DiGA, an Innovation Made in Germany – Status Quo and a Perspective of Potential Users

Philippe Hervé Jacquemin Technical University of Darmstadt philippeherve.jacquemin@stud.tu-darmstadt.de

Abstract

The German health care system has to face raising costs, an increase in demand as well as a shortage of staff, making an efficient use of resources as well as the design of innovative services and digital solutions necessary. Even though the digitalization of the health care system is far behind, Germany was the first country to integrate DiGA, a special form of digital health apps, into the health care market. While this is a very promising development, it is still unclear whether patients actually know about these apps and if processes are efficient enough to promise a significant benefit to them. Therefore, we discuss the different stakeholders and performed an online survey with 262 participants from Germany to study the patients's view on DiGA. The results show that their intention to use is high, but many are not aware of the actual DiGA offered.

Keywords: DiGA, Digital Healthcare, Germany

1. Introduction

Demographic change and an aging population, increasing demand for health care services, and a resulting increase in health care expenditure are key challenges health care systems must overcome today (European Commission et al., 2019). The global COVID-19 pandemic contributes to these challenges and brought increased attention to the topic of eHealth due to the stay-at-home approach and the need to move from in-person meetings to virtual space (Jabbarpour et al., 2021; Lin et al., 2021). These challenges and current developments highlight the need for new digital business models in the health care sector to relieve physicians, reduce physician-patient contact and improve patient outcomes (Lin et al., 2021). In this regard, many organizations, government agencies, and policymakers are focusing on digital solutions to address the challenges associated with the health care sector (Idrish et al., 2017). Especially in Germany's general practitioner (GP)-centered health care system,

Melanie Reuter-Oppermann Technical University of Darmstadt oppermann@is.tu-darmstadt.de

in which GPs are the first point of contact for patients, it is deemed necessary to ease the workload of physicians, enhanced by COVID-19 (Aerzteblatt, 2020). In recent years, the German government has acknowledged the potential of eHealth and passed several new legislations such as the Digital Health Care Act (Digitales-Versorgungs-Gesetz), which are meant to simplify the implementation and anchoring of digital solutions like online video consultations, a secure health care data network for treatment in the daily care (Federal Ministry of Health, 2020), the electronic patient file (ePA - elektronische Patientenakte) or the electronic prescription (eRezept), which is currently still in the piloting stage (Federal Ministry of Health, 2022). In October 2020, Germany was the first country in the world providing an entitlement for statutory insured persons to be treated with certain certified health apps, reimbursed by their health insurance companies (Federal Ministry of Health, 2019). These digital health apps, which can be prescribed by physicians or psychotherapists or directly approved by the health insurance companies, if an indication exists already, are called Digitale Gesundheitsanwendungen (digital health applications) or DiGA for short (Federal Institute for Drugs and Medical Devices, 2019).

Despite all the measures introduced by the German government, the progress of digitalization in the German health care sector remains slow and the overall level of digitization low (Hansen et al., 2019; McKinsey et al., 2021). In particular, the prescription by physicians and thus the use of DiGA by patients has not yet arrived in regular care, despite the digitalization boost during COVID-19 (Dahlhausen et al., 2021). Germany's largest health insurer, Techniker Krankenkasse, registered a total of 19,025 prescription codes for DiGA through December 2021 for its 11.6 million members. Thus, the prescription rate is below 0.17% (Techniker Krankenkasse, 2022).

To the best of our knowledge, there is no scientific study so far that captures the perspective and attitude of potential patients with regard to DiGA. We aim to identify possible reasons for restraint by providing the patient perspective, thus giving insights into the DiGA chain from end-users to physicians to developers. Therefore we provide answers for the following research questions:

(1) How are DiGA under the umbrella term of eHealth defined and classified?

(2) Which stakeholders are affected by DiGA and what are their key interests and concerns?

(3) What is the level of awareness of digital services and especially DiGA in Germany? What are the requirements from the patient's perspective? Which added value do they see?

To answer these research questions, we provide an overview of literature and define relevant terms in the area of eHealth and DiGA in particular in Section 2. In Section 3, we identify the key stakeholders in the DiGA chain before presenting the methodology (Section 4) and the results of our online study on the awareness, the requirements and the potential added value from the patients' point of view (Section 5). The paper closes with a discussion and an outlook on future research in Section 6.

2. Foundations

A quick search on PubMed alone with the search term (telehealth OR telemedicine OR eHealth OR mHealth) reveals that the number of publications on these four terms increased exponentially from 888 publications in the year 2000 to 11,731 in 2021. The majority of international studies examined the medical efficacy and the benefits the new concepts bring to the health care system (Almathami et al., 2020; Eze et al., 2020). Eze et al. (2020) found telemedicine similarly effective to in-person interventions across several medical specialties in their review of telemedicine in the OECD. However, the authors stated that overall there was a lack of quality in the reviewed studies. Another research strand focuses on the technical aspects of eHealth solutions and usability. Zhao et al. (2016) came to similar conclusions when reviewing studies on the effectiveness of mobile phone applications to change patients' health behavior. Also, usability and ease-of-use is a major focus among the literature on the technical implementation of eHealth solutions (Klaassen et al., 2016). In addition, legal and regulatory aspects around the introduction of eHealth services are discussed. The need for informed consent, data protection and confidentiality, as well as lacking legislation on the application of telemedicinal interventions were among the most referred to legal challenges identified by Nittari et al. (2020), calling for a regulatory framework to ensure medical efficacy, usability, and organizational and workflow fit (Eze et al., 2020). Ethical aspects of telehealth were considered by Chaet et al. (2017), for example. The authors state that fidelity, competence, privacy and continuity of care must also translate to digital health services. While a systematic review by Jiang et al. (2019) reported digital health services to be cost-effective, Eze et al. (2020) found the evidence on the cost-effectiveness of digital health interventions to be limited and hard to generalize. In a study on the cost- effectiveness of telemedicine in diabetes management, Lee and Lee (2018) concluded that a potential for cost savings in diabetes care exists.

There are significantly less scientific publications about DiGA. Most publications are published in German journals and magazines (e.g. Bundesgesundheitsblatt, Gesundheitswesen) and deal, for example, with the interoperability of DiGA (Weber and Heitmann, 2021), the effect on the German health care system (Esser et al., 2020) or the evaluation of them (Geier, 2021). However, there is a lack of research on the classification of DiGA in the eHealth terminology in general and the acceptance of DiGA in Germany.

2.1. Classification of DiGA under the umbrella of eHealth

Terms such as telehealth, telemedicine, eHealth, and mHealth are used to describe the concept of the digitalization of medical services (Otto et al., 2018). Although there are already numerous studies and various publications on the topic, there is still lack of clearly defined terminology and concepts. In this work, we mainly follow the terminology of Otto et al. (2018). Otto et al. (2018) found eHealth to be the overarching term in the domain of digital health care technologies. In the most widely used definition of eHealth (Shaw et al., 2017), Eysenbach (2001) defines eHealth as "an emerging field in the intersection of medical informatics, public health, and business, referring to health services and information delivered or enhanced through the Internet and related technologies." Otto et al. (2018) emphasized the ability of patients to use mHealth without the immediate involvement of medical professionals. The most common terms subsumed by eHealth are telehealth, telemedicine, and mHealth (Eze et al., 2020; Otto et al., 2018). The difference between the terms telehealth and telemedicine is particularly poorly defined (Otto et al., 2018). The authors determined telemedicine to be a subclass of telehealth and concluded that telehealth describes a holistic understanding of health and well-being, while telemedicine has the medical and diagnostic care that involves physicians as its focus (Otto et al., 2018).

In Germany, digital health apps (DiGA) have emerged as a recent form of mHealth (Dahlhausen et al., 2021). Germany's pioneering role is substantiated by Belgium introducing a process based on the German DiGA system and France and the Netherlands have also started to implement a similar system (Jeindl and Wild, 2021). The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) defines DiGA as medical products, mainly in the form of mobile or desktop applications, that rely on digital technologies. They are used in secondary or tertiary prevention and are associated with low risks. Their main function must contribute to the medical purpose which is to support the "recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment or alleviation or compensation of injuries or disabilities". DiGA are used by both patients and medical professionals or solely by patients. They are described as "digital assistants in the hands of patients". Additionally, DiGA can be applied in combination with devices, sensors or other hardware such as a heart rate monitor or wearables (Federal Institute for Drugs and Medical Devices, 2019). Since the introduction of the Digital Health Care Act in late December 2019, statutory insured persons in Germany have the right to be treated with DiGA that can be prescribed by medical professionals, such as GPs or psychotherapists as an active form of treatment and are reimbursed by the statutory health insurance funds. When an indication is already given, DiGA can also be ordered directly from the health insurance provider (Federal Institute for Drugs and Medical Devices, 2019). On average, the use of a DiGA for 90 days costs about $447 \in (\text{Vetters et al., } 2022).$

DiGA have to comply with data privacy, usability criteria, and proven medical efficacy. After a successful evaluation, DiGA are listed in a specially created online directory, the DiGA-directory (Federal Institute for Drugs and Medical Devices, 2019, 2022). A special process has been put into place by the BfArM to allow DiGA to be accepted into the DiGA directory three months after application, either permanently when medical efficacy is proven beforehand or preliminary. Ideas for new DiGA are not commissioned by the government, but developers come up with a new idea for specific use cases and request approval from the BfArM. The BfArM provides advisory support in the application process with information on procedural details, required evidence, etc., and conducts the review of the app. After the preliminary introduction, a DiGA provider must prove medical efficacy within one year or in exceptions within two years (Federal Institute for Drugs and Medical Devices, 2019, 2021). To be permanently listed in the DiGA directory, DiGA developers have to demonstrate a positive effect on care. This can be either a medical benefit or a patient-relevant structural and procedural improvement, which must be demonstrated in the direct relationship with the patient. The medical benefit refers in particular to the improvement of the health status, a shorter duration of the disease, an increased survival probability or the improvement of quality of life. Patient-relevant structural and procedural improvements refer to structures and methods that offer an improvement in care, e.g., a strengthened role of patients in health care through information for increased health literacy, support and structuring of therapy for increased adherence or help with disease-related difficulties in everyday life (Federal Institute for Drugs and Medical Devices, 2019).

This fast track procedure has so far been viewed positively by DiGA providers and the importance of close coordination between BfArM and DiGA providers before, during, and after the application process has been highlighted for successful introductions (Heimann et al., 2021). A survey among DiGA providers found that 80% of DiGA would not have been introduced without the possibility of preliminary approval. This allows for a transitional phase and the collection of sustainable evidence on medical efficacy while rigorous standards concerning quality and safety remain in place (Geier, 2021). Until March 2022, 126 applications were submitted for listing in the DiGA directory (Vetters et al., 2022). As of the beginning of June 2022, 31 DiGA have been approved by the BfArM for prescription by medical professionals. Of these 31 DiGA, twelve have been permanently approved, while the remaining 19 have been approved preliminary. Applications for a variety of medical conditions are currently present in the DiGA directory. 14 DiGA are related to psychotherapy (e.g., depression, phobias, insomnia, and quitting smoking), three are related to chronic pain (e.g., pain in the knee, arthritis), three to diabetes, two to neurology (stroke or multiple sclerosis), two to obesity, two to tinnitus, one helps with the treatment of cancer, and one each targets patients with irritable colon, erectile dysfunction, logopaedic training and stress/burnout (Federal Institute for Drugs and Medical Devices, 2022).

2.2. Potentials and barriers of eHealth and DiGA as perceived by German physicians

In an interview study with 18 physicians and psychotherapists in Germany on their attitudes towards

DiGA, Dahlhausen et al. (2021) found that the benefits include greater flexibility in terms of time and location of the medical service offered, patient empowerment through an increased sense of responsibility and However. self-efficacy, and improved adherence. none of the 18 interviewees had prescribed DiGA to their patients. In a follow-up online survey, Dahlhausen et al. (2021) found that the medical specialty had a significant effect on the attitudes toward DiGA. Furthermore, medical professionals feel that patients benefit more from the use of DiGA than health care professionals. These benefits include improved adherence, improved health competence, improved disease management, direct health benefits, and improved access to care (Dahlhausen et al., 2021). In contrast to that, considerable barriers still exist when adopting and implementing DiGA and other eHealth applications. The most prevalent barriers mentioned in the interviews were lack of information about DiGA, the uncertainty of the medical efficacy and evidence, and also concerns regarding the technical implementation. Furthermore, legal uncertainty, data protection risks, high training needs, insufficient developer support, additional workload, and the requirements to adjust the workflow were also rated as barriers to the implementation of DiGA and telehealth applications (Dahlhausen et al., 2021).

In a cross-sectional survey in 2016, Waschkau et al. (2020) investigated the attitudes towards telemedicine of 388 postgraduate medical trainees, mostly general practitioners, from 13 of 16 federal states in Germany. More than half of the postgraduate trainees see a change in the physician-patient-relationship (54%) through telemedicine. The most agreed-upon benefit of telemedicine is the exchange of information across spatial boundaries, viewed by 61% as beneficial. Other possible benefits of the use of telemedicine such as the reduction of costs, helping patients with mobility restrictions, improved access to medical care, and the improvement of primary care for patients were viewed as beneficial by about a third of the respondents. Also, 31% saw the use of Big Data Analytics as helpful in the support of treating complex disease patterns. The postgraduate trainees rated receiving laboratory results via the internet as the most useful telemedical application already in existence (Waschkau et al., 2020).

3. Stakeholders involved in the DiGA chain

To establish DiGA as an essential part of health care delivery, a systemic perspective is crucial. The most important stakeholders from our point of view are DiGA developers, health insurance providers, physicians and psychotherapists, as well as patients that all have different objectives and face individual challenges. Still, the collaboration and cocreation of the stakeholders is necessary. In the following, we briefly discuss the different stakeholders and point out potential research questions.

DiGA developers primarily pursue financial interests. For the success of their developed application it is therefore important that they obtain a registration (temporarily or permanently) in the DiGA directory and are thus integrated into the health care system. For this purpose, it is important that physicians are convinced of DiGA and that they are willing to prescribe them. In the context of DiGA developers, it is interesting how easily the medical benefit can be demonstrated, which financial incentives exist, how the pricing works, and how the processes have to be designed.

From the health insurance companies' point of view, it is a question of costs and benefits, as they have to cover the costs for DiGA. In Germany, health insurance companies comply with the principle of economic efficiency (Section 12 of the Fifth Book of the German Code of Social Law: Federal Ministry of Justice, 2022). They have an interest in financing treatment methods and offers that are successful for the patients, but at the lowest possible costs. In this context, it is especially of interest what the advantages of a supportive treatment by a DiGA are, how they perform compared to conventional treatment provided only by physicians/psychotherapists and whether there is potential for cost savings in the health care sector.

Physicians have a special role, as they have to be willing to prescribe DiGA and propose them to their patients. On the one hand, they have an interest in prescribing DiGA if they provide high-quality therapy for their patients, but at the same time, they may feel that they are being substituted or that they are suffering financial losses due to fewer chargeable services. Of particular interest is which incentives exist for physicians to prescribe DiGA, what (financial) advantages and disadvantages occur as a consequence, and how work processes have to be adapted as a result. Physicians'/psychotherapists' adoption is important for digital health solutions to find their way into the regular health care system by informing patients and prescribing them.

Patients pursue the interest that their disease or symptoms are treated as fast and successfully as possible. Particularly in view of the relatively high prices of DiGA, patients are interested in keeping costs as low as possible for themselves or in having the costs covered in full as it is the case at the moment. They are dependent on their physician for the prescription of DiGA (or, in the case of an existing indication, directly on the health insurance provider to approve it) and for information and support when using DiGA. The greatest potential here may be improved self-management of the disease or increased treatment success through better adherence, but concerns arise from the disclosure and collection of sensitive (health) data.

In summary, an efficient system and incentives for all stakeholder will be necessary for a long-term success of DiGA. While our overarching research project takes a systems perspective, we first address patients as end users in this work. They are the last link in the chain and their willingness to use eHealth solutions and in particular DiGA is an essential component for further diffusion in the health care sector. We have studied the awareness, the requirements and the potential added value of DiGA from the patients' point of view.

4. Methodology

In 2022, we conducted an online survey with patients in the form of a structured, self-administered questionnaire. Our aim is to investigate the attitude of potential patients toward eHealth offerings in Germany and to assess which ones they have already used, as well as to specifically identify the requirements, the awareness of their legal prescribing entitlement, and the associated added value from the patients' perspective toward DiGA. This helps to draw conclusions about the intention to use. We pretested the survey questionnaire among fellow researchers for clarity, framing, and the time needed to participate.

The questionnaire consisted of five higher-level sections. The first section collected demographic characteristics and information about the physician-patient relationship. The second section aimed at the participants' technology affinity. The third section looked at the availability and use of digital services in the health care sector, followed by section four, referring in particular to DiGA. In the last section, possible changes in attitudes toward digital services due to COVID-19 as well as potentials and barriers from the patient's perspective were explored.

A total of 262 participants completed the online questionnaire in early 2022. The characteristics of the participants are shown in Table 1. The median observed age was 26 to 35 years, with 48.1% (126/262) of participants identified as males, 49.2% (129/262) identified as females, 2.3% (6/262) identified as divers¹ and one person chose not to disclose gender. In line with

Table 1. (Characteristics	of the	respondents.
------------	-----------------	--------	--------------

Table 1. Characteristics of the respondents.				
Variable	Value	%		
Number of participants	262			
Gender				
Male	126	48.1		
Female	129	49.2		
Divers	6	2.3		
Missing/nondisclosed	1	0.4		
Age				
18-25	101	38.5		
26-35	95	36.3		
36-45	32	12.2		
46-55	10	3.8		
56-65	16	6.1		
66-70	2 5	0.8		
> 70	5	1.9		
Missing/nondisclosed	1	0.4		
I have a regular GP that I always go to.				
Yes	156	74.8		
Close GP-patient-relationship				
Strongly disagree	30	11.5		
Disagree	55	21.0		
Neutral	36	13.7		
Agree	58	22.1		
Strongly agree	17	6.5		
No	66	25.2		

the age distribution, most participants are employed (40.8%, 107/262), whereas an almost equal proportion of respondents are students (39.7%, 104/262). While we did not specifically target younger age groups, we did distribute the survey also to university students who might have been more responsive than other addressees.

5. Results

As mentioned in the introduction, the progress of digitalization in the German health care sector is slow and the overall level of digitization is low (Hansen et al., 2019; McKinsey et al., 2021). Thus, we wanted to find out which digital health care services the participants have already used. Participants most frequently used the option of online appointment scheduling (64.9%, 170/262). With 53.1% (139/62), slightly more than half of the participants have already used some form of mHealth apps (e.g., fitness apps, calorie counters). It is striking that the actual services offered by the health care sector, for example video consultation, electronic patient file (ePA), e-prescription (eRezept), teletherapy and telemonitoring, have only been used to a very limited extent. Of these services, the video consultation with 13.0% (34/262) and the telephone consultation with 12.2% (32/262) were used the most. Digital offerings such as electronic patient records (8.8%; 23/262), chat service (8.4%; 22/262), teletherapy (2.3%; 6/262) or telemonitoring (0.8%; 2/262) have rarely been used to

¹Term used in Germany for people who do not identify as male or female.

date.

To measure attitudes, we asked participants if they proactively seek information about digital services from the health care sector. In this way, we wanted to find out the intrinsic motivation, i.e., whether there is a general interest, fun and desire to engage with digitalization and the service offerings. In this context, 39 people (14.9%) state that they proactively seek information. 222 participants (84.7%) do not inform themselves proactively. One participant did not give an answer. When asked if they have already heard or read about DiGA, only one person (0.4%) answered that his/her doctor has informed him/her about DiGA. 48 participants (18.3%) state that they have already informed themselves about DiGA. 213 persons (81.3%) have never heard of it. In response to the 5-point Likert scale question "I would be more likely to use a digital health application (DiGA) if my doctor would inform me about it and explicitly recommend its use.", 107 participants (40.8%) state that they strongly agree; 104 participants (39.7%) indicate that they agree. 30 participants (11.5%) answered this question with neutral, 12 participants (4.6%) with disagree and 9 participants (3.4%) with strongly disagree. With a total of 80.5% positive consent, this question shows quite clearly that physicians are expected to take the initiative in providing information and explanations to their patients (mean = 4.1; σ = 1.0005). The participants rely on their physician and want to be informed. Overall, participants think - after reading an informational text in the survey about what DiGA are and what they provide - that DiGA give useful information about the management and treatment of diseases or symptoms. This statement was strongly agreed by 92 people (35.1%), agreed by 135 participants (51.5%), neutral by 22 (8.4%), disagreed by 7 (2.7%) and strongly disagreed by 6 (2.3%). A positive attitude toward the information value provided by DiGA is shown here as with 86.6% agreement (mean = 4.15; $\sigma = 0.854$). Furthermore, we aligned with the items of Perceived Usefulness of the TAM (Davis, 1989) and the Performance Expectancy of the UTAUT (Venkatesh et al., 2003) and publications with their application in the field of health care (e.g., Hossain et al., 2019) for drawing conclusions about the attitudes. When measuring reliability in the pretest, five of these questions were found to have high internal consistency. The survey shows a Cronbach's alpha, which ensures the internal consistency and should be ideally higher than 0.7 (Nunnally, 1978), of 0.885. This allowed us to measure attitudes towards DiGA with the following questions: "Using a digital health app (DiGA) would help me complete tasks (such as documenting health scores, doing exercises, etc.) faster.", "Using a

digital health app (DiGA) would improve my health.", "Using a digital health app (DiGA) would help me manage my daily life better.", "I find the use of a digital health app (DiGA) useful as a supplement to my physician's care." and "Using a digital health app (DiGA) would make it easier for me to manage my disease/symptoms." With a mean score of 3.8 (σ = 0.773) on a 5-point Likert scale, this shows that participants have a positive attitude toward DiGA.

When asked about the **benefits** of using a digital health application (DiGA) to support the treatment of a disease/symptoms, 82.8% (217/262) state that the greatest benefit is the increased flexibility. Patients can carry out their treatment independently of time and place and thus plan and carry out the integration of therapy units or regular tasks in the context of a disease on their own responsibility. This gives them a participatory role in the treatment of their disease. In line with the benefit of increased flexibility, 71% (186/262) see the benefit of improved self-management. The advantage of a reminder about activities or exercises to be carried out and at the same time the function of the DiGA as a motivator to continuously complete tasks and exercises is seen by 68.3% (179/262) of the respondents. Another 63.7% (167/262) see DiGA as a complementary treatment to refresh and also repeat therapy contents. Participants see the least potential in using DiGA in terms of creating cost savings for the health care sector (32.4%; 85/262), improving quality of care (30.1%; 81/262), and also closing gaps in care (29.4%; 77/262). The main purposes for using a DiGA are seen by 83.6% (219/262) in the active support of treatment (e.g., exercises for mobility, behavioral therapy for psychological disorders), 79.8% (209/262) in the facilitation of recording values (e.g., reminder and facilitated entry of blood sugar values), 70.2% (184/262) in knowledge transfer with, for example, additional information about the disease and 60.3% (158/262) in decision support and behavior recommendation (e.g., indication based on the data that medical professionals should be consulted again).

Regarding **barriers**, participants are most concerned about their privacy. 60.3% (158/262) of the respondents state that they are concerned about the collection of sensitive (health) data via a DiGA. Some of these participants use the text box and made it clear that transparency is fundamental to their use: who can access which data, for what purpose, and when the data was transferred or accessed. Another 52.3% (137/262) state that they consider technical issues to be one of the largest barriers. 37% (97/262) consider the lack of information about available applications or prescription options as a barrier for further dissemination of DiGA. Participants are less concerned that their personal relationship with the physician will suffer. 32.8% (86/262) state that they are afraid of losing the personal physician-patient relationship. In this regard, some participants state that they fear that particularly overburdened physicians will provide treatment inadequately and instead shift much of the treatment to the DiGA, even though they are predominantly intended to provide complementary treatment and not as a replacement. Very few perceive a lack of trust and a generally skeptical attitude towards technology in terms of health as an impediment (20.6%; 54/262). Additionally, only 19.5% (51/262) would think that it is additional effort. Further barriers and concerns are lack of guidance about the use (34.7%; 91/262), lack of technical equipment (34.7%; 91/262), too much self-responsibility (30.2%; 79/262), and doubts about medical benefits (26.0%; 68/262).

Based on the items of the intention to use of the UTAUT (Venkatesh et al., 2003) and TAM (Davis, 1989) model and publications with their application in the field of health care (e.g., Hossain et al., 2019), we asked participants about their intention to use a DiGA in the future. The construct intention to use consists of two statements: The participants were asked to assess their future behavior in relation to the statements "I would be open to use a digital health app (DiGA) as part of my treatment in the future." and "If I had the opportunity, I would actually use a digital health app (DiGA) on a regular basis." using a 5-point Likert scale. All participants (262) responded to both of the questions. The first item shows strongly disagree (2.7%; 7/262), disagree (3.8%; 10/262), neutral (10.3%; 27/262), agree (38.2%; 100/262) and strongly agree (45.0%; 118/262). The mean is 4.19 ($\sigma = 0.956$) and the median is 4.00, which shows a high intention to use for the participants. The second item has been answered with strongly disagree (4.2%;11/262), disagree (6.5%; 17/262), neutral (21.8%; 57/262), agree (45.8%; 120/262) and strongly agree (21.8%; 57/262). The mean is 3.74 ($\sigma = 1.005$) and the median is 4.00, which shows a high intention to use for the participants also for the second item. These two statements represent the construct intention to use. Construct reliability was assessed using Cronbach's alpha. The value for Cronbach's alpha is 0.889 based on 262 participants and and therefore the construct intention to use posses reliability. The mean of the construct intention to use is 3.9676 ($\sigma = 0.93048$) and the median is 4.00, indicating a high intention to use DiGA.

COVID-19 is confronting the world with unprecedented economic and social challenges, but also health care systems worldwide are affected

by major changes (Lin et al., 2021; Wherton et al., Many countries have introduced eHealth 2020). applications specifically because of COVID-19. Due to the stay-at-home approach, the lockdowns and the concept of social distancing for combating COVID-19, most regular in-person meetings have been moved to the virtual space and nearly all areas of life are undergoing the transformation from in-person meetings to virtual meetings (Lin et al., 2021). It has become increasingly important to be able to treat patients remotely and not by infection-prone visits to practices, which is not always easy due to the variety of different treatments. For this reason, digital health care services became inevitable (Garattini et al., 2021). Therefore, we would like to explore the extent to which attitudes toward digital health services (e.g., DiGA, video consultation, e-prescription, etc.) have changed, potentially resulting in a more long-term impact. Asked about a change in attitude, the participants answered negatively changed (2.3%; 6/262), not changed (69.8%; 183/262) and positively changed (27.9%; 73/262). The mean is 2.26 $(\sigma = 0.487)$ and the median is 2.00. Asked on a 5-point Likert scale specifically about whether participants would be more willing to use a DiGA today compared to the time before COVID-19, the participants answered strongly disagree (18.3%; 48/262), disagree (8.0%; 21/262), neutral (34.4%; 90/262), agree (28.6%; 75/262) and strongly agree (10.7%; 28/262). The mean is 3.05 ($\sigma = 1.237$) and the median is 3.00. Surprisingly, these results lead to the conclusion that no change in attitude has happened. However, this must be questioned, because participants were only surveyed once after COVID-19 has started.

DiGA have experienced a significant price increase in recent months. While a DiGA costs on average 411€ six months ago, it is already 447€ as of March 2022 (Vetters et al., 2022). Even if the costs for DiGA are covered by the German health care system, it is interesting to know what amount the participants would be willing to pay (WTP) for a DiGA. The B2C market could become interesting for DiGA developers in the future. Therefore, the information about the WTP is helpful for alternative approaches. For example, patients could be offered a trial period for a small amount of money as well. In addition, not every health care system in the world can afford such expenses or has a completely different structure. In countries, where the distribution of such apps addresses the end user directly, the WTP can help with determining the pricing. As a result, 196 participants (74.8%) would not be willing to pay for using a DiGA, whereas 66 participants (25.2%) were willing to do so. The average is about 15€ per month.

6. Discussion and Outlook

In a pioneering role, Germany was in 2020 the first country in the world to provide statutory insured individuals with an entitlement for treatment with prescribable DiGA apps. However, they have not arrived in daily health care yet. The establishment requires the cooperation and acceptance of all stakeholders involved, especially the DiGA developers, health insurance companies, physicians/psychotherapists and patients. To the best of our knowledge, our study is the first examining the awareness, the requirements and the potential added value from the patients' point of view.

Our paper contributes to a unified understanding about eHealth and the related terms mHealth, telehealth, and telemedicine. In addition, we extended the taxonomy and include the concept of digital health applications (DiGA). Therefore, we provide a detailed definition and the current state in practice. With our work we provide a contribution to the beginning of scientific research on DiGA. However, in our view, there is an urgent need to conduct system-wide research involving all stakeholders. Our online study among potential patients provides important insights into the current use of digital services in health care and the attitudes toward DiGA. It shows that the current use of digital services is mainly limited to online appointment scheduling and general health apps. Digital services such as the electronic patient file or video consultation hours introduced in recent years as a measure to digitalize the health care sector are scarcely used by the participants.

We were able to show that participants have a predominantly positive attitude toward DiGA and see benefits such as increased flexibility and increased self-management, but also what concerns and barriers exist. In particular, participants have privacy concerns about their sensitive (health) data or see even technical problems as the main barriers. To provide inspiration for potentially new distribution channels such as B2C, we capture the willingness to pay, which shows that a large proportion of participants would not be willing to pay anything for DiGA. Nevertheless, about 25% would be willing to pay something for the usage. The average is about 15 \in per month.

The practical implication of our work is that there is an urgent need for action regarding information for patients. It has been shown in our survey that the majority of participants are open to the use DiGA, but simply have no awareness about it. The majority state that they have never been informed about it by their physician, but would be open in this regard. Thus, the acceptance by the physician and at the same time the recommendation is a decisive point for users. The DiGA market has the potential to grow in the future as people are willing to use them.

However, this study is also faced with limitations, which need to be considered when interpreting and utilizing the findings, as well as for the design of similar studies. First, many of our participants belong to younger age groups of 18 to 25 (38.5%) and 26 to 35 (36.3%). As many young people in Germany do not have a regular GP, they could profit significantly from DiGA. Also, it is more likely that young people use digital services and apps. Our study provides important insights into their awareness of and attitudes toward DiGA and may be useful for the future design of DiGA. As hardly any of them seem to have heard about DiGAs before the survey, it would be valuable to let them test and comment on existing DiGA in more detail. As most of currently existing DiGA target diseases that are more prevalent in older age groups, getting their input and opinions would also be important, but might be more difficult to capture in standard online surveys. We will address that in future research and use different approaches to better reach the older age groups. Overall, future research should investigate in the medical efficiency of DiGA more detail and which age / patients groups can profit the most from using DiGA and should therefore be targeted by developers. As only three participants have already used a DiGA, it would be interesting for future research to survey patients who are currently using or used a DiGA to investigate their experiences and requirements. In addition, we want to conduct system-wide research around DiGA involving all stakeholders based on our findings and those presented in Section 2.2 from studies with physicians in Germany. According to our findings, physicians/psychotherapists and health insurance companies are the most important distribution channels to bring DiGA into regular medical care to the patients.

References

- Aerzteblatt. (2020). Deutscher Hausärzteverband warnt vor Überlastung der Praxen (aerzteblatt.de, Ed.). Retrieved June 4, 2022, from https:// www.aerzteblatt.de/nachrichten/117864/ Deutscher - Hausaerzteverband - warnt - vor -Ueberlastung-der-Praxen
- Almathami, H. K. Y., Win, K. T., & Vlahu-Gjorgievska, E. (2020). Barriers and facilitators that influence telemedicine-based, real-time, online consultation at patients' homes: Systematic

literature review. Journal of Medical Internet Research, 22(2), 1–25.

- Chaet, D., Clearfield, R., Sabin, J. E., & Skimming, K. (2017). Ethical practice in telehealth and telemedicine. *Journal of general internal medicine*, *32*(10), 1136–1140.
- Dahlhausen, F., Zinner, M., Bieske, L., Ehlers, J. P., Boehme, P., Fehring, L., et al. (2021).
 Physicians' Attitudes Toward Prescribable mHealth Apps and Implications for Adoption in Germany: Mixed Methods Study. *JMIR mHealth and uHealth*, 9(11), 1–12.
- Davis, F. D. (1989). Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Quarterly*, *13*(3), 319–340.
- Esser, M., Boreham, A., Ring, C., & Schreier, J. (2020). PNS100 The New Reimbursement Route for Digital Health Applications (DIGA) in Germany: Critical Appraisal and First Evaluation of the Possible Effect on the German Healthcare System. Value in Health, 23, 658–659.
- European Commission, Folkvord, F., Hocking, L., Altenhofer, M., Harshfield, A., & Faulí, C. (2019). Benchmarking deployment of ehealth among general practitioners (2018) : Final report (J. Valverde-Albacete, F. Lupiáñez-Villanueva, & A. Devaux, Eds.). Publications Office.
- Eysenbach, G. (2001). What is e-health? Journal of Medical Internet Research, 3(2), e20.
- Eze, N. D., Mateus, C., & Cravo Oliveira Hashiguchi, T. (2020). Telemedicine in the oecd: An umbrella review of clinical and cost-effectiveness, patient experience and implementation. *PloS* one, 15(8), 1–24.
- Federal Institute for Drugs and Medical Devices. (2019). The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V - A Guide for Manufacturers, Service Providers and Users. Retrieved June 4, 2022, from https://www.bfarm.de/SharedDocs/ Downloads/EN/MedicalDevices/DiGA_Guide. pdf?__blob=publicationFile
- Federal Institute for Drugs and Medical Devices. (2021). 5 Tips for DiGA applicants. Retrieved September 17, 2022, from https://www.bfarm. de/EN/News/Blog/_docs/2021-10-06-tippsdiga-antragsteller.html
- Federal Institute for Drugs and Medical Devices. (2022). DiGA-Verzeichnis. Retrieved June 4, 2022, from https://diga.bfarm.de/de/verzeichnis

- Federal Ministry of Health. (2019).
 Bundesgesundheitsminister Jens Spahn im Bundestag zum Digitale-Versorgung-Gesetz (DVG). Retrieved June 4, 2022, from https:
 / / www . bundesgesundheitsministerium . de / presse / pressemitteilungen / dvg - 2 / 3 lesung.html#c165941
- Federal Ministry of Health. (2020). Driving the digital transformation of Germany's healthcare system for the good of patients. Retrieved June 4, 2022, from https://www.bundesgesundheitsministerium.de/en/digital-healthcare-act.html
- Federal Ministry of Health. (2022). Das E-Rezept kommt! Retrieved June 10, 2022, from https: //www.bundesgesundheitsministerium.de/erezept.html
- Federal Ministry of Justice. (2022). Sozialgesetzbuch (Code of Social Law): SGB. Retrieved June 10, 2022, from https://www.gesetze-im-internet. de/sgb_5/__12.html
- Garattini, L., Badinella Martini, M., & Mannucci, P. M. (2021). Improving primary care in Europe beyond COVID-19: from telemedicine to organizational reforms. *Internal and emergency medicine*, *16*(2), 255–258.
- Geier, A. S. (2021). Digitale Gesundheitsanwendungen (DiGA) auf dem Weg zum Erfolg – die Perspektive des Spitzenverbandes Digitale Gesundheitsversorgung. Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 64(10), 1228–1231.
- Hansen, A., Herrmann, M., Ehlers, J. P., Mondritzki, T., Hensel, K. O., Truebel, H., & Boehme, P. (2019). Perception of the Progressing Digitization and Transformation of the German Health Care System Among Experts and the Public: Mixed Methods Study. *JMIR public health and surveillance*, 5(4), 1–10.
- Heimann, P., Lorenz, N., Blum, N., & Schifferings, C. (2021). Erfahrungen von Herstellern digitaler Gesundheitsanwendungen (DiGA) dem Fast-Track-Verfahren mit des BfArM. Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 64(10), 1249–1253.
- Hossain, A., Quaresma, R., & Rahman, H. (2019). Investigating factors influencing the physicians' adoption of electronic health record (EHR) in healthcare system of Bangladesh: An empirical study. *International*

Journal of Information Management, 44, 76–87.

- Idrish, S., Rifat, A., Iqbal, M., & Nisha, N. (2017). Mobile health technology evaluation: efficacy Innovativeness and vs. cost effectiveness. International Journal of Technology and Human Interaction, 13(2), 1-21.
- Jabbarpour, Y., Jetty, A., Westfall, M., & Westfall, J. (2021). Not telehealth: Which primary care visits need in-person care? *Journal of the American Board of Family Medicine : JABFM*, 34, 162–169.
- Jeindl, R., & Wild, C. (2021). Technologiebewertung digitaler Gesundheitsanwendungen für Refundierungsentscheidungen. *Wiener medizinische Wochenschrift*.
- Jiang, X., Ming, W.-K., & You, J. H. (2019). The cost-effectiveness of digital health interventions on the management of cardiovascular diseases: Systematic review. *Journal of Medical Internet Research*, 21(6), 1–11.
- Klaassen, B., van Beijnum, B. J. F., & Hermens, H. J. (2016). Usability in telemedicine systems -A literature survey. *International journal of medical informatics*, 93, 57–69.
- Lee, J. Y., & Lee, S. W. H. (2018). Telemedicine cost-effectiveness for diabetes management: A systematic review. *Diabetes technology & therapeutics*, 20(7), 492–500.
- Lin, Y.-W., Ivanov, A., Chang, H.-L., & Shaw, M. J. (2021). Role of telehealth adoption in shaping perceived quality of care: Empirical analysis. *ICIS 2021 Proceedings*, 1–16.
- McKinsey, Richter, L., & Silberzahn, T. (Eds.). (2021). *eHealth Monitor 2021*. Medizinisch Wissenschaftliche Verlagsgesellschaft.
- Nittari, G., Khuman, R., Baldoni, S., Pallotta, G., Battineni, G., Sirignano, A., Amenta, F., & Ricci, G. (2020). Telemedicine practice: Review of the current ethical and legal challenges. *Telemedicine journal and e-health*, 26(12), 1427–1437.
- Nunnally, J. C. (1978). *Psychometric theory*. McGraw-Hill.
- Otto, L., Harst, L., Schlieter, H., Wollschlaeger, B., Richter, P., & Timpel, P. (2018). Towards a Unified Understanding of eHealth and Related Terms-Proposal of a Consolidated Terminological Basis. *HEALTHINF*, 533–539.
- Shaw, T., McGregor, D., Brunner, M., Keep, M., Janssen, A., Barnet, S., et al. (2017). What

is eHealth (6)? Development of a conceptual model for eHealth: qualitative study with key informants. *Journal of medical Internet* research, 19(10), 1–12.

- Techniker Krankenkasse. (2022). DiGA-Report 2022. Retrieved June 4, 2022, from https://www. tk.de/presse/themen/digitale-gesundheit/ digitaler-fortschritt/diga-report-2022-2125138
- Venkatesh, V., Morris, G. B., Michael G.and Davis, & Davis, F. D. (2003). User acceptance of information technology: Toward a unified view. *MIS Quarterly*, 27(3), 425–478.
- Vetters, R., Schaffelhofer, F., & Finck, F. (2022). Digitale Gesundheitsanwendungen. https : / / www . ey . com / de_de / forms / download - forms / ey - whitepaper - digitale gesundheitsanwendungen
- Waschkau, A., Flägel, K., Goetz, K., & Steinhäuser, J. (2020). Evaluation of attitudes towards telemedicine as a basis for successful implementation: A cross-sectional survey among postgraduate trainees in family medicine in Germany. Zeitschrift fur Evidenz, Fortbildung und Qualität im Gesundheitswesen, 156-157, 75–81.
- Weber, S., & Heitmann, K. U. (2021). Interoperabilität im Gesundheitswesen: auch für digitale Gesundheitsanwendungen (DiGA) verordnet. Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 64(10), 1262–1268.
- Wherton, J., Shaw, S., Papoutsi, C., Seuren, L., & Greenhalgh, T. (2020). Guidance on the introduction and use of video consultations during COVID-19: important lessons from qualitative research. *BMJ Leader*, 4(3), 120–123.
- Zhao, J., Freeman, B., & Li, M. (2016). Can Mobile Phone Apps Influence People's Health Behavior Change? An Evidence Review. *Journal of Medical Internet Research*, 18(11), 1–12.