

Digital Communication in Visceral Medicine: Regulatory Framework for Digital Communication

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Keywords

Digital communication · Telemedicine · DiGA · Digital health literacy · COVID-19

Abstract

Background: Germany has seen rapid development in the digitization of medicine in recent years. Especially, the COVID-19 pandemic has dramatically accelerated this process. Nevertheless, it is accompanied by legal innovations that promote the application of digital tools as well as create respective remuneration options. Ultimately, this continued implementation of digital innovations and telemedicine approaches will lead to the improvement of care and the more efficient provision of medical services. **Summary:** The article primarily describes the development and current status of digitization using 2 key examples of telemedicine and digital innovations – video consultation and digital health applications. Starting with the liberalization of remote treatment options, video consultation gained many users, especially during the COVID pandemic. The introduction of digital health applications with the possibility of reimbursement by the statutory health insurance funds has put Germany in a leading position in international comparison in this respect. **Key Messages:** Digitization in healthcare offers enormous opportunities both to professionals working in the healthcare sector and to patients. However, in order to successfully use digital tools in practice, the legal, organizational, and financial framework must be clarified. All medical professionals are well advised to further qualify themselves in this area in order to keep pace with developments.

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Introduction

Digitization of healthcare systems is a huge task that affects stakeholders and decision makers in Germany and around the world alike. The potential benefits of digitization for the healthcare system are enormous. The hope is that digitization will lead to more effective and efficient processes, allowing healthcare providers to spend more time with their patients, as well as give patients better and faster access to their healthcare providers. But, the challenges are enormous since digitization affects all areas of the healthcare system – and is not easy for a federal system with self-administration to manage.

For many years, Germany has been at the end of the virtual table of implementation and use of digital technologies in healthcare. At the end of 2018, a kind of wake-up call went through Germany in that regard: with its highly regarded Digital Health Index as part of its #SmartHealthSystems study, the Bertelsmann Stiftung provided evidence of where Germany is positioned in terms of digitization: sixteenth out of 17 countries [1].

Since then and even before, however, a lot has changed in the digitization of the German healthcare system. Politics such as the Federal Ministry of Health, different stakeholders such as the gematik, the National Association of Statutory Health Insurance Physicians, or leading health insurance companies as well as healthcare innovators such as the health innovation hub (hih) in Berlin or our institution, the Coordinating Unit for Digital Medicine Baden-Württemberg (KTBW), have initiated, moved ahead, and implemented many digital innovations in re-

cent years. Such initiatives and efforts have been dramatically pushed forward by the COVID-19 pandemic leading to more digitization even for administrative parts of healthcare systems.

This review will provide an overview of the relevant developments, innovations, and the infrastructural framework for digital innovations in the German healthcare system with the focus on 2 lead examples of digital innovations, which received enormous boosts over the last 12 months not only from the COVID-19 pandemic – telemedicine and digital health applications (in Germany called DiGAs for “Digitale Gesundheitsanwendungen”).

Telemedicine

One focus of this review is on telemedicine. Probably no other digital tool in health care around the world has experienced a greater boost from the COVID-19 pandemic and could now act as a role model in digitization of healthcare systems. The article traces the development of telemedicine in recent years, more in terms of the legal framework than the technical aspects, and explores its role in the German healthcare system.

Until a few years ago, taking care of patients via telemedicine (e.g., video consultations) was largely unknown. In the meantime, both, the options and the usage rate have increased significantly. The first step to set things up was the liberalization of the ban on remote treatment. The ultimate boost came from the COVID-19 pandemic, which accelerated the implementation of digital innovations dramatically.

Telemedicine approaches are changing the way healthcare providers, especially physicians, and patients interact. But, according to §7 of the professional code of conduct for physicians, with a few exceptions, telemedicine treatment without prior direct patient contact was forbidden in Germany until a few years ago. Since then, the development of the legal framework for telemedicine first and foremost in the field of video consultation has gained speed. On July 23, 2016, the representative assembly of the State Medical Association in Baden-Württemberg decided to liberalize the ban on exclusive remote treatment if conducted within model projects approved by the State Medical Association. The first telemedicine project with exclusive remote treatment started operationally in 2017 in Baden-Württemberg, interestingly conducted by the Association of Statutory Health Insurance Physicians in Baden-Württemberg, a program named “DocDirect.”

In May 2018, the Federal Medical Association decided on the general liberalization of the ban on remote treatment and recommended that State Medical Associations implement the liberalization of their respective profes-

sional codes. Since then, telemedicine applications have been legally possible in 16 of the 17 State Medical Associations even without prior patient contact. The “gold standard” in place until then, which is a personal patient contact, can since be replaced by video consultation if this is medically justifiable, the necessary medical care is maintained, and the patient has been informed about the special features of this type of medical care.

It is important to note that confidentiality, especially on sensitive medical data, is an integral part of the medical profession and is obviously also non-negotiable in the context of telemedicine. The legal framework is provided by the General Data Protection Regulation (GDPR or DSGVO) and the Federal Data Protection Act (BDSG), regulating the processing of personal data. According to these rules and regulations, the treating physician acts as the person responsible for organizing data protection in their practice whatsoever. In general, the medical liability in exclusive remote treatment corresponds to the previous liability of the physician in analogue treatment. Liability exists in the event of a breach of the treatment contract and occurs, for example, if the remote treatment is not justifiable or in the event of a breach of the physician’s duty of care [2].

However, the decisive step to set telemedicine up for success was still missing, as no remuneration option existed for this kind of medical care. This barrier was by far more important than other reasons such as technical hurdles, the complexity of the topic itself, and a lack of incentives in everyday practice to dedicate oneself to telemedicine contributing to the reluctance. It was not until October 2019 that a reimbursement option for telemedicine was created on a larger scale within the framework of the so-called uniform evaluation standard (EBM), making their provision interesting for physicians. Thus, physicians were able, for example, to also bill 80% of the flat rate for insured persons in the GP sector within the framework of exclusive remote treatment. Nevertheless, a limitation rule was still in place stating that a physician may not carry out >20% of his cases via video consultation.

Telemedicine, especially video consultation, has experienced its breakthrough with the beginning of the COVID-19 pandemic, as more and more physicians in practice and more and more patients preferred video communication to avoid the risk of infection. While telemedicine was provided just 100 times in 2017, the number of applications rose to 1,200 in 2019 and tripled again with the introduction of a reimbursement. In May 2020, in the midst of the first wave of infections in Germany, 1 in 2 physicians offered video consultation hours in their practice, and a further 10% were in the process of setting up a telemedicine service (see Fig. 1) [3]. The number of video consultations provided increased to 1.2 million in the second quarter of 2020 alone. Especially, patients were show-

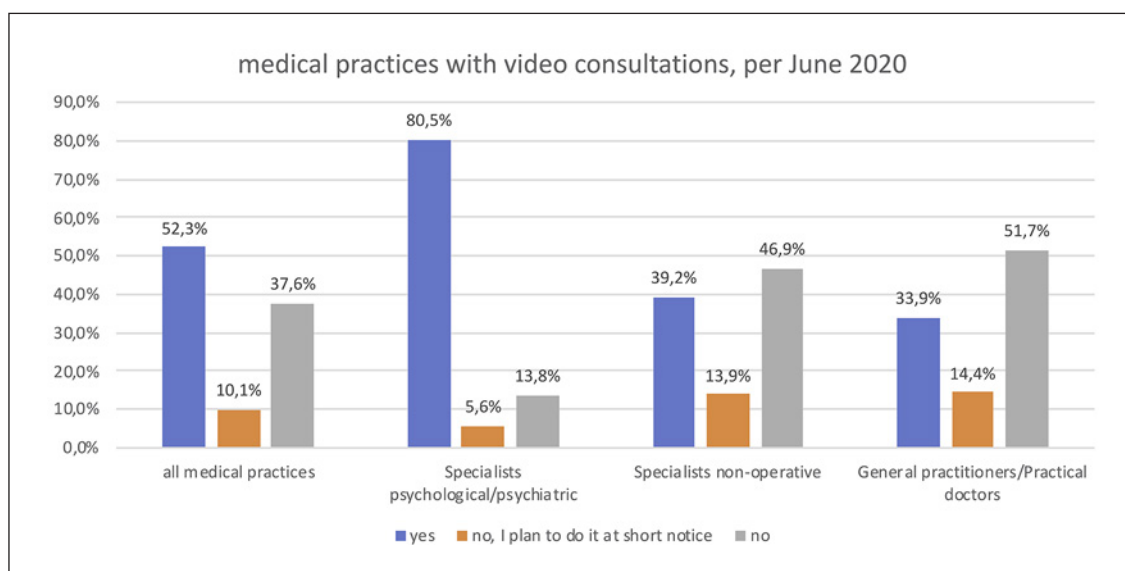


Fig. 1. Usage rate of telemedicine/video consultations (own presentation based on that by Obermann et al. [3]).

ing increasing interest and acceptance in the possibilities of telemedicine, while the downloads of the 5 most frequently used apps for video consultation spiked as demonstrated by AppTweak [4].

In 2020, the requirements for reimbursement were relaxed in view of the COVID-19 pandemic, and the Federal Association of Statutory Health Insurance Physicians and leading health insurance companies were provisionally suspending the limitations until the pandemic is over. Overall, the effects of the pandemic on the use of telemedicine are likely to be sustainable. A 2020 survey among physicians in Germany, France, Italy, Spain, and Great Britain suggested that the proportion of telemedical advice and treatment in these countries will increase permanently overall – from 15% before the crisis to 34% in the future [5]. In Germany, in a recent poll as part of the study “Ärzte im Zukunftsmarkt Gesundheit,” almost three-quarters (74%) of GPs assume that in future every fifth consultation will take place via video consultation [3].

In a future-oriented healthcare system, telemedicine (e.g., video consultations) will not be missing. To sustain acceptance rates within stakeholder groups, healthcare providers as well as patients need to acquire competencies to make best use of these healthcare innovations. Therefore, one major task will be to provide digital health literacy to patients and healthcare providers alike, a task we made one of our priorities. Overall, telemedicine has the potential to considerably advance the German healthcare system: it can help improve medical care not only in the pandemic (e.g., in rural areas or through the more effective treatment of high-risk patients) [6] and is most likely accompanied by financial advantages through increased efficiency [7].

Apps on Prescription – DiGAs (Digital Health Applications)

Whereas telemedicine has recently experienced an enormous boost by the COVID-19 pandemic, the fast-track implementation of other new digital applications in the German healthcare system has been made possible by legislative intervention. Through the “Digital Health Care Act” (DVG), the so-called “DiGAs,” digital health applications, were brought into reimbursement by the statutory health insurers, so that they are now available for around 73 million insured citizens.

Standard care for those with statutory health insurance in Germany now also includes digital health applications (DiGA). This new entitlement to benefits for insured citizens was introduced with the DVG (see Fig. 2). These applications – apps or browser based – upon application by the DiGA provider are evaluated by the Federal Institute for Drugs and Medical Devices (BfArM) on the basis of a publicly available catalogue of criteria and, if the evaluation is positive, are temporarily or permanently listed as reimbursable DiGAs. After listing, they can be prescribed like drugs and reimbursed by the statutory health insurances from the get go. Only those DiGAs that have been able to demonstrate a benefit for patients in the form of a medical benefit or positive health care effects proven in a clinical trial setup will find final inclusion in the DiGA directory [8]. On the other hand, digital health applications should not only benefit patients but also bring advantages to the prescribing physicians and psychotherapists; for example, it can be advantageous for a physician if patients regularly record their data themselves and provide these data to the physician in a clear and structured

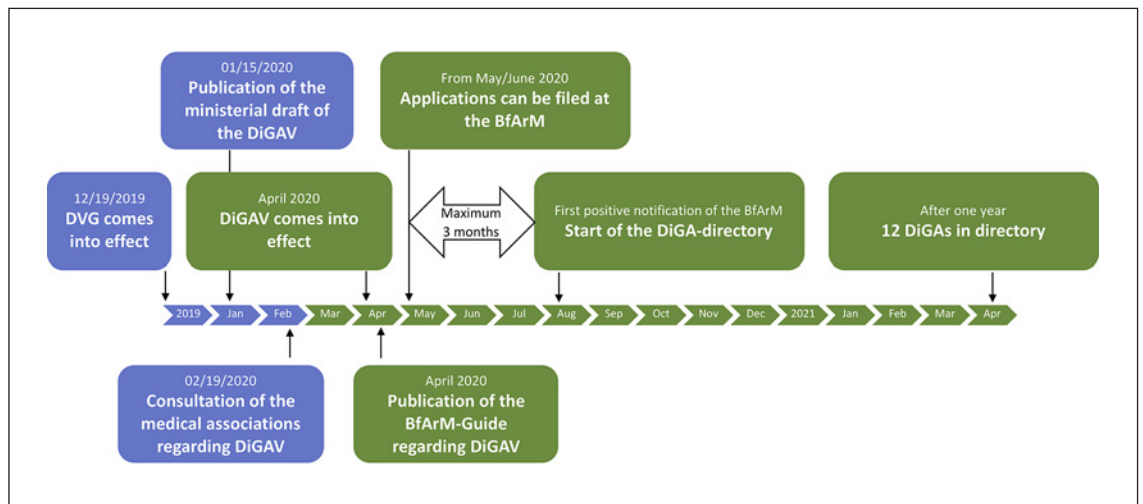


Fig. 2. Introduction process of digital health applications (own presentation based on BfArM [8]).

way for monitoring as well as research purposes with respect to the uses of patient-reported outcome measures. Communication channels can also be greatly accelerated through the use of digital means, and communication as a whole can benefit, resulting in positive healthcare benefits as well as improvement of overall outcome.

The DVG also regulates the reimbursement by the health insurance companies: in the first year, a fixed price is reimbursed according to the information provided by the DiGA provider. With proven evidence in real-world application and the final listing, a price is negotiated between the provider and the National Association of Statutory Health Insurance Funds.

This structured access for health apps to the entire health system of a country, in the case of Germany a health market of around 73 million insured persons, is so far unique worldwide, and Germany has suddenly taken on a pioneering role in this area of digitization in the healthcare system. Thanks to a rapid “fast-track” procedure, standardized processes, and simplified remuneration, the German market is becoming attractive for DiGA developers and providers and is attracting international eHealth providers. Key to approval and listing by the BfArM and ultimate placement in the healthcare market as well as adequate reimbursement remains the evidence that a DiGA has achieved in terms of medical benefits or in the proof of positive healthcare effects. This is often a formidable task and might need the support of an academic partner in preparing the evaluation concept [8].

In short, DiGAs can be prescribed by physicians and psychotherapists at the expense of the statutory health insurance after being listed at the Federal Institute for Drugs and Medical Devices (BfArM), so such DiGAs are part of digitally enabled care. For this purpose, the legislator has described a surprisingly short, binding introduction pro-

cess, the so-called “fast track,” which defines fixed decision deadlines and criteria for the authorization body. Areas of application for DiGAs include diagnostics and monitoring, chronic disease management, therapy, and therapy support, for example, in the field of depression or cancer. In general, DiGAs may cover these areas of applications:

- Prevention – applications to prevent illnesses: apps, virtual trainers, and fitness trackers to change an unhealthy lifestyle that can lead to chronic illnesses (e.g., diet, smoking, and exercise).
- Diagnosis – digital diagnosis applications: technologies that enable remote diagnosis or bring together more comprehensive data for diagnosis.
- Intervention – eHealth technology-supported interventions: eHealth technologies that are used by service providers for treatment and that can possibly also be used by the patient at home (temporarily), for example, in the context of psycho- or physiotherapeutic therapies.
- Management – applications for the management of chronic diseases: apps that contain certain functions depending on the disease, for example, mood diary, reminder of therapy compliance, networked heart rate sensors, pulse monitors, or insulin devices, some with alarm functions.
- Monitoring – remote monitoring of acute (COVID-19) or chronic patients: applications for digital remote monitoring of clinical parameters for acute or chronically ill (high-risk) patients.
- Support – patient support networks: online networks for patients to share information, experience, and treatment options.

The first DiGAs were added to the DiGA directory of BfArM in October 2020. Meanwhile, by status of June 1, 2021, a total of 15 DiGAs were listed in the DiGA direc-

Table 1. List of DiGAs with ICD classification (own presentation based on <https://diga.bfarm.de/de>)

DiGA name	Publisher	Disease
CANKADO PRO-React Onco	CANKADO Service GmbH	C50 Malignant neoplasm of breast
Deprexis	GAIA AG	F32.0 Mild depressive episode F32.1 Moderate depressive episode F32.2 Severe depressive episode without psychotic symptoms
Elevida	GAIA AG	G35 Multiple sclerosis
Invirto - Die Therapie gegen Angst	Sympatient GmbH	F40.0 Agoraphobia F40.1 Social phobias F41.0 Panic disorder
Kalmeda	Mynoise GmbH	H93.1 Tinnitus
M-sense Migräne	Newsenselab GmbH	G43 Migraine
Mika	Fosanis GmbH	C53 Malignant neoplasm of cervix uteri C55 Malignant neoplasm of uterus C56 Malignant neoplasm of ovary
Mindable: Panikstörung und Agoraphobie	Mindable Health GmbH	F40.0 Agoraphobia F41.0 Panic disorder
Rehappy	Rehappy GmbH	G45 Transient cerebral ischaemic attacks and related syndromes I60 Subarachnoid haemorrhage I61 Intracerebral haemorrhage +5 more
Selfapys Online-Kurs bei Depression	Selfapy GmbH	F32.0 Mild depressive episode F32.1 Moderate depressive episode F32.8 Other depressive episodes +6 more
Somnio	mementor DE GmbH	F51.0 Non-organic insomnia
Velibra	GAIA AG	F40.0 Agoraphobia F40.1 Social phobias F41.0 Panic disorder F41.1 Generalized anxiety disorder
Vivira	Vivira Health Lab GmbH	M16.0 Primary coxarthrosis M16.1 Other primary coxarthrosis M16.2 Coxarthrosis resulting from dysplasia
Vorvida	GAIA AG	F10.1/F10.2 Mental and behavioural disorders due to use of alcohol
Zanadio	aidhere GmbH	E66 Obesity

tory with indications such as multiple sclerosis, panic disorder, tinnitus, migraine, cerebral ischaemia, non-organic insomnia, depressive episode, social phobias, psychosomatic management of malignancies, musculoskeletal pain, obesity, and post-stroke care (see Table 1 for details) [9].

To achieve an entry into the DiGA directory, DiGA providers must submit a comprehensive evaluation concept, which needs to be supplied together with the initial application. In this context, the proof of real-world evidence from the actual healthcare context, in which the DiGA is implemented, is very important: only through the provision of positive healthcare effects or positive

medical benefits DiGAs can be permanently included in the DiGA directory and thus remain reimbursable. According to the DiGA guideline of the BfArM, manufacturers of DiGAs should acquire the support of a manufacturer-independent academic institution to obtain the proof of positive healthcare effects or medical benefits, that is, in areas of preparing the evaluation concept, scientific evaluation of the study designs, conducting the respective clinical trials, and thus the generation of the evidence. For such support, there are now professional service providers available, such as the *diga.guide* initiative of the Health Care Innovation Institute GmbH, which has already published several white papers on “evaluation of

digital health applications” as well as “evaluation concept and study designs” [10].

Furthermore, the long-term reimbursement for a respective DiGA is negotiated based on the extent of the positive effects they achieve with patients. In this respect, evidence for positive healthcare effects or positive medical benefits are equally important prerequisites for conducting price negotiations with the statutory health insurers. Not to forget the gatekeepers or enablers of such new concepts of reimbursed health apps: without a prescription by physicians (general practitioner or specialist) or by psychotherapists, the new DiGA concept will not be crowned with success. Therefore, knowledge about and acceptance of DiGAs and their positive effects on the side of physicians and psychotherapists are of critical importance for the implementation of reimbursed DiGAs. A fact that has not been addressed precisely enough so far: physicians and psychotherapists need to be active parts of such new endeavours, and they have to envisage DiGAs as a positive perspective for their own daily practice not as a threat or additional workload. Nevertheless, the new legislation on the use of digital solutions in the healthcare system and the related ordinance as well as the associated guidelines of the BfArM represent a courageous first step by the legislature to break new ground, to enable Germany to rapidly introduce digital applications in the healthcare system and still have a certain regulatory effect with maintained stringency.

Conclusion

In summary, digitization has been given a tremendous boost by the development of the legal, technical, and social framework conditions in the recent past, but most dramatically by an unexpected pandemic. On the one hand, DiGAs are thereby intended to improve medical practice and on the other hand to enable innovations to enter the statutory healthcare system. The successful application of telemedicine requires a good understanding of the scope of the new technology on the part of patients as well as physicians and other healthcare professionals and a willingness to engage with new processes and tools. Much of this is linked to different legal, technical, and financial requirements, which providers and users of telemedicine procedures should keep well in mind. Additionally, their digital competencies will determine the success of digital innovations in the healthcare market. If those questions are answered well, telemedicine and for that matter digital medicine can contribute to better medical care and help to make the best possible use of precious medical resources.

In the past 2 years, digital innovations have moved much more into the focus of health policy. The legal

framework was laid along a brief series of laws on important issues in which Germany was lagging behind internationally. Self-administration has also contributed to improving the framework conditions, particularly in the area of telemedicine. Last but not least, Germany has taken on a pioneering role internationally with the introduction of remunerated DiGA.

Now, the players in the healthcare sector are called upon to fill eHealth in Germany with life, hospitals and outpatient physicians, telemedicine providers and pharmacies, health insurance companies, and, last but not least, the patients alike. However, digital readiness seems still very different as patients seem much more open than healthcare providers [11], when it comes to the acceptance of health apps and digital services, and health insurance companies seem better positioned digitally than some service providers. It is obvious there is still a lot to do for everyone involved to help eHealth achieve a breakthrough in Germany.

However, the decisive impetus for digital change has already been set from outside: the COVID-19 pandemic and its consequences have finally opened the door to digital healthcare. The pandemic has impressively shown the value that digital innovations and telemedicine can have in order to make processes in the healthcare system as efficient and safe as possible for everyone involved. These digital innovations now need to be systemically evaluated and sustainably implemented into the healthcare system, in the COVID-19 context and post-COVID.

Conflict of Interest Statement

Prof. Dr. Oliver G. Opitz and Dr. Armin Pscherer are founders of the Health Care Innovation Institute GmbH.

Funding Sources

The Coordinating Unit for Digital Medicine Baden-Württemberg (KTBW) is generously funded by the State of Baden-Württemberg, the Ministry of Science and Arts (MWK), the Ministry of Social Affairs, Health and Integration (MSI), and the Ministry of Economics (WM).

Author Contributions

The three authors wrote the manuscript together.

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