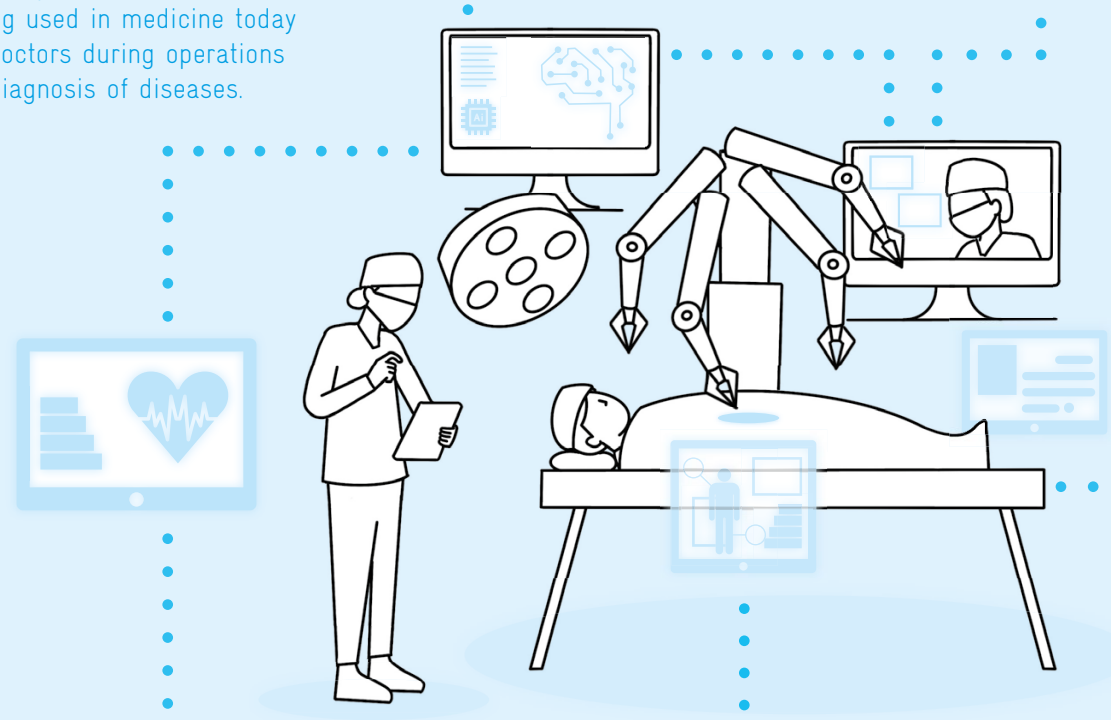
B 4 Digital Transformation in the Healthcare System

The digitalization of the healthcare system is associated with great potential for innovation and value creation with regard to better quality and more efficient healthcare. In particular, the increasing availability of health data in combination with new digital analysis methods opens up opportunities for more personalized diagnostics and treatment.

Telemedicine applications such as video consultations enable patients to be cared for across geographical distances.

By analyzing health data, new insights can be gained that enable a change towards personalized medicine.

Artificial intelligence methods are already being used in medicine today to support doctors during operations and in the diagnosis of diseases.



B 4 Digital Transformation in the Healthcare System

The digitalization in the healthcare system is associated with great potential for innovation and value creation.[364] In administration as well as in treatment and care, digital technologies can increase the efficiency of service provision through renewed and optimized processes and thus improve the allocation of resources.[365] In addition, the application of digital technologies and the use of health data can contribute to significantly increasing the quality of healthcare, for example by improving individual diagnostics and developing innovative treatments.

International comparative studies show that Germany lags far behind other European countries in the digitalization of the healthcare system.[366] For example, in recent benchmarking studies Germany mostly only ranks in the bottom third.[367] One example of the slow implementation of digitalization in the healthcare system is the failed introduction of electronic prescriptions (e-prescriptions). Despite a 16-year planning and preparation phase, it was not possible to bring this into use on 1 January 2022 as planned. Further massive deficits in the digitalization of the healthcare sector were revealed during the COVID-19 pandemic.[368]

Against the background of these deficits, this chapter is dedicated to the question of how the implementation of the digital transformation in the healthcare system can be advanced and the associated innovation potentials can be unlocked. To this end, starting from an inventory of the framework conditions and measures already implemented, the view is successively broadened and directed towards future potentials and innovations in the healthcare system.

B 4-1 Stakeholders, Legal Regulations and Elements of the Digital Transformation

Legal regulations provide the framework to be able to leverage the potential associated with the digitalization of the healthcare system and to improve healthcare. The technical basis for the digital transformation of the healthcare system is the so-called telematics infrastructure (TI), which networks the stakeholders in the healthcare system and enables the secure, cross-organisational exchange of information and data. The electronic patient record (ePR), which bundles the health data of patients, is the most important TI application. In addition, health apps such as digital health applications (Digitale Gesundheitsanwendung, DiGA) and telemedical applications such as video consultations are key elements of the digital transformation of the healthcare system.

Stakeholders in the Health System and Legal Regulations as a Framework for Digital Transformation

The stakeholder landscape in the German healthcare system is complex and heterogeneous. There is a multitude of stakeholders with distributed responsibilities and competences resulting from the principle of self-administration. In addition to service providers such as doctors, psychotherapists and other members of the healing and nursing professions, patients, too, are stakeholders in the healthcare system. Others include hospitals, pharmacies and care facilities, the statutory health insurance funds (Gesetzliche Krankenkassen, GKV) and private insurance providers, as well as science, the economy, numerous interest groups and politics.[369]

While the Federal Government has the task of defining the legal framework for the healthcare system and its stakeholders, the Länder are responsible for outpatient and inpatient care. Finally, the service providers as well as the insurers in their capacity as payers are responsible for the execution of medical care and the billing of services.[370]

The first legal regulations for the modernization and digitalization of the healthcare system were addressed in Germany as early as 2003 with the Act on the Modernization of the Statutory Health Insurance Funds (GKV Modernization Act).[371, 372] Among other things, the creation of an information, communication and security infrastructure, the later TI, as well as the introduction of the ePR were decided in this act.[373] However, the implementation of the measures provided for in the act was slow in the following decade.

To accelerate the processes of digitalization, the E-Health Act was first passed in 2015, setting specific deadlines for the introduction of the TI and the ePR. Finally, further laws were passed in the past legislative period to accelerate the digital transformation of the healthcare system. For example, with the Appointment Service and Care Act passed in 2019, the statutory health insurance funds were obliged, among other things, to provide all statutorily insured persons with an ePR by 1 January 2021.[374] The Digital Care Act, which also came into force in 2019, aims to improve care through digitalization and innovation.[375] In it, the possibility was created to prescribe digital health applications (DiGAs) and to bill their use via the statutory health insurance funds.[376] In addition, the Act facilitated the provision of telemedical services such as video consultations.[377] The Patient Data Protection Act, passed in 2020, provided, among other things, for the mandatory use of the e-prescription as of 1 January 2022, as well as the possibility for statutorily insured persons to release their ePR data for research purposes.[378]

Telematics Infrastructure (TI) as the Backbone of the Digitalization of the Healthcare System

A digital infrastructure that connects all stakeholders in the healthcare system and enables secure, cross-organizational exchange of information and data is the basis for successful digitalization. In Germany, the so-called telematics infrastructure (TI) fulfils these tasks. It consists of decentralized components[379] such as card readers as well as centralized hardware and software components, including the secure e-mail service Kommunikation im Medizinwesen (KIM).[380] These components and services provide the technical platform for networking stakeholders and for offering specialized applications such as the ePR and e-prescription.[381]

Gematik was founded in 2005 as a joint initiative of the umbrella organizations in the healthcare sector for the conceptual preparation and establishment of the TI.[382] Furthermore, the E-Health Act set mandatory deadlines for medical service providers to connect to the TI by 31 August 2018.[383] However, conflicting stakeholder interests in gematik's shareholders' meeting in conjunction with the required two-thirds majority for decisions prevented the connection of medical service providers by the set deadlines. Therefore, a restructuring was carried out within the framework of the Appointment Service and Care Act and the Federal Ministry of Health took over 51 percent of gematik's shares, making it its main shareholder. In addition, it was determined that decisions in the shareholders' meeting could be made by simple majority.

In addition to the conception and establishment of the TI, gematik's tasks also include the operational coordination and further development of the TI and associated specialist applications.[384] To ensure the functionality and security of the TI, gematik specifies functional and technical requirements for components, technical services and providers of operational services, thus setting standards for the digital healthcare system. It is also responsible for the approval of components, services and providers in the TI. Furthermore, gematik has the task of monitoring new technological developments and taking them into account in the expansion of the TI. In this context, a redesign towards TI 2.0 took place in 2021.[385] This aims in particular to create added value beyond the digitalization of analogue data through the user-friendly and secure networking of stakeholders and the use of data.[386]

Based on the Health IT Interoperability Governance Regulation, which came into force on 15 October 2021, gematik coordinates interoperability and thus promotes frictionless and efficient data transfer between the stakeholders in the German healthcare system.[387]

The reform of gematik has helped to overcome blockades that delayed and hindered the establishment of the TI for years. In the coming years, it will be important to rapidly expand the TI and further develop it in line with changing needs.

Electronic Patient Record (ePR) as a Core Element of Digital Healthcare

An ePR records the most important health-related information of insured persons in a digital documentation system and makes this information available to service providers across disciplines, institutions and sectors. It is a core element of a digitalized healthcare system.[388]

Through immediate and location-independent access to structured information, an ePR can enable more needs-based and better coordinated care. For example, it can improve compliance with medical prescriptions through integrated medication intake management.[389] In addition, the use of an ePR can also contribute to greater cost-effectiveness in healthcare.[390] For example, a meta-analysis from the USA concludes that hospitals that use an ePR with basic functions have 12 percent lower average costs than hospitals that do not use an ePR. The study attributes the savings primarily to the reduction of medication errors, more efficient organizational processes and shorter hospital stays.[391] Finally, the use of ePR data for research purposes can help to diagnose diseases earlier and find more appropriate treatments.[392]

The introduction of ePR was already planned in Germany as part of the GKV Modernization Act in 2003. However, the self-administration stakeholders failed in implementing the ePR in the following years. It was not until the laws on the digitalization of the healthcare system passed in the 2017 to 2021 legislative period that a concrete roadmap for the introduction of the ePR was established.[393]

As part of the first expansion phase since January 2021, statutorily insured persons were enabled to use an ePR provided by their health insurance fund. This enabled the first documents such as the emergency data record,[394] the medication plan and doctors' letters to be stored in the ePR. The second expansion phase, which came into force in January 2022, provides for statutorily insured persons to be able to access their vaccination certificate digitally, among other things. In the third expansion phase, which is planned to start in January 2023, people with statutory health insurance are to be given the option of releasing their data stored on the ePR pseudonymized for research purposes.[395]

The use of the ePR has so far been on a voluntary basis. By the end of 2021, only 312,000 of the approximately 73 million statutorily insured persons in Germany had opted for this.[396] For the establishment of the ePR and the allocation of data processing rights, the Patient Data Protection Act (Patientendaten-Schutzgesetz) currently provides for a multi-stage consent procedure (opt-in procedure[397]) by the insured persons. Users must give the respective treating health care providers access to their ePR data by consent, whereby the consent must be given separately for each health care provider involved in the treatment.[398] This cumbersome consent procedure as well as the lack of awareness of the ePR contribute to the fact that only a few insured persons decide to set up the ePR and that it is therefore not used nationwide, as was also the case in France (see box B 4-1). The Commission of Experts therefore considers the introduction of an opt-out procedure[399] planned in the coalition agreement to be a purposeful adjustment. In addition, the statutory health insurance funds should demonstrate to the insured the added value of using the ePR for better care by means of useful applications, such as the electronic storage of the medication plan.

Telemedicine Applications as a Complement to Care

In addition to medical care over spatial and temporal (asynchronous) distances,[400] telemedicine also includes general care concepts for the provision of medical services with the help of information and communication technologies.[401] Despite the great potential of medical video consultations for improved healthcare, the use of corresponding services remained at a low level for a long time. From March to December 2019, for example, around 2,800 video consultations were carried out throughout Germany. Largely influenced by the COVID-19 pandemic and some regulatory simplifications, this number rose to over 2.5 million in the same period of the following year.[402]

Telemedicine applications can have a positive impact on healthcare.[403] On the one hand, they can help to improve the general health status of pa-

tients. On the other hand, they can save time and costs for the service providers.[404] Particularly against the background of the current and increasing shortage of doctors in rural regions, telemedical applications are associated with great potential for ensuring care.[405] However, according to studies, citizens in rural areas tend to have a lower acceptance of telemedical services than citizens in urban areas.[406] In addition, older people use telemedical health services to a lesser extent than younger people.[407]

To increase the use of approved and therapeutically useful telemedicine options, the service providers, especially the physicians in private practice, play an important role. They need sufficient financial incentives to opt for this form of treatment. At present, services provided by telemedicine are generally charged at the same rates as conventionally provided services, but in some cases at lower rates.[411] Grants and subsidies are available for the additional expenditure required in the introductory phase – for the acquisition of software and hardware, further training, additional information and education of patients.[412] Such subsidies for the initial investment costs of service providers appear to make sense in view of the dynamic efficiency gains associated with the widespread use of telemedicine. Against this background, it also seems reasonable in an initial phase to remunerate services provided by telemedicine with the same fees as comparable services provided conventionally. Once telemedicine has become established, the efficiency gains for service providers should be distributed appropriately between them and the insured, and cost rates should be adjusted accordingly, i. e. reduced.

Box B 4-1 The Austrian Electronic Health Record and the French Dossier Médical Partagé

In Austria, the electronic health record ELGA, which enables access to health data by service providers across disciplines and institutions, has been gradually introduced since 2015.[408] As part of the introduction of ELGA, the Electronic Health Record Act created the legal basis for an opt-out regulation. According to this, an ELGA is initially created for all citizens, but they can opt out at any time via the ELGA objection centre. In June 2021, just under 97 percent of citizens in Austria had an ELGA, which is also being used accordingly: as of October 2021, 89 percent of all laboratory results and 91 percent of medical discharge letters were recorded in a structured, exchangeable and machine-readable form.[409]

The establishment of the French ePR (Dossier Médical Partagé, DMP) has been very slow since its introduction in 2006. Of the nearly 40 million DMPs planned, only about 580,000 existed in 2016. The main reasons cited are the restrictive and complicated access management and the opt-in rule. After the reform in 2018 with various structural adjustments, such as the improvement of interoperability and stronger funding incentives for service providers, the use could be increased to eight million DMPs.[410]

Potential of Digital Health Applications

With the introduction of the DiGA (Digitale Gesundheitsanwendung – digital health application, or app) in October 2020, Germany is the first country where physicians and psychotherapists can prescribe 'apps on prescription'.[413] DiGAs are certified medical devices whose main function is based on digital technologies and which are used to diagnose and treat diseases.[414] Unlike common health and fitness apps, the costs for DiGAs are reimbursed by the statutory health insurance funds.

A prerequisite for the prescription of a DiGA is its inclusion in the DiGA directory. For a DiGA to be included in the official DiGA directory by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), the developers must, among other things, state which positive healthcare effect the application achieves and provide evidence on data protection requirements. Within the framework of the fast-track approval procedure, which provides for an assessment period by the BfArM of a maximum of three months, there is also the possibility of a provisional inclusion in the DiGA directory for a maximum of one year, in addition to permanent inclusion.[415] A total of 20 of the 28 DiGAs currently approved for reimbursement in standard care have so far only been provisionally included in the directory. Most of the approved DiGAs are aimed at the

treatment of mental illness.[416] According to the umbrella organization of occupational health insurance funds, at least 39,000 statutorily insured persons had used an application listed in the DiGA directory by the end of 2021.[417]

To achieve a faster reimbursement decision, the evidence required in the approval process for inclusion in the DiGA directory could be made more dependent on the risk of undesirable side effects and the degree of vulnerability of the target group.[418] Furthermore, the data generated during the prescription and use of DiGAs should be used by the statutory health insurance funds to evaluate them regularly with regard to their medical effectiveness. Developers should do this with a view on the technical functionality of the DiGAs.

Due to their direct relation to patients, the attitudes of healthcare providers towards app-based treatments are of significant importance for the dissemination of DiGAs. Studies show that most of the physicians and psychotherapists surveyed have a fundamentally positive attitude towards DiGA[419] and health apps[420] and recognize a clear added value for patients in their use. Nevertheless, the majority of respondents refer to existing uncertainties and a lack of information regarding the use of DiGAs, data security and medical evidence, which ultimately makes adequate advice and support for patients more difficult.

According to an arbitration procedure concluded in December 2021 to regulate maximum prices in the framework agreement between DiGA manufacturers and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), reimbursement in the first year after inclusion in the DiGA directory will in future be made up to group-specific maximum prices.[421] These are based in particular on the respective indication group and are to be adjusted every six months if necessary. Exceptions to the reimbursement limit exist for applications that mainly address rare diseases or whose main function is based on artificial intelligence. Likewise, the first 2,000 prescriptions of an application are exempt from the maximum price. The long-term reimbursement amounts of the individual applications beyond the first twelve months are determined in negotiations between the National Association of Statutory Health Insurance Funds and the individual developers.

To link the amount of reimbursement more closely to the actual added value and the long-term use of the respective application, current considerations are also discussing use- or performance-based reimbursement models.[422] This could create even stronger incentives for high-quality products on the part of the developers and avoid an excessive cost burden on the statutory health insurance funds.

B 4-2 Use of Health and Healthcare Data for Research and Innovation

Data are essential for the further development of medical research, public health research[423] and healthcare. Especially through the development of new diagnostic and therapeutic options, they can contribute to significantly improving healthcare and supporting innovations in the healthcare industry, for example in the health tech sector (see box B 4-2).

Data are generated both in the medical research and development process and in the treatment of patients. Digitalization contributes to improving the availability of existing health data along the entire medical care chain and to generating new data on a large scale. The analysis of this data opens up innovation potential, especially in data-based medical research.

Potential of Data in the Healthcare Sector

Data that are explicitly collected for medical research purposes can help to gain new medical and therapeutic insights and enable their translation into application. For example, data from clinical trials provide information on the safety and efficacy of therapeutic agents. In addition, data from biobanks and clinical registries can be used to research the causes of diseases.[424]

Moreover, data from everyday care generated in connection with the treatment of patients can be used for research within the scope of secondary use.[425] For example, these data can be used in medical research to conduct comparative effectiveness studies as well as to track the course of treatments.[426] Care and billing data also make it possible to develop new concepts for healthcare within the scope of public health research. The comprehensive pooling of health data from care, which is made possible by an ePR, facilitates its use and holds great potential for improving health services.[427] For exam-

ple, anonymized data have been used in the United Kingdom for over 30 years, among other things, to investigate questions of drug safety, drug use and the effectiveness of health policy measures.[428]

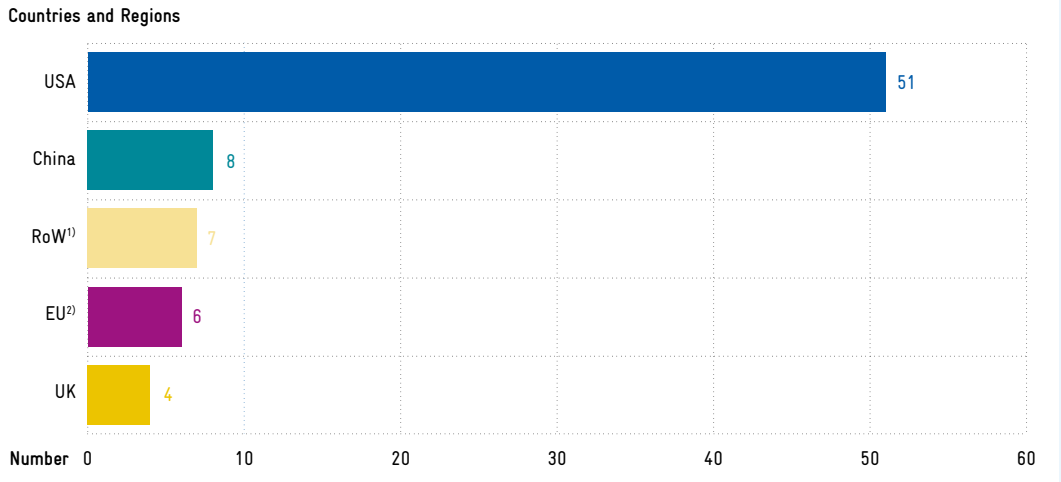
Through the comprehensive analysis of data with digital technologies, new insights can be gained in research that enable a change towards personalized medicine.[429] For example, data-driven medical research is based on the analysis of large amounts of data using high-performance computers. Particularly in the field of analyzing medical images, artificial intelligence methods are already well developed and are used, among other things, to help doctors diagnose diseases such as skin cancer.[430]

Genetic data have the potential to significantly advance disease research. For example, in the case of SARS-CoV-2, genome sequencing with digital high-throughput methods makes it possible to detect virus variants and their changes in terms of their transmission behaviour. The sequencing results can also be used to measure the severity of diseases caused by the SARS-CoV-2 variants and to take targeted measures.[431] The '1+ Million Genomes' initiative funded under Horizon 2020 aims to systematically bring together data from regional, national and international projects with strict regard to data protection and data security and to make them accessible for research.[432] By 2022, scientists in the EU should thus be able to access at least one

Box B 4-2 Health Tech Innovations

Between 2019 and 2021, the number of unicorns, i.e. start-ups with a market valuation of more than US$1 billion, doubled globally from 38 to 76.[433] The USA accounts for by far the most unicorns, with 51 (see figure B 4-3). Eight companies of this type are based in China and six in the EU, with Ottobock[434] and ATAI Life Sciences[435] two of them in Germany. The market valuation of all health tech unicorns is over US$160 billion, of which US-American unicorns account for about 75 percent. In addition to developing individual diagnoses and treatments using artificial intelligence, the companies operate in the areas of early detection and behaviour management, among others.[436] For example, Oxford Nanopore, a spin-off of Oxford University, is developing new sequencing technologies that can be used to diagnose cancer.[437] In the area of behaviour management, the app Noom uses the latest findings from behavioural research to empower people to improve their health and live healthier lives.[438]

Fig. B 4-3 Number of health tech unicorns by countries and regions 2021



1) ROW = Rest of the World. Includes Switzerland and Israel with two unicorns each, and India, Canada and South Korea with one unicorn each.
2) Two unicorns each are based in Germany and France; Ireland and Sweden each account for one unicorn.
Source: Own representation based on data by www.holoniq.com/healthtech-unicorns/.

million genome sequences across countries. The volume of data enables researchers to gain new and more robust insights into the origins of diseases and to develop opportunities for new personalized diagnoses and treatments.

Interoperability, Infrastructure and Data Access

To ensure the usability of health and healthcare data for research purposes on a large scale and with high data quality, structured and standardized data collection as well as secure and efficient data access are required. Interoperability must be ensured to enable the exchange between different IT systems across interfaces and the linkability of data from different sources.[439] Likewise, the data potentially usable for research should be findable, accessible, interoperable and reusable in accordance with the FAIR Data Principle.[440]

On the policy side, there are various initiatives aimed at promoting interoperability, access to data and the expansion of the data infrastructure. For example, researchers from medicine, computer science and other disciplines from all German university hospitals have been working together in consortia in the Medical Informatics Initiative (MII), which has been funded by the Federal Ministry of Education and Research since 2016, to develop interoperability solutions, among other things.[441] As part of the initiative, licences for the medical terminology SNOMED CT were used for the first time in Germany. Based on this terminology, a core data set is being built up by the consortia of the MII, which enables the overarching use of health data for research.[442]

The National Research Data Infrastructure (Nationale Forschungsdateninfrastruktur, NFDI), which was adopted in 2018 and is currently under construction, pursues the systematic development, sustainable securing and accessibility of data from research and science. In this context, two consortia from the field of health research are being funded with the aim of creating new possibilities for data analysis and facilitating the shared use of health data.[443] The NFDI4Health consortium, the National Research Data Infrastructure for personal health data, focuses on data generated in clinical and public health studies, among others. The aim of the German Human Genome-Phenome Archive, the second funded consortium, is to establish a genome archive.

Box B 4-4 Findata

The example of Findata, an authority founded in Finland in 2019, shows how the secondary use of health data can be promoted and simplified. In a one-stop shop model for health data, Findata bundles the application processing as well as the linking and provision of the data. To gain access to the data, scientists only need to submit a single application. Once the application is approved, Findata processes the data, pseudonymizes it and makes it available to researchers remotely in protected virtual spaces.[444]

The administrative effort for accessing and using health data must be as low as possible for scientists. This task can be performed by the Research Data Centre Health, which is currently being set up and is modelled on Findata (see box B 4-4).[445] It can ensure efficient application and approval procedures for data use and guarantee data protection.

B 4-3 Barriers to Digital Transformation

Despite the great potential associated with digitalization for the improvement of care as well as the further development of the healthcare system, Germany lags far behind other European countries in international comparison. The reasons for this are complex and lie, among other things, in the structure of the healthcare system, considerations and concerns regarding data protection as well as a still too low acceptance of digital health applications both among service providers and patients.

Absence of an Overall Strategy

The multi-layered and heterogeneous landscape of stakeholders in the German healthcare system makes its digitalization a difficult undertaking. Initiatives in health research have been launched in recent years with the Telematics Infrastructure 2.0, the Medical Informatics Initiative and the NFDI consortia, which are intended to increase the networking of the stakeholders at national and European level and improve the utilization of data.[446] However, an overall strategy for the digitalization of the healthcare system is still lacking. This has now been announced in the coalition agreement.[447]

Balancing Act Between Data Protection, Data Security and Data Use

Health data is often sensitive personal data. Therefore, in the healthcare sector more than in other areas, there is a delicate balance between IT security and data protection on the one hand and the potential of data use on the other.

According to Article 9 of the European General Data Protection Regulation (GDPR), special care must be taken when collecting, passing on and using personal health data. This is often seen as a considerable obstacle to digitalization in the healthcare sector.[448] However, the GDPR allows for regulatory leeway at the national level. A look at other European countries such as Estonia and Denmark shows that the GDPR alone is not an obstacle to the use of data in the healthcare sector. There, GDPR-compliant opt-out regulations allow the transfer and use of data from electronic patient records for research purposes.[449] In Germany, comparable regulations are lacking so far.

Another obstacle is the multitude of Länder data protection laws, which are interpreted differently by the Länder data protection commissioners regarding the disclosure and use of health data for research purposes. This contributes to legal uncertainty and delays the implementation of data-dependent research projects.[450]

Hesitant Uptake of Digital Health Services

The digitalization of the healthcare system cannot be successfully implemented without the various stakeholders in the system accepting, understanding and applying the new technologies and applications. Service providers are hesitant about digital products. Reasons for this include a lack of information and digital skills.[451]

To bring digital applications such as ePR, e-prescription and DiGAs into widespread use, there must be a corresponding demand on the part of patients. In a representative survey conducted in May 2020, 55 percent of respondents said they were essentially open to new digital applications; more than 65 percent agreed that the COVID-19 pandemic had highlighted the positive benefits of these applications.[452] However, 45 percent of respondents expressed fears that digital applications would (tend to) worsen the doctor-patient relationship. Furthermore, 26 percent of respondents said that digital applications were too complicated and 40 percent that their data was not secure with them.[453] In addition, more than 40 percent of respondents said they did not feel well informed about digital applications by statutory health insurance funds and service providers.

Overall, these studies point to further potential for improvement on the part of both service providers and citizens, especially regarding the information base.

B 4-4 Recommendations for Action

The digitalization of the healthcare system is associated with great potential for innovation and value creation regarding better quality and more efficient healthcare. In particular, the increasing availability of health data in combination with new digital analysis methods creates opportunities for more personalized diagnostics and treatment. In international comparison, Germany lags far behind other European countries in the digitalization of the healthcare system.

The Commission of Experts recommends the following measures to the Federal Government to reduce existing barriers and to be able to leverage the innovation potential associated with digitalization:

Developing and Rapidly Implementing a Digitalization Strategy for the Healthcare Sector

— To advance the digital transformation of the healthcare system, the digitalization strategy for the healthcare system announced in the coalition agreement should be developed and implemented quickly. The strategy should specify concrete responsibilities, define milestones and set out a timetable for implementation.

— All relevant stakeholders of the healthcare system should be involved in the drafting and development of the strategy. The implementation of the strategy requires a coordinating body with the broadest possible enforcement powers. It must be carefully examined whether this role can be assigned to gematik, which according to the coalition agreement is to be expanded into a digital health agency.

— To enable an efficient and smooth exchange of data and information and to ensure interoperability between IT systems, sufficient space must be given to the establishment of interoperable and international standards within the framework of the strategy.

— In addition, continuous monitoring of the implementation progress and its regular publication should be integrated in the strategy.

Exploiting the Innovation Potential of Health Data

— The Commission of Experts supports the Health Data Use Act announced in the coalition agreement to improve the scientific use of health data. The GDPR-compliant use should be designed for scientists in such a way that the administrative burden is as low as possible.

— The Commission of Experts welcomes the fact that all insured persons are to be provided with a GDPR-compliant ePR via opt-out, which they can manage independently. However, to be able to exploit the potential associated with the ePR data, the option for insured persons to release the data should also be designed to be as low-threshold as possible – especially for research purposes, but also for the exchange of data between care and research.

Promoting the Use of Telemedicine Applications and DiGAs

— For the possibilities of telemedicine to be used more, sufficient financial incentives are required for the service providers. Where this is not currently the case, the same services should therefore be remunerated equally in the introductory phase, regardless of whether they are provided by telemedicine or conventionally.

— Potential providers of DiGAs must present comprehensive documentation of medical evidence as well as other satisfied factors as part of the accreditation process. Although this is a mandatory requirement for quality healthcare, the introduction of flexible, adaptive study designs and requirements should be explored. After approval, developers should continuously review the technical functionality and statutory health insurance funds the medical effectiveness of the DiGA.

— To provide incentives for quality improvement and assurance on the part of DiGA providers, suitable performance-based remuneration models should be introduced.

— To ensure the broad acceptance of digital health applications, the information base on the functionality, handling and added value of these applications should be improved.

Improving the Framework Conditions for Digitalization

— To improve the digital health literacy of health workers, digital elements should be increasingly integrated into the curricula of health professions.

— General digitalization barriers also affect the digitalization of the healthcare system. These include, above all, an insufficiently developed digital infrastructure, especially in rural areas. To advance the digital transformation in the healthcare sector, the Commission of Experts calls for the rapid quantitative and qualitative expansion of the digital infrastructure.