID32).

One Patient Representative missed a holistic vision in the proposal that addresses all healthcare, not just regulations on health data use (ID12). An MD wished “that we (…) don’t talk it up, I think the approaches are good” (ID41). In addition, “agile thinking from the IT world must finally be allowed, and then also take the time to act in an agile manner” (ID41). The second MD stated that it is good that the topic is being driven forward at the EU level, so Germany must follow suit (ID42). The experts from the Private Sector agreed and stated that “if we do not digitalize quickly now, (...) we will lose the race with medical progress” (ID51). They would like to see “a lot of what is in there now also come about; that it is not somehow watered down with opening clauses, with more vague formulations” (ID52).

Opt-in, Opt-out, Voluntariness

Regarding access to the ePA or participation in the EHDS, the views of the interview participants differed regarding opt-in or opt-out procedures. Also, one Patient Representative initially emphasized the voluntary nature of the ePA, which is not intended for secondary data

[3] An approach with which data can be processed and made available.

use in the EHDS (ID11). The second Patient Representative argued, “opt-out yes, but first, make the functional scope much larger” (ID12). One Policy Maker confirmed that this discussion still needs to be held politically (ID31).

From the perspective of both MDs, an opt-out mechanism was favored (ID41; ID42). The efficiency of the healthcare system was brought up, as the recurring query of patient data costs an incredible amount of time (ID42). Moreover, from their point of view, it was seen as highly problematic in terms of patient welfare if patients were enabled to withhold information from doctors (ID41; ID42).

> It is extremely pointed out here that one has the possibility to withhold preliminary psychiatric information from the physician, in particular. The psychiatric medication, however, is one of the classics in the interaction profile, which, together with an antibiotic, can also lead to cardiac arrest (ID41).

SHI and the Private Sector stated that both providers and insured persons need incentives to participate and sanctions for non-participation (ID22; ID51). Both also indicated that this is not meant to be a standard sanction but rather that the groups incur an increased expense due to non-participation or are charged for an increased cost due to non-participation (ID22; ID51).

Infrastructure and Resources

Before discussing digitalization in healthcare, a Patient Representative described a fundamental problem prevalent in Germany, the lack of broadband expansion (ID12). This means, in turn, that even if there is a prevailing offer in the healthcare sector, precisely those regions were possibly cut off from it in which healthcare could largely benefit from digitalization (ID12). The Patient Representative rated the original unique path of the telematics infrastructure as the biggest mistake that could be made (ID12). An expert from the Private Sector confirmed “there is still no infrastructure there” and stated, “we are not ready at all” (ID51). Metaphorically, a Policy Maker on a business trip to Estonia was told:

> “You are trying to develop the Mercedes with the TI and it has been standing in the garage for 20 years. We developed the Golf and we’ve been driving it around for 20 years” (ID32).

The second Policy Maker confirmed that some sort of German perfectionism slows down progress (ID31). Conversely to this statement, an expert from SHI said that Germany is “building an infrastructure, and it’s not completely rolled out yet either, that is based on design principles and state of the art from 15 years 20 years ago” (ID21). The connectors in use are no

longer state of the art and exclude other service providers to date (ID21; ID22). The Private Sector confirmed that there are still hardware connectors in use that do not function in many areas and that software solutions are already being used everywhere else (ID51; ID52). An MD also reported from her experience that many things rolled out do not work properly (ID42). According to an expert from SHI, a changeover to software connectors would also be indispensable to integrating other healthcare professions (ID21).

From a clinical perspective, an MD reported that due to a lack of framework conditions, hospital information systems had been developed very differently (ID41). One is now faced with the problem of harmonizing the status quo with new approaches (ID41). An "adjustment of standards, interfaces, and systems has not yet taken place, which is holding us back" in Germany at the moment, according to an expert from the Private Sector (ID52). In this context, a Policy Maker said the "hurdle right now is the lack of interoperability at all levels" and "the lack of open interfaces, which can enable data traffic" (ID31).

> "Everything is running digitally in the doctor's office, everything is running digitally in the hospital, and in between, there's a doctor's letter that has to be sent by mail" (ID31). "This leads to uncertainty in the system, and I think we have to improve these processes" (ID31).

According to an expert from SHI and an MD, although there is now theoretically sufficient funding for digital progress in the healthcare sector, there are resource-related problems (ID22; ID41). From the point of view of SHI, one would also have to think about data storage in terms of mass, necessary computing power, and energy consumption when proceeding further. In addition, concerns were expressed about the shortage of skilled workers, which is already evident (ID22). "Many basics that are going on right now that are attached to heads (may) not work anymore soon" (ID22). The MD from a university hospital stated that in its public setting, one could not compete with the Private Sector and other domains in the search for software developers because salaries are strictly regulated (ID41).

EHDS

From the point of view of a Patient Representative, the EHDS is "a very good draft in terms of infrastructure, which simply shows where the journey must go, because, in the long term, I think the entire national systems, and that is of course above all the recording of health data, electronic patient files and so on, must be harmonized" (ID12). One Private Sector expert welcomed "more networking, standardization, uniform application channels, centralization of national data centers and databases and registers, towards such national nodes" (ID52) and called for "these health data access bodies to be named early and for them to start their work

early" (ID52). Policy Makers also appreciated the push regarding infrastructure but emphasized that this can only succeed if it can build on prevailing structures (ID31; ID32). One of them criticized the lack of a European Access Body on an infrastructural level and as well (ID31).

> "So, I think we need this European Health Data Access Body, besides those of the Member States, to generate access to European data pots. And we also need a European platform to link the nodes" (ID31). "And as a platform, I would like to see centralized services offered as well" (ID31). "We offer you an anonymization tool, a data synthesis tool, and everybody would uniformly use that. Then the data is still decentralized in different places. But because they used similar systems, they are interoperable" (ID31).

4.2 Perspectives on Health Data

Data Availability and Quality

All ten interview participants agreed that much health data is generally available in Germany. However, opinions differed widely on whether this data should be available, how access should be regulated, and its quality (control).

One Patient Representative spoke of a veritable data collection rage in Germany without a clear goal and honest patient orientation (ID11). She also expressed significant concerns about data quality, "we simply have the problem that we do not even know which data are correct and which are not correct. Or up to date and which ones are not up to date" (ID11). Additionally, it was pointed out that people who do not want to participate in digital offerings could "find possible solutions to boycott the data quality" (ID11). Under these conditions, "shit in, shit out" (ID11) is to be expected in digitalization, and it is questionable whether physicians can then trust such data (ID11). Further, she said, "they will only get valid data that actually brings something for research if they let the patients participate voluntarily" (ID11). Therefore, she insisted on the patients as a control instance, "the patients have to be involved at this point because only they have a vested interest in keeping the data up to date" (ID11). Quite in contrast to this was the opinion of an MD who stated, "if I set this as a goal, then I set in advance that I actually have an insufficient doctor who is so bad at the documentation that even the patient laymen notice it" (ID41). He added that data quality is high, "especially what is technically provided" (ID41). "But of course, we have the problem that, on the one hand, the data quality will always remain limited if I stay in the freedom of the text and need the freedom of the text because I cannot, cannot dichotomously describe a patient" (ID41). Thus, it will be important to educate all actors on high data quality (ID41).

The Private Sector brought in that each stakeholder group holds interesting data for various reasons, but so far, it has been inadequately shared (ID52). The second interviewed Patient Representative also came from this perspective and pointed out that there is "hardly any other country that has such extensive data, especially in the healthcare sector, but on the other hand, the use of data is not so difficult in any other country and also the merging of data" (ID12).

> "There we are again with this topic of federalism, self-government, yes, so, that is an absolute absurdity that, that somehow the economically strongest country in Europe now in a pandemic, we could neither reliably say (how) many infected we have, nor how many are vaccinated, the RKI[4] had to conduct a survey to find out approximately how high the vaccination rate is" (ID12).

EHDS

Regarding the EHDS, this Patient Representative stated that this draft is very liberal and provides for a "very comprehensive use of health data" (ID12). It would be "totally unusual in Germany that health data are collected and made available for anything afterward" (ID12). However, the current use of data was associated with too many restrictions; there is a need for better access, for example, to be able to evaluate treatment processes better (ID12). Should such a data pool come in this form, an expert from SHI predicted: "the opportunity to actually create a, a great development for all of us" (ID22).

From a Policy Maker's perspective, the EHDS also sees a lot of good ahead regarding future health data availability and use (ID31; ID32). One added it is essential that "these data sets, which are then also made available in the corresponding access bodies under certain conditions for training purposes for algorithms, because only in this way will we be able to ensure, that safe products enter the European market" (ID31). Safe products based on AI must have been trained and tested on European data (ID31). Otherwise, it would have a bias and is not as applicable (ID31).

An expert from SHI and an MD pointed out the need for appropriate translation and interpretation services, which can only work if the data are processed according to a specific nomenclature (ID21, ID41). "If these codes mean the same thing everywhere, but I get it presented in a language I understand, it is a great advantage that we should definitely use as well" (ID41).

[4] The Robert Koch Institute (RKI) is the German government's public health institute.

Data Security

Most interview participants presented data protection in healthcare as very important but also as overregulated and too fragmented. From the point of view of one Patient Representative, the actual protection of health data is already lacking in the analog world; at the counter in the doctor's office or the multi-bedroom in the hospital, "digitalization is exacerbating the whole problem" (ID11). She also described a lack of transparency; patients should fully know their data and be able to determine how it is shared and with whom (ID11). MDs commented, "the issues of data protection and data security are important and have been placed at the absolute center" (ID41). However, the corresponding legislation was considered problematic (ID42). According to experts from SHI, this considerably slowed down progress in digitalization (ID21; ID22). One of the experts stated:

> "The real problem in the GDPR is the G, namely, it is not a data protection regulation, but a general regulation, which means that this is a general regulation, but it contains in the order of about 60 exceptional circumstances, where the member countries, so to speak, where the member countries unit, can make their own regulations." (ID21)

One Policy Maker confirmed that it is a hindrance "that we have 17 data protection laws in Germany, one for the federal government and then one for each state" (ID32). In the context of the GDPR, "once again we have been particularly stupid because we have used all the opening clauses to be extra sharp" (ID32). An MD and a Private Sector expert agreed that "the EU GDPR is used in Germany as a bar to say that everything is forbidden, we are innocent. Because that's what the EU dictated" (ID41). "And then it's so incredibly easy to hide behind issues like data protection" (ID52). Data protection is being used as a defensive measure to prohibit things, not like the TÜV[5] for cars, to enable something (ID52). The Policy Makers, an MD, and an expert from the Private Sector clarified that other countries successfully demonstrate to work in compliance with data protection and still be innovative and progressive (ID31; ID41; ID52).

In fact, according to one SHI expert, the German approach and the accompanying weak range of services can even lead to health data ending up in much more unprotected communication channels (ID21).

> "As it happens nowadays where then people take pictures of their discharge reports and send them via WhatsApp to the doctor when they come out of the hospital because they, uh, yeah, don't want to go that way or can't go that way because and so there's, I can imagine, I can

[5] Technical inspection associations.

> imagine a whole range of, a whole range of services that are already used in the non-medical environment, yes, but which it is better not to use for the transmission of medical and health data because they could fall into, the data could fall into hands where they do not belong" (ID21).

Policy Makers and Private Sector experts stated that there is a need for standard privacy protections that are wholistically designed (ID31; ID32; ID51; ID52). According to one Policy Maker, the EHDS was perceived as a welcome push in that direction (ID32).

4.3 People Related Themes

Patient Value

All interview participants expressed in some ways that digitalization in healthcare can only be successful if it is accompanied by patient value. One Patient Representative said, "first of all, we have to make a patient benefit really tangible" (ID11). "Digitalization is not a purpose in itself" (ID11). It is essential that data are correctly collected, that patients are involved, and that values can be directly experienced by patients (ID11). She also said that non-discriminatory access to these services is needed, especially to help people for whom digitalization is ultimately most useful (ID11). An expert from SHI even stated, "for me, in fact, the basis of the whole thing is far ahead of digitalization, namely, to have everyone's interest being interested in health" (ID22). A Policy Maker added that it must not only be about patients; the added value in digital offerings must also be brought closer to the healthy (ID32).

However, against the backdrop of weak infrastructure and over-regulated data protection, an MD questioned the technical feasibility of what is left and whether this can even benefit (ID41). A Private Sector expert claimed it is "outrageous that patients in different clinics, different states experience such a different digital experience" (ID52).

Policy Makers also supported this view and reported that, to this moment, primarily background processes have been taken care of, and too little explanation of patient benefits has been provided (ID31; ID32). "We need to better present this benefit, so we also need appropriate applications in there, those that add value to patients" (ID31). An expert from the SHI added that solutions perceptible to insured persons did not develop well (ID21).

The Policy Maker stated there needs to be a functioning electronic health record; access to it must be quick and follow simple administrative processes (ID31). In this context, a Patient Representative stated that the registration of the ePA and the nearfield communication coupling with the insurance card for the e-prescription app are far too complex and time-consuming (ID12). Digitalization is supposed to simplify, enable, and connect, but Germany managed to

complicate things further with it (ID12). In addition, according to the Patient Representative, the offering was too weak (ID12). If a physician search, online appointment scheduling, video consultation, or transmitting specific data to the physician were enabled, or hospital onboarding was included, much more perceptible added value would be available (ID12). An SHI expert said that nowadays, you could store documents, PDF files, and maybe even images, but nothing is navigable data (ID21). This lack of offering also tempts users to use dubious services from dubious providers (ID21). Both Policy Makers confirmed that benefits need to be better presented and that appropriate applications are needed that actually do offer added value to patients (ID31; ID32).

EHDS

In the view of the Policy Makers, the basic idea of the EHDS is a vast opportunity for all EU citizens to take data across Europe, which can be retrieved in an emergency and should also be available for research (ID31; ID32). One Patient Representative saw excellent advantages in the cross-border flexibility of the EHDS (ID11). She added that a significantly better research performance could be expected, particularly about rare diseases, although data sovereignty must remain with the patients (ID11). The second Patient Representative saw great opportunities to better record, store, and use health data in the future to improve healthcare research and therapy approaches (ID12).

One physician spoke of an incredible booster that would be given to medicine if a corresponding data pool was available, enabling numerous new approaches and improving research (ID42). The EHDS would also allow more targeted and individualized diagnostics and promote prevention, according to an expert from the Private Sector (ID51). He added that the potential would go far beyond pandemic situations and would also apply, in particular, to lifestyle-related diseases (ID51). The second expert from the Private Sector also saw these advantages and said, “it is absolutely obvious that we do this” (ID52).

Usability and User Value

Alongside the patient values described above, there was agreement across all stakeholder groups that user values (e.g., for MDs) and usability were also needed in digitalization in healthcare. From the perspective of Patient Representatives, it was brought in that “doctors also need added value” (ID11). “I think (…) digital transformation, digital applications, and processes in healthcare will only be successful if it focuses on all user groups” (ID12). To this was added that usability also plays a significant role for patients besides value (ID12).

An MD comments, “it does the patient no good if the doctor moans and screams when he is supposed to do what is supposed to benefit the patient” (ID41). “It has to benefit both. There has to be a balance restored among these different aspects” (ID41).

Regarding the current state of the ePA, Policy Makers stated that the lack of usability starts with getting access to it, “the main thing that is missing is a quick and easy way to get the ePA” (ID31). Referring to user value, “we entered the TI in the wrong way, with the insurance member data management, no doctor is interested in that, no patient is interested in that” (ID32). This was also the view of a Private Sector expert, “the medical profession does not understand why they should use the ePA. There are no convincing arguments” (ID52). As reported by an SHI expert, “the record is not used because there are no services, none that generates effective values for the insured, and there are, and there are no services because there is no demand because there are so few records” (ID21).

Nevertheless, from the MDs’ point of view, the theoretical idea of ePA in general and in the context of EHDS was seen very positively, as it could bring great benefits and significant time savings to the physician as a user (ID41; ID42).

> “I would welcome it very, very much, I must say, so, especially with the primary data, that would be worth its weight in gold, of course, if simply my medication schedule was already on the card and you don’t have to type it all out somehow or ask for it, and the patients can’t remember what the antihypertensive is called or what, these are things where I think to myself, that would be obvious, that would save an immense amount of work” (ID42).

> “Of course, it is a blessing when a Spanish tourist falls from a plane, and I can read his health card so that I understand in German because I am not able to speak Spanish, and even without a Google translator, I can understand what diseases he has, even if he would otherwise probably not have any information at all” (ID41).

Education, Literacy, and Transparency

All interviewees stated in some way that more information and education about digitalization in the healthcare sector is needed. In addition, it can be deduced from the interviews that related policies, including the EHDS, must be well explained to reach citizens and stakeholders.

Communication was described from the perspective of SHI, Policy Makers, and the Private Sector as insufficient so far but, at the same time, crucial for future digital progress in healthcare (ID22; ID31, ID32; ID51). One Policy Maker stated that to bring people along, not only must patient benefits be generated, but they must also be clearly demonstrated (ID32). The public discussion was said to be characterized by thunderous voices from a few critics (ID32).

While an SHI expert stated that "it must be well explained what advantage the individual insured person has as a result" (ID21), the second expert from this area also sees a particular responsibility on the part of patients to inform themselves about offerings (ID22). A Patient Representative suggested that it is also crucial that "the doctors can also experience patient benefit. So that, they need to understand why they are doing this in the first place" (ID11). A Policy Maker also stated that it is essential to create trust with transparency (ID31). It must also be communicated "that it's not about profiling or identifying individual data, identifying individuals, but about using CVs, for training purposes" to offer safe products (ID31).

Using the ePA as an example of use, the second Policy Maker stated, "who knows that ePA exists? Who knows how it can be used? And I am not just talking about citizens; I am talking about physicians. I am also talking about the other healthcare providers, including nursing" (ID32). One MD confirmed only knowing about it because she had been actively looking for it (ID42).

> "So, I think most people, and especially if it's the older generations then, they've never heard of it. And accordingly, if they've never heard of it, then the probability that they know what's going on with their data and how it will work is very low (ID42). So, there would have to be more active education in any case" (ID42).

She saw Gematik as primarily responsible for strengthening communication and education (ID42). Regarding a possible opt-out approach, she stated, "I don't think people would know where to get out. They have no idea at all what it is" (ID42). About the EHDS, she specified that "an appropriate explanation of the whole thing, how the data is used and above all how it is secured, is what I think would be really important, that this is communicated differently again" (ID42). A Patient Representative confirmed this view (ID12).

> "I can't imagine, without that, a bridge is built here, without that there are intermediate stages here or yes, one drives quasi a, a longer, lasting information campaign, so one would, one would give this now tomorrow to the referendum, then I am sure that the majority of the population would reject this in this form" (ID12). "You have to break it down, you can't present the whole proposal 1:1, so to speak, but you have to give a layman's summary of it again" (ID12). "I'm a bit afraid that many, many citizens won't be picked up by it at the moment" (ID12).

A Policy Maker also described the EHDS proposal as very abstract and, for many, still difficult to grasp, although he also reports voices from other MS of the EU (ID32). The other MD stated that he himself has difficulties telling what the proposal contains (ID41). The EHDS is far from being sufficiently well received by stakeholders in terms of information (ID41).

5 Discussion

From the interviews, it can be concluded that Germany is not yet ready for the EHDS. A wide range of problems was described, most of which are interrelated and result in slow progress in digitalization. The problem framing according to the first research question ran in the main themes (1) Systemic Characteristics, (2) Perspectives on Health Data, and (3) People Related Themes. And so did the expectations regarding the EHDS. The results presented were consistent with the assumptions of this research that a large part of the problem of digitalization lies in the complexity of the German healthcare system. The diversity of players, the power dynamics reflected in the high level of fragmentation, the political framework, the low participation of patients and users, and the mass and quality of health data and its protection have determined the developments and pace to date. According to the interviews, it can be affirmed that Germany has faced various unfavorable conditions regarding digital progress in the healthcare sector, as indicated by Bratan et al. (2022).

The research verified my hypothesis that the attitudes and motivations of the experts interviewed on digitalization in healthcare follow different motives. I found that all respondents have a positive attitude toward digital progress, provided that stakeholder-related particular interests are not affected, and specific standards are met.

Systemic Characteristics

With a view to systemic characteristics, it is worthwhile to refer to and discuss other research on digitalization in the German healthcare system, its results, and recommendations for action. For example, Thiel et al. (2018) have already called for digital health to be comprised as a central component of German health policy. Looking at the past legislative period, it can be noted that significant progress has been made here in meantime (Bratan et al., 2022). The demand to develop a corresponding e-health strategy for Germany can be found in both the study by Thiel et al. (2018) and Bratan et al. (2022). According to Thiel et al. (2018), effective strategies have the most significant influence on successfully implementing the continuous challenge of digitalization. Such a strategy does not yet exist in Germany, although, according to the interviews, the starting signal for the development of one is to be given in the second half of 2022. In line with this, due to the high fragmentation of the healthcare system, the need for a strong and uniform governance course, ergo a digitalization strategy, was demanded from all stakeholder groups of my study. The publication of the EHDS proposal in May 2022 thus came just in time to be considered in the context of its development (European Commission, 2022).

Examining these findings in the context of the preceding theoretical considerations affirms that systems thinking is helpful to better understand and classify problems (Meadows, 2008). Given the multitude of actors that need to be united in the German healthcare system to achieve common progress, my study confirms that the challenge of building a successful governance structure for digitalization in healthcare has not yet been successful (Greer, Wismar & Figueras, 2015). Referring to the TAPIC framework, there is a need for improvement in all five characteristics, with transparency, stakeholder participation, and political capacity being the most comprehensively identified (Greer, Wismar & Figueras, 2015). However, the upcoming digitalization strategy in Germany and the EHDS suggest an improvement.

To analyze prevailing power dynamics in more detail, it is worth looking at Moon's (2019) framework for power in global governance. The interviews showed that primarily institutional and structural power are prevailing in developing digitalization in German healthcare. According to Moon (2019), institutional power is wielded when actors can influence decision-making processes and actions through the application of norms, thus also influencing and potentially limiting the scope of action of other actors (Moon, 2019). Strong self-governing bodies have a high degree of such power, based on my results. In contrast, the structural power of Policy Makers in the field has been insufficient for many years to achieve more successful digital progress (Moon, 2019). It must be noted that the structures and the distribution of power date back to the pre-digital era and were very successful at the time (Matusiewicz, Pittelkau, & Elmer, 2018). Thiel et al. (2018) determined the need for appropriate organizational infrastructure and digital health authorities. With the takeover of 51 percent of Gematik's shares, the federal government now has majority power in Germany's digital health agency, which should lead to faster decision-making processes in the future (Bratan et al., 2022). So, the role of Gematik has already evolved in the meantime and is expected to be further strengthened during the current legislative period (SPD, Bündnis 90/Die Grünen, & FDP, 2021; Bratan et al., 2022). For the implementation of the EHDS, however, it remains to be clarified which institution should assume the "Health Data Access Body" role in Germany. Moreover, during the interviews, there were also calls for establishing a "European Health Data Access Body" to be considered by the European Commission.

According to the Policy Makers interviewed, the distribution of power within the framework of the EHDS needs to be revised and adjusted, whereby corresponding debates in the Council and the European Parliament are expected here. So far, the EU has only supported MS in health policy; with the EHDS, the EU's competencies would be more far-reaching than has been the case so far (Schölkopf, 2010; European Commission, 2022).

Another point that still needs to be discussed or pushed politically is the creation of the necessary infrastructure in Germany, which starts with broadband expansion, as already called for by Bratan et al. (2022). They also call for "ensuring interoperability across the health system," "better integration of good international practice on e-health," and better secondary data use, which would be addressed with the current version of the EHDS proposal (Bratan et al., 2022; European Commission, 2022).

Furthermore, the issues of access and involvement need to be revisited in the political discourse. In this regard, one Patient Representative stated that successful digitalization could only take place if patients can participate on an entirely voluntary basis and if there is transparency. In the case of the EHDS, the voluntary nature of secondary data use would not be given and has to be discussed. MDs had a contrary view and are critical of voluntariness and the ability to optionally withhold health data, which could negatively impact patient well-being in an emergency. The SHI experts and the Policy Makers favored at least a change from the currently existing opt-in variant of the ePA to an opt-out solution. The current status of the ePA runs according to an opt-in mechanism, whereas the current coalition agreement provides for a switch to opt-out (both voluntary) (SPD, Bündnis 90/Die Grünen, & FDP, 2021; Bratan et al., 2022). For the EHDS, however, voluntariness would still need to be clarified about secondary data use (European Commission, 2022).

Thiel et al. (2018) also noted that "frameworks and timelines for planning and implementation" are among the success factors for digitalization in healthcare. While the EHDS proposal provides for such, according to all interviews conducted, these are not adhered to in Germany and require adaptation (European Commission, 2022).

Perspectives on Health Data

Apart from the slow systemic progress, the availability of health data that could be used has increased enormously (OECD, 2022). My results indicate that the problem now is to achieve a digital turnaround in healthcare with an aging infrastructure and a large amount of health data. Thus, the system has recently become overwhelmed with ambitious goals and legislation, considering the diversity of problems and the limited availability of technical experts to implement them.

One patient representative claimed that the data quality was deficient. According to my research, current studies on the German healthcare system cannot substantiate this statement. I could find a guideline on data quality in medical research, but not research results on the actual state of data quality (Nonnemacher, Nasseh & Stausberg, 2014). The European Commission

has already considered data quality and corresponding quality labels in the proposal for the EHDS, but it refers predominantly to secondary data use (European Commission, 2022). However, since high-quality health data are also essential in primary data use, possible mechanisms should be considered. The participant suggested patients as an appropriate control authority, whereas one MD opposed this. This deviation should be picked up and discussed to elaborate a common way forward.

Bratan et al. (2022) devote an entire chapter to data privacy and cybersecurity in their study. They have also incorporated the "improvement of IT security in healthcare facilities" into their recommendations for action (Bratan et al., 2022). The results of my study do not contradict this; instead, they complement the need for standardization of data protection legislation in Germany as derived from the interviews. In this context, the EHDS is seen by some participants as a suitable basis for advancing the standardization of data protection.

People Related Themes

Patient Representatives had a progressive attitude toward digitalization if it is accompanied by an actual patient value, which, according to one representative, has been entirely inadequate to date. In this respect, it essentially agrees with all the other stakeholder groups in this study; patient benefits have so far been far too little at the center of digitalization. Placing the results of my research in the TAPIC approach, there is a lack of participation but also a lack of transparency (Greer, Wismar & Figueras, 2015). Bratan et al. (2022) called for a "stronger orientation of digitalization toward added value for healthcare" as a whole.

The fact that there was a public consultation in 2021 in preparation for the EHDS, but a Patient Representative and both MDs reported more than a year later and after the publication of the proposal that the topic has not yet reached their stakeholder groups sufficiently and, in some cases, themselves, shows in my assessment that there is an enormous lack of awareness and information (European Commission, 2022). I further deduced from the interviews that the EHDS proposal has not yet been adequately explained, and digital health literacy in the population and healthcare professions needs to be significantly further, which is also what Bratan et al. (2022) called for. Cornet (2017) stated that, in the Netherlands, in addition to creating the technical and legal conditions and the semantic infrastructure, patients and actors also had to be enabled to utilize their potential. Therefore, if the approaches are better explained, the benefits are more tangible, and people see clear added value, digitalization will also meet with greater acceptance and approval. Thiel et al. (2018) noted that consensus and trust are also

needed to build competence. Thus, progress can be successfully advanced if the various stakeholders rely on a joint agreement (Thiel et al., 2018).

Limitations

Producing knowledge and insights from the experiences of experts in the field of digitalization of the German healthcare system has helped to generate a broad understanding of the status quo and existing problems, as well as to question different assessments of the EHDS. However, my approach is, of course, not without limitations, which vary in nature.

The scope and duration of the master's thesis caused several inclusion limitations. For example, my selection of expert groups includes five essential but far from all important expert groups significantly involved in digitalization. For instance, Gematik has played a central role for many years but has not been represented. Also missing are participants from the research community, which are explicitly addressed in the EHDS proposal. Furthermore, other medical professions, as well as pharmacies, are missing. As for the population's voice, I included only Patient Representatives but not patients or healthy citizens (Bigdeli et al., 2020). Likewise, much has been reported about powerful self-governing bodies with many particular interests, but they are only represented in the study to a limited extent. It also remains unclear whether, in general, a higher number of interview participants would have led to even more in-depth results or, possibly, whether more contrasts could have been identified. A further restriction results from the inclusion criteria for participation in my study, as all participants had to have a corresponding level of experience in digitalization in healthcare to be able to answer the questions. Therefore, these were exclusively participants who work closely with the topic of digitalization, are involved with it, and are possibly more open to the matter than others. More critical voices that are generally rather dismissive of the topic of digitalization and did not meet the inclusion criteria were therefore not heard.

Furthermore, the thematic focus on complex systems, health system strengthening, and governance that I predetermined limited the study and analysis thematically. The thematic analysis also refers only to what stakeholders said, not necessarily why and how they said it. A rhetorical or philosophical analysis of the interviews could certainly complement my results.

Apart from that, it should also be noted that I only focused on an in-depth analysis of the German healthcare system and the domestic rootedness of the slow progress per se. The EHDS targets all MS of the EU, so a cross-country comparative study could also have been very fruitful.

Future Research

Future research should include other stakeholder groups in the direction of my research approach, in any case, Gematik, pharmacies, other medical professions, and research institutions. In addition, citizens should be given a more significant role and, if possible, not only included by Patient Representatives. Another interesting approach could be to provide scientific monitoring of the upcoming digitalization strategy for the German healthcare system. Furthermore, a qualitative research approach on the standardization of data protection regulations in Germany would be helpful, whereby the federal data protection commissioner and all state data protection commissioners could be interviewed. Since the topic emerged in my interviews and I could not find any recent literature on it, I suggest further research on the quality of health data in Germany. A quantitative study on expectations and fears regarding the advancing digitalization in healthcare, taking demographic and socioeconomic aspects into account, would also help assess attitudes in the population.

Since the EHDS refers to all MS of the EU and I only depicted the German healthcare system in my study, I would also recommend implementing similar research approaches in other MS to provide comparability of countries.

6 Recommendations for Action

The opportunities for digitalization in the healthcare sector in Germany are far from being fully utilized. Besides, the EHDS proposal forms a large-scale basis for further EU-wide progress in this area. My analysis and discussion allow for nine recommendations for action accordingly. On the one hand, in the direction of the German healthcare system, to improve digitalization and increase readiness for the EHDS. These align to some extent with the recommendations from Thiel et al. (2018) and Bratan et al. (2022). On the other hand, there are recommendations in the direction of the European Commission regarding the need for adaptation and suggestions for improvement concerning the EHDS proposal in terms of feasibility from the German angle.

Concerning the German Healthcare system

1. *Development of a holistic governance strategy*

A joint digitalization strategy for healthcare in Germany will be of fundamental importance in the future. It should be developed holistically, considering legal, structural, technical, social, and medical requirements and developments, and involve all relevant stakeholder groups. It should be continuously developed and adaptable as needed. Targets should be set realistically, and implementation should be monitored on an ongoing basis. Mechanisms for regular data quality assessments should be included.

2. *Development of a common position on the EHDS proposal*

The recent publication date of the EHDS and the upcoming digitalization strategy allow for the early development of a common position on the proposal. Given that the EHDS can also help tackle existing problems, I think it is essential to use this opportunity to deal with the topic early on and discuss it among all stakeholders. A common line would help to provide substantial feedback to the European Commission and greatly facilitate the implementation. Moreover, the German Health Data Access Body should be nominated soon for clear responsibilities.

3. *Step-by-step assurance of interoperability*

Interoperability is essential to benefit from the potential of digitalization throughout Germany to improve the healthcare system. Realistic goals should be set step by step, considering the necessary technical, human, and time resources. It would be practical to consider already the interoperability standards provided for in the EHDS.

4. *Standardization of health data protection legislation*

Data protection legislation in Germany hinders good use of health data, for example, its use for research and development. The fact that there are numerous data protection laws at the federal and state levels, as well as multiple data protection officers, is an obstacle to innovation. To generate more significant benefits for citizens and the healthcare system in the future, standardization should occur. The EHDS could be used as a suitable basis.

5. *Increase stakeholder participation and citizens' involvement*

My study has shown that stakeholders and citizens have too little involvement in the digitalization of healthcare. I assume such participation can largely contribute to a more successful implementation of policies and a much better acceptance of products by potential users. Transparency and education about patient values and user values are essential. I even assume that better engagement will lead to better policies and products.

6. *Increase digital health literacy*

Strengthening digital health literacy is crucial to enable stakeholder groups and citizens to benefit from the range of digital offerings in the healthcare sector. Actions should be offered to all health professions and the public to improve digital health literacy.

Concerning the European Commission

1. *Awareness, education, and involvement*

The EHDS proposal has not yet sufficiently reached Germany's most important stakeholders and citizens. I urgently recommend raising awareness, increasing education, better explaining the proposal, and enhancing stakeholders' involvement in the further process. In Germany, stakeholder involvement plays a crucial role in successfully implementing such a project.

2. *Clarification of European infrastructure*

Since valuable health data are available at the European level, for example, through the European Medicines Agency, it would also make sense to install a European Health Data Access Body. Furthermore, the demand for a European platform on which standard applications could be offered, upon which the MS could build, can be derived from the interviews.

3. *Review of deadlines and competencies*

According to my interviews, the planned EHDS deadlines cannot be met in Germany. Thus, an adjustment and discussion with the MS would be advisable. Furthermore, the question of competencies within the EHDS should be clarified with the MS, which would go beyond the previous level of influence.

7 Conclusions

Germany is not yet ready for the EHDS. Due to a multitude of unfavorable influencing factors that have slowed down progress in digitalization in the healthcare sector, Germany would face a massive challenge with the proposed EHDS and envisaged deadlines.

This study found a large agreement and little deviation among experts from five main stakeholder groups in the German healthcare system on the problems associated with digitalization and their respective expectations regarding the EHDS. A lack of viable governance addressing the healthcare system's prevailing structural fragmentation and power dynamics resulted in a deficiency in standardization and interoperability and weak infrastructure. Therefore, the need for a joint governance course was identified and promised as part of a forthcoming German digitalization strategy in healthcare. Hence, the publication of the EHDS proposal came just in time to be enclosed accordingly. Moreover, improvements in data collection, access, and use are needed. Participants agreed that data security and protection are critical but, at the same time, over-regulated. Consequently, they called for standardization of data protection legislation for health data in Germany, whereas the EHDS is generally seen as an opportunity to bring about progress. Patient values, user values, and usability play a significant role in the progress of digitalization in healthcare, issues that are not yet sufficiently tangible for several respondents in the context of the EHDS. Moreover, it was observed that digitalization topics and related legislation are not adequately communicated and explained. About the EHDS, it has become clear that most stakeholder groups have not sufficiently received the project.

From all the observations, recommendations for action could be derived both for the German healthcare system and its actors as well as the European Commission. These include improving governance and cross-stakeholder collaboration, enhancing infrastructure, increasing user- and patient-centeredness and education, and adjusting time targets of recent German legislation and the EHDS to realistic deadlines.

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Annex 1 – Interview information sheet

Research project:	Is Germany ready for the European Health Data Space? An analysis of challenges and potential improvements to patient care and the healthcare system from the perspective of expert groups.
Context:	Master Thesis – Master of Science (M.Sc.) in Global Health
Institutions:	Maastricht University (UM) Representation of the European Commission in Germany (EC)
Project Leader/Interviewer:	Lukas Wrosch
Supervision:	Bart Penders, PhD (UM) | Robert Gampfer, PhD (EC)

Objectives of the study

The project aims to question what challenges and opportunities for improvement exist for the German healthcare system in the context of the European Health Data Space (EHDS) from the perspective of different expert groups. The analysis should reveal whether and if, which deviations exist across the surveyed groups but also within the groups. From this, recommendations for action for the successful integration of the German healthcare system into the EHDS will be derived.

The research is conducted solely for the master's thesis of Lukas Wrosch and serves to obtain the degree 'M.Sc. in Global Health' at UM. The supervisor of UM is Bart Penders, while on the part of the EC, support is provided by Robert Gampfer.

Participants

Twenty experts from five different stakeholder groups will be interviewed to provide as broad a picture of the German healthcare system as possible and make it comparable. The experts are deliberately selected because of their experience and expertise, ensuring the substantive quality of the research results. Inclusion criteria are therefore, that the participants have at least five years of professional experience in the German healthcare system and have been working in a position responsible for digitalization and/or the EHDS for at least three years.

Further information

All participants will take part in an interview lasting approximately one hour and will mainly report on challenges and potentials from a personal perspective. Participation in the survey is voluntary. All participants have the right to withdraw from the study without providing a reason and to skip individual elements or questions. Participants will not be disadvantaged by refusal or withdrawal.

The interviews will be conducted via the Zoom video conferencing platform (official UM account), recorded, and subsequently transcribed, anonymized, and analyzed. Recording of the interviews is required. It is done via an external recording device and is then transcribed by the interviewer. The audio files will be stored with anonymized labels on a protected server of UM and will be deleted at the end of the project (after grading of the master thesis) at the latest by the end of September 2022. The transcripts of the interviews will also be stored anonymously, i.e., without names and personal details, on the server of UM in order to ensure that no conclusions can be drawn about an individual person.

Important: The EC will not have access to audio files or transcripts. The study results will be sent to all participants as well as to the EC after project completion in the form of the complete master thesis.

The interviewer is committed to data secrecy and works in accordance with the regulations of the European Union's General Data Protection Regulation (GDPR). The scientific analysis of the interview text is carried out by the interviewer. Through qualitative research, differences and commonalities of the groups will be investigated, which will serve as a basis for subsequent recommendations for action. With the results, a publication in a scientific journal is aimed. The study has received ethical clearance from UM and is listed under the identifier FHML/GH_2022.008.

If questions about the study arise, all participants have the opportunity to ask and receive answers at any time - for this purpose, the e-mail address below can be used.

Contact details

Lukas Wrosch | l.wrosch@student.maastrichtuniversity.nl

Annex 2 – Interview consent form

Research Project:	Is Germany ready for the European Health Data Space? An analysis of challenges and potential improvements to patient care and the healthcare system from the perspective of expert groups.
Context:	Master Thesis – Master of Science (M.Sc.) in Global Health
Institutions:	Maastricht University Representation of the European Commission in Germany
Project Leader/Interviewer:	Lukas Wrosch
Supervision:	Bart Penders, PhD (Maastricht University) Robert Gampfer, PhD (European Commission)
Interview date:	_____
Interview-ID:	_____

I agree to participate in an interview within the framework of the above-mentioned research project. For this purpose, I have been informed about the aim and the process of the research project, have received, and read the information sheet, and agree to the recording of the interview under these conditions.

The interview will be conducted via the Zoom video conferencing platform (official Maastricht University account), recorded, and subsequently transcribed, anonymized, and analyzed. Recording of the interviews is required. It is done via an external recording device and is then transcribed by the interviewer. The audio files will be stored with anonymized labels on a protected server of Maastricht University and will be deleted at the end of the project (after grading of the master thesis) at the latest by the end of September 2022. The transcripts of the interviews will also be stored anonymously, i.e., without names and personal details, on the server of Maastricht University in order to ensure that no conclusions can be drawn about an individual person.

The interviewer is committed to data secrecy and works according to the regulations of the European Union's General Data Protection Regulation (GDPR). The scientific analysis of the interview text is carried out by the interviewer. Through qualitative analysis, differences and commonalities of the groups will be investigated, which will serve as a basis for subsequent recommendations for action.

I agree that individual sentences from the transcripts that cannot be linked to me personally may be used as material for scientific and educational purposes. I have been informed and agree that publication in a scientific journal will be aimed at with the results of the study.

My participation in the survey and my consent to the use of the data as described above are voluntary. I have the right to opt out of the study without giving reasons and to skip individual elements or questions. I also have the option to revoke my consent at any time. I will not be disadvantaged by refusal or revocation.

Under these conditions, I agree to give the interview and consent to it being recorded, transcribed, anonymized, and analyzed.

_____	_____
Place, date, signature of interview participant	Place, date, signature of the interviewer

Contact details

Lukas Wrosch | l.wrosch@student.maastrichtuniversity.nl

Annex 3 – Interview guide

1. Welcome and thanks for the participation
2. A short round of introductions
3. Privacy Terms and possible queries about the information sheet or consent form?
4. Short introduction of the technical framework (audio recording), formal framework (master thesis, qualitative expert interview)
5. Description of the interview process and approximate duration
6. Introduction 1st block:
    a. Compared to, for example, Nordic or Baltic countries, there is considerable potential for improvement in digitalization in the German healthcare system.
    b. Assumption: Generally, reasonable data use/digitalization is seen positively by the respective stakeholder group if other basic principles are not affected, whereby the respective motives may differ.
    c. Start of audio recording
    d. Problem Framing Digitalization in the German Healthcare System from the Participants' Perspective
    e. What are the problems?
    f. What are the reasons? Have specific mistakes been made, if applicable?
        i. Anticipate statements throughout
        ii. Questions about understanding, whether everything was understood correctly?
        iii. If necessary, ask critical questions.
        iv. If necessary, introduce a change of perspective (e.g., from technical explanations to patient benefits)
7. Introduction 2nd block:
    a. Now to the EHDS - ambitious approach of the European Commission, Legal Proposal of May 3, 2022 - Complex systems - merging two complex systems, usually goes hand in hand with opportunities and challenges
    b. Challenges and hurdles with the EHDS from the perspective of each stakeholder group.
        i. Anticipate statements throughout
        ii. Comprehension questions, whether everything was understood correctly?
        iii. Critical follow-up questions, if necessary.
    c. Opportunities and potential from the perspective of the respective stakeholder group
        i. Anticipate statements throughout
        ii. Questions of understanding, whether everything has been understood correctly?
        iii. Critical follow-up questions, if necessary
8. Summary and outlook
9. Conclusion of discussion