PROSPECTS
FOR TELEMEDICINE
—

SCALING PRECONDITIONS AND MARKET POTENTIAL

Smart
Data Economy

IMPRINT

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EXECUTIVE SUMMARY

The COVID-19 pandemic has given an enormous boost to telemedicine, i.e., the practice of medicine using digital communications to deliver care at a distance. Although many telemedicine projects were conducted in recent decades, many of these projects failed to achieve widespread implementation. On the other hand, the Smart Data Economy project by the Federal Ministry for Economic Affairs and Energy (BMWi) includes the Telemed5000[1] pilot project which specifically addresses this aspect of upscaling telemedicine applications to large patient cohorts. As part of scientific assistance for the SDW programme, this short study now takes a look at central factors influencing the scaling of telemedicine and also estimates the market potential for telemedicine in Germany in 2030. The basis is an in-depth literature research and interviews with experts from telemedicine projects.

Telemedicine, in its various forms, can be integrated into many medical specialities. However, the potential of the various applications differs to a large degree and, in addition to paying attention to specific care and technical aspects, the economic perspective should never be ignored. The following influencing factors can be identified for successful and broad implementation:

BENEFIT & EVALUATION:

Meaningful, robust evaluation results with evidence of benefits for patients and other stakeholders according to their perspectives and needs are considered to be essential prerequisites for telemedicine applications. In order to be effective on a broad scale, representative use under realistic conditions is required. Current efforts focusing on ecosystems and trial platforms for products of the digital health economy could also be an interesting option for telemedicine applications in order to explore the benefits and prepare robust evaluations.

BUSINESS/OPERATOR MODEL:

Taking into account the different perspectives of the groups of actors and stakeholders involved from within their specific incentive structures is critical to success. This often requires demanding negotiation processes and a balancing of interests to find a solution. This can be an obstacle, especially in the case of telemonitoring, since the actors involved come together from different market segments with sometimes incompatible exploitation strategies. In Germany, the innovation path of a telemedicine application typically depends on the involvement

of the statutory health insurance organisations, representing insured citizens as an interest group, also because private individuals/households are relatively reluctant to pay. However, a business model that does not fit into the logic of adequate cost-to-benefit ratios of statutory health and long-term care insurance funds is unlikely to be realised. Adopting suitable forms of remuneration and reimbursement is particularly necessary in order to take advantage of the opportunities of digitalisation, especially in the current pandemic situation. Although telemedicine is not yet the focus of the new regulatory framework for eHealth, its iterative nature suggests that it will be adapted in this direction.

Techno-structural integration:
The broadest possible broadband availability with acceptable data rates is the linchpin of widespread use of telemedicine. Especially in rural regions, which by definition would benefit most from telemedicine and its broad possibilities, telemedicine cannot be implemented due to insufficient bandwidths. Good data transmission also influences acceptance on the part of both medical service providers and patients. Uniform standards are particularly important when it comes to achieving complete data interoperability. For this purpose, various standards have already been defined that can be implemented and/or integrated by many projects. The projects are hence in principle ready for connection to a centralised infrastructure. However, clearly defined IT interfaces and services are still lacking, but this does not fundamentally hinder the feasibility of telemedicine applications. The projects mostly make do with their own infrastructure, but monitor the developments in the field of telematics infrastructure and can adapt the necessary interfaces as required.

USER INVOLVEMENT & SUPPORT:

A positive perception of the benefits of telemedicine applications is the basis for further increasing acceptance on the part of users, i.e., medical service providers and patients on the one hand, and of cost bearers on the other. Support by medical service providers in patient information/education on telemedicine and the promotion of digitalisation competence with reference to health in general has a paramount role to play here. Current regulatory innovations in the field of eHealth will probably help to enable patient groups with suitable indications to gain experience and enjoy the related benefits. Whether this benefit will be sustainable has yet to be tested and proven. The clarification

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1   Telemed5000, an intelligent system for the telemedical co-care of large collectives of cardiological risk patients. URL [https://www.telemed5000.de/]

and, if necessary, further development of the legal framework conditions is increasingly geared to implementing telemonitoring applications as a driver, so that this treatment format is not frequently cast aside due to alleged liability risks. Similar risks are also possible with the other types of telemedicine applications, even though these are less likely due to the low-threshold use of medical devices. However, the lack of sufficient legal framework conditions, for example, with regard to billing and liability issues, could increasingly prove to be an obstacle.

Data management:
It is foreseeable that further standardised certifications for data-driven models and systems will become mandatory, especially in the healthcare sector, so that secure, transparent data management and guaranteed data protection within the framework of the GDPR already have a major impact on the broad feasibility of telemedicine. This is particularly important to note whenever patient data is exchanged. Furthermore, upscaling the number of patients to be cared for requires the use of intelligent methods for adequate data pre-processing in order to save medical resources. Future research-compatible interoperability standards lend themselves to further data re-use, but require, among other things, a data management plan for their implementation. The data collected and/or generated in telemedicine applications should, in the sense of data sovereignty, be aggregated and made available to patients after voluntary provision.

Depending on how these factors play out in practice, the economic potential of telemedicine is greater or smaller, so that we use three scenarios in our estimates: S (small: pessimistic basic assumptions), M (medium: realistic assumptions) and L (large: optimistic assumptions). However, even the pessimistic 'S' scenario assumes that the growth of telemedicine triggered by the COVID 19 pandemic will continue, albeit at a low level. Our calculation of the economic potential is based on estimated investment costs for IT hardware, software and services which medical service providers may have to purchase in order to use telemedicine applications. This will create a market which ICT suppliers can serve. Our estimates refer to the three most important categories of telemedicine applications, i.e., teleconsultations between doctors and patients, teleconsilia between doctors and telemonitoring of patients, before we then extrapolate the results to telemedicine as a whole.

This translates into a market potential for telemedicine in Germany in 2030 in the order of 1.4 billion euros (with conservative basic assumptions), 2 billion euros (with realistic basic assumptions) and 3.6 billion euros (with optimistic basic assumptions). The detailed investigation is simplified by breaking it down into the three categories of telemedicine applications in order to increase its informative value. That being said, this still provides a valuable starting point for the first time for further research at national level and along medically validated treatment pathways.

€ 3,614 million

€ 2,028 million

€ 1,424 million

	SCENARIO S	SCENARIO M	SCENARIO L
Other telemedicine applications	€ 570 million	€ 811 million	€ 1,446 million
Telemonitoring	€ 548 million	€ 730 million	€ 1,460 million
Teleconsilia	€ 234 million	€ 355 million	€ 526 million
Teleconsultation	€ 72 million	€ 132 million	€ 182 million

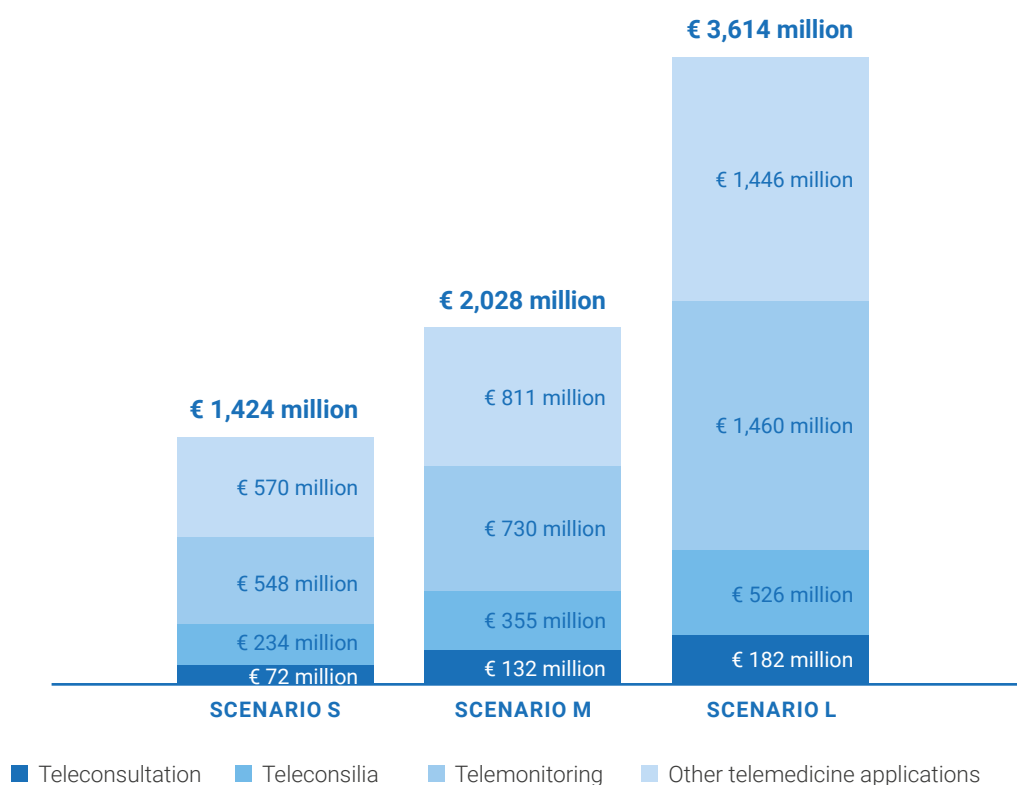■ Teleconsultation ■ Teleconsilia ■ Telemonitoring ■ Other telemedicine applications

Fig. 1: Market potential for telemedicine and selected telemedicine applications in Germany in 2030

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THE COVID-19-PANDEMIC HAS GIVEN A BOOST TO THE DIGITALISATION OF HEALTHCARE AND THE CORRESPONDING REGULATORY FRAMEWORK. THE OBJECTIVE OF THIS STUDY IS THEREFORE, TO PUT TELEMEDICINE IN THE CONTEXT OF CURRENT EVENTS.

1 INTRODUCTION

Digitalisation in the health sector has gained significant momentum, not least due to the COVID 19 pandemic and the associated dangers and restrictions. Prior to this, hopes had already been high that all-encompassing digitalisation would go hand in hand with a nationwide healthcare system, especially in rural regions, a networked, data-driven health economy and potential cost savings in hospital days (see Szecsenyi et al. 2018). Some of these effects have already been proven for individual applications (cf. Köhler et al. 2018). The fact that the pandemic meant that a large number of people had to directly experience the challenges of medical care in a very short time has given an enormous boost to people's acceptance of digital health apps. According to a survey by doctolib (2020), which polled a total of 1,026 people aged 18 to 75, more than half (55%) of participants said they were more open to digital health services since the COVID 19 pandemic than before. Among those aged 65 to 75, as many as 75% of respondents said they recognised the benefits of digital products.

The term telemedicine is not new and, historically speaking, does not necessarily belong to the digitalisation of medicine. An event from 1876 is considered to be the first use case, when British inventor Alexander Graham Bell used his latest invention, i.e., the 'telephone apparatus' to call his colleague Thomas A. Watson, who was present in the next room, for help because he had accidentally spilled acid on his suit (see Deter et al. 2011). This first telephone emergency call was still based on analogue technology and had very little to do with our current understanding of 'telemedicine'. The oldest telemedicine service still operating in Germany is the Tele-medical Maritime Assistance Service (TMAS), which offers a worldwide 24 hour emergency medical hotline for direct and immediate medical advice by specialists particularly experienced in maritime medicine (see Paulus et al. 2009). Over the past decades, repeated forays were seen in the form of publicly or privately funded research and development projects. And yet, only very few telemedicine applications have made it into mainstream care so far.

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THE TERM TELEMEDICINE CAN BE TRACED BACK TO THE BEGINNINGS OF ANALOGUE TELEFONY

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The aim of the present study is, on the one hand, to investigate which factors are still inhibiting the widespread rollout of telemedicine applications. On the other hand, we also shed light on those factors that have a particularly favourable effect on the possible continuation of the projects beyond initial funding.

Especially in response to the COVID 19 pandemic, some major changes have taken place in the digitalisation of health and the related regulatory framework. With this study, we also want to de-scribe current events in their respective context and in doing so provide an inventory of telemedicine in Germany from a healthcare, technical and economic perspective. We also address the question as to whether current regulatory and technical developments have the potential to have a lasting impact on the state of telemedicine.

Broad implementation of telemedicine applications calls for economic stakeholders to drive the exploitation of project results. Unlike products in the industrial digital economy, the health market is diverse with a constant focus on reimbursability by the so-called cost bearers, i.e., in particular the health and long-term care insurance funds. Telemedicine applications typically involve a large

number of stakeholders from different market segments, which makes it particularly difficult to define the potential market for telemedicine. In this study we now present for the first time perspectives for market penetration in a differentiated form and provide an estimate of the market potential for telemedicine applications.

The methodological basis of the study is a multi-stage approach consisting of project or literature research and structured discussion with representatives from business and academia.

Project research: To take stock of the status of telemedicine in Germany and its economic perspectives, data on telemedicine projects and their costs were researched. The starting points for the research of telemedicine projects were the vesta information portal[2], the list of funded projects in the area of 'new forms of care' of the Innovation Fund[3] (Federal Joint Committee; G BA), the funding catalogue of the Federal Government[4] as well as information websites of some initiatives of the federal states of Baden-Württemberg[5], Bavaria[6], North Rhine-Westphalia[7], Schleswig-Holstein[8] and Saxony[9]. From all portals, only those projects were selected that actually fall under the term 'telemedicine' as defined in this short study (see chapter 2). The result of our research is presented in the Annex to this short study.

Literature analysis: Empirical and theoretical/conceptual literature was included in the analyses. The empirical studies considered data on the acceptance of eHealth solutions and on health economics. The conceptual literature mainly comprised sources on clinical evidence of the benefits of telemedicine applications and on methods and concepts of health data management. Based on the literature and the result of the project research, factors that influence the wide-spread implementation (scaling) potential of telemedicine applications were identified and condensed into categories. Furthermore, three successful types of telemedicine application were selected in order to examine the influencing factors under specific conditions.

Qualitative interviews: Ten expert interviews were conducted as part of the study. The interviewees were selected on the basis of those telemedicine projects that were considered in more detail and relevant literature. The interviewees were in each case (co)responsible for the implementation of telemedicine projects or were identified in relevant publications as experts in the field of telemedicine and its transfer to standard care.

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2   vesta information portal of gematik GmbH . URL [https://www.informationsportal.vesta-gematik.de]
3   List of funded projects, New forms of care, Innovation fund of the G-BA . URL [https://innovationsfonds.g-ba.de/projekte/neue-ver-sorgungsformen/]
4   Funding catalogue of the federal government . URL [https://foerderportal.bund.de/foekat/jsp/StartAction.do]
5   Coordination Office Telemedicine Baden . URL [https://www.telemedbw.de/]
6   Bavarian Telemedicine Alliance . URL [https://www.telemedallianz.de/]
7   State initiative eHealth.nrw . URL [https://egesundheit.nrw.de/]
8   Telemedicine in Schleswig-Holstein . URL [https://www.schleswig-holstein.de/DE/Fachinhalte/G/gesundheitsland/gesundheitsland_Tele-medizin.html]
9   vital digital, specialist portal of the Free State of Saxony . URL [https://www.vital.digital.sachsen.de/]

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Market potential assessment: We estimate the market potential for telemedicine in Germany on the basis of the required investments of medical service providers, i.e., doctors and hospitals in particular. We choose the year 2030 as the time by which regular operation of telemedicine applications (TMA) can be expected. This estimate is based on the assessment of the major TMA categories, i.e., teleconsultation, teleconsilium and telemonitoring, which today and in the foreseeable future will represent the majority of telemedicine applications.

Chapter 2 of the study first takes a closer look at the term 'telemedicine' and its distinction from the field of eHealth or digital health. Chapter 3 provides an overview of current telemedicine applications in Germany along the lines of care, technology and economy. These application-spanning issues, which were identified during the search of existing literature and in discussions with our expert panel, are prerequisites for successful scaling of telemedicine as presented in chapter 4. Chapter 5 finally assesses the market potential of telemedicine on the basis of the three TMA categories of teleconsultation, teleconsilium and telemonitoring.

The study was carried out as part of scientific assistance for the BMWi Smart Data Economy (SDW) technology programme where companies and research institutions are designing and testing innovative data products and data services in 20 application-oriented joint projects. Two of the projects, i.e., Telemed5000 and AIR_PTE[10], belong to the healthcare industry, whilst the prototype telemedicine application of the Telemed5000 project implements one of the three example scenarios in this study.

We would like to express our sincere thanks to Dr. Fabian Werner (BMWi), Dr. Regine Gernert (DLR project management agency), Hanna Kolkmann (DLR project management agency) and Louisa Wagner (DLR project management agency) for their support and valuable advice during the course of the short study.

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10 AIR_PTE, AI methods for predicting treatment outcomes. URL [https://www.digitale-technologien.de/DT/Redaktion/DE/Kurzmeldungen/Aktuelles/2020/SDW/2020_10_06_SDW_AIR_PTE.html]

02

2 eHEALTH, DIGITAL HEALTH AND TELEMEDICINE: TERMINLOGY AND DELIMITATIONS

Although the terminological confusion surrounding digitalisation in the health sector has already been mentioned many times (Leppert et al. 2016), it continues to exist, unfortunately at regulatory level too. This section now classifies the terms of eHealth, digital health and telemedicine which we will refer to later in the study (see Fig. 2).
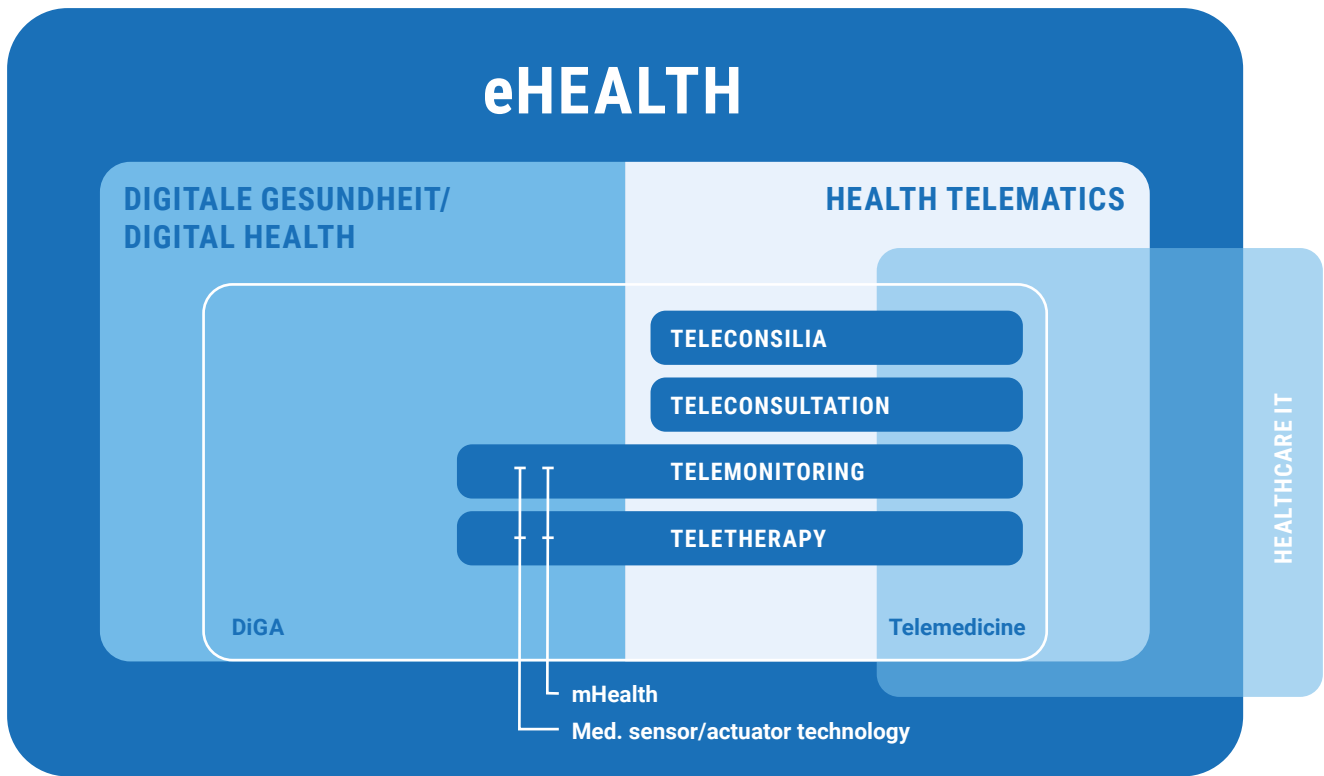
Fig. 2: Hierarchy of eHealth and other digital application fields, based on Leppert (2016)

The German Medical Association defines the term eHealth (electronic Health) as the cost-effective and secure use of information and communication technologies (ICT) to promote general health and health-related areas (health systems, health reporting, health promotion as well as general knowledge and research) (see Bundesärztekammer 2015). This includes a 'wide range of ICT-supported applications where information can be processed electronically, exchanged via secure data connections and patient treatment and care processes can be supported' (Federal Ministry of Health 2020). eHealth thus serves to improve health and support healthcare, including all related medical and non-medical services (see Leppert 2016). However, pure administrative tasks which are supported by ICT are not classified under eHealth.

Health IT describes all IT systems for the outpatient and clinical sector. It encompasses the complete IT infrastructure and predominantly provides the technical components and services, as well as the corresponding software applications for visualising, analysing, capturing and manipulating data.

Digital health, a subcategory of eHealth, aims to help people to assume responsibility for maintaining their health by enabling and permitting the monitoring, management and improvement of their health state (see Meister et al. 2017). Special aspects of digital health are digital health applications which since 2019 have been regulated in the Digital Healthcare Act (DVG, Digitale-Versorgung-Gesetz) and the Digital Health Applications Ordinance (DiGAV, Digitale-Gesundheitsanwendungen-Verordnung) (see Krüger-Brand et al. 2020). However, the Digital Health Applications Ordinance excludes all applications that exclusively establish direct communications between providers and recipients of health services.

The term 'mHealth' (mobile health) refers to the use of mobile devices to support healthcare by improving data availability (collection, communication and visualisation) (see Meister et al. 2017). The concept can hence be assigned to digital health on the one hand. On the other hand, by connecting corresponding mobile devices to a data exchange infrastructure, (health) data that is entered can also be transmitted to medical service providers, cost bearers and, in turn, back to patients in the form of analyses and/or recommendations for action. A certain part of the mHealth concept hence also belongs to the field of health telematics.

Some telemedicine applications also use special medical sensors located on or in the patient's body in order to continuously record their vital signs (including blood pressure, ECG, pulse, oxygen saturation, body weight, lung function, temperature, blood sugar and intraocular pressure). Special camera sensors can also be used to record defined sequences of patient movements. The data recorded can then be used as input for medical actuators, for example, implants that can be controlled remotely and/or by signals, such as an insulin pump. This includes special robots (arms) operating in automated or remote-controlled mode, especially in care and rehabilitation.

The health telematics subcategory deals with direct, digital communications between providers and recipients of health services. It includes all ICT applications in healthcare to overcome physical distances and, under certain circumstances, also time differences under secure conditions (see Leppert 2016). The basis for standardised and secure communications in the German healthcare system is, among other things, the so-called telematics infrastructure (TI) which is designed to enable a secure communication channel between medical service providers, cost bearers and insured persons. Since the comprehensive introduction of the TI still has some hurdles to overcome, even health-related telematic applications that are not (yet) connected to the TI and rely on dedicated communication channels (see box on p. 29) are listed under health telematics.

Telemedicine is essentially a collective term for various medical care concepts which have as their common denominator the remote provision of medical (core) services in diagnostics, therapy and rehabilitation using information and communication technology (see Bundesärztekammer 2015). Telemedicine does not describe an independent discipline, but can rather be understood as the integration or application of health telematics in areas of medicine, whereby different use cases

arise depending on the specific nature of the discipline (see Gigerenzer et al. 2016). The German Medical Association considers telemedicine to be an integral part of almost every medical specialty and generally complementary to face-to-face care (see Bundesärztekammer 2015). We will therefore use the term 'telemedicine applications' (TMA) in the further course of this study.
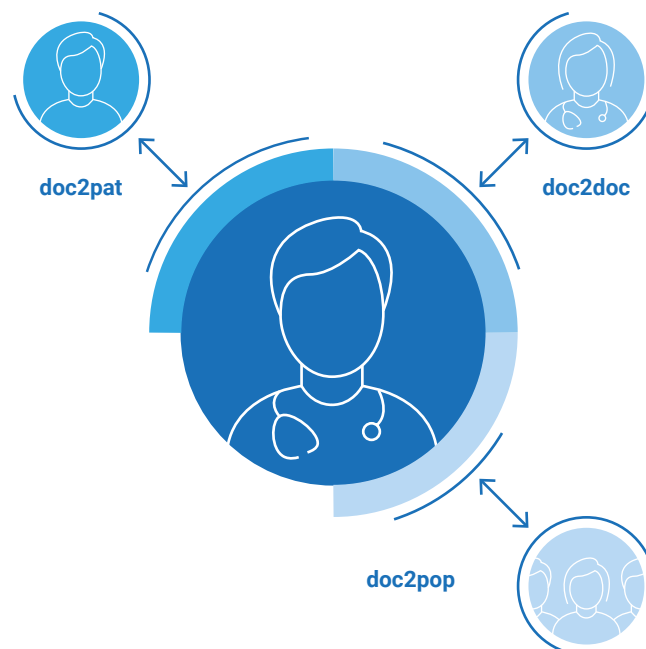
Fig. 3: Forms of communication in telemedicine

The focus of communications is on medical service providers – i.e., all medical groups, such as panel doctors, hospitals, pharmacies, transport services, etc. that provide a medical service – and patients as service recipients. TMAs are usually understood to be applications that enable exchange between medical service providers (doc2doc) as well as applications where medical/therapeutic communications take place between doctors and patients (doc2patient) (see Fig. 3). This classification is supplemented by the term 'doc2pop', i.e., communications between one medical service provider and a large number of patients (patient population). This aspect is particularly relevant for the organisational and technical implementation of TMAs, as we will show in the further course of the study.

The different types of TMA applications can be broken down into the following categories:

- **Teleconsilium:** ICT here enables two or more healthcare providers at different locations to consult regarding a patient diagnosis or treatment (doc2doc). This field of application already began in the 1990s with so-called tel-eradiology, i.e., remote radiological diagnosis by specialists using ICT.

- **Teleconsultation:** This typically refers to doc2patient communications between doctors and patients. The most recent version is the video consultation format. Due to the amendment of the medical (model) professional code of conduct, treatment exclusively via communication media is in principle also permitted in individual cases if this is medically justifiable, the required medical diligence is maintained and, in addition, the patient is informed accordingly (see Kassenärztliche Bundesvereinigung et al. 2016b). In this study, teleconsultation also includes the sub-area of telediagnostics, where ICT communication between medical service providers and patients is also used for diagnosis.

- **Telemonitoring:** This includes individual applications for ICT-supported remote measurement, monitoring and control of patient-specific vital signs. Telemonitoring (also referred to as remote patient monitoring, RPM) is possible in both home and clinical settings (for instance, in intensive care units). In addition, mobile devices (such as sensors) are increasingly used nowadays, which again illustrates the connection to mHealth. Since the main issue here is to care for an entire patient population, telemonitoring involves doc2pop communication. Data is usually pooled in a telemedicine centre to which all the patient ata from home or clinical environments is sent.

- **Teletherapy:** This term refers to the ICT-supported provision of medical, physiotherapeutic or psychological therapy services.
The term was originally used in radiotherapy where it describes a special form of this discipline. During the course of time and with growing importance of health telematics, the words 'telematics' and 'therapy' were merged to form the term 'teletherapy'. Applications are used, for instance, in surgery (telesurgery), speech therapy, psychology/psycho-therapy, physiotherapy and rehabilitation (telereha).

The basis for the implementation of a TMA is a more or less comprehensively structured infrastructure that links all stakeholders in the healthcare system, such as doctors, dentists, psychotherapists, hospitals, pharmacies and health insurance companies, and enables digital communications and the exchange of health-related data (see Nolting et al. 2017). This infrastructure usually connects an application at the patient end with the health IT of the medical service provider who delivers the telemedicine service. Certain telemedicine applications also use special optional medical devices or sensors and actuators that are also interconnected within the infrastructure.

Following the definition of the German National Association of Statutory Health Insurance Funds (GKV SV), the TMAs considered here refer exclusively to concrete patient-related care contents (see GKV-Spitzenverband 2016).

Not included here are applications that exclusively serve the non-professional context for individual patients' health-related use. This also includes, for example, digital applications from the mHealth market, which do not implement or integrate any medical (core) services provided by medical or psychological professionals. The distinction between digital health applications and TMAs is at times fluid within the scope of the eHealth Act and the Digital Healthcare Act. Whilst TMAs serve to enable the provision of a medical (core) service and therefore involve a comparable reimbursement pattern, digital health applications belong to the category of remedies and aids that are prescribed and therefore subject to different reimbursement procedures. This is also the reason why no applications in the field of ambient assisted living (AAL) are considered that focus on nursing aspects, since they too do not focus on medical (core) services. Nevertheless, there are also many overlaps and transitions are fluid, especially between digital health applications and TMAs (see box on p. 36).

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3 THE STATUS QUO

Many telemedicine projects are already underway in Germany, albeit mostly at prototype stage. However, the large number of funders and stakeholders involved makes an overview difficult. A relatively comprehensive synopsis is available on the vesta information portal. Initially created by Fraunhofer FOKUS as part of the eHealth initiative by the Federal Ministry of Health, the initial idea was to establish a platform for communicating existing care solutions and to support their transfer to other indications or regions (see Nolting et al. 2017). Furthermore, all telemedicine projects funded by the statutory health insurance scheme must apply for inclusion in this information portal (see Schnee 2019). At present (August 2020), 127 telemedicine projects are listed. However, it is difficult to assess the up-to-datedness of the portal (see Lehmann et al. 2018). What's more, only a small share of the projects that have already been completed have become part of standard care services which is probably partly due to a lack of scientific evaluation (see Schnee 2019). This aspect is to play a central role in the projects currently under the direction of the Innovation Committee of the Federal Joint Committee (G BA)[11]. The share of telemedicine projects in the Innovation Fund currently totals around 10%, and the trend is rising.

An overview of current developments in telemedicine applications can best be derived from the three perspectives of care, technology and economics. The healthcare perspective has a central role to play when it comes to demonstrating the benefits of TMAs. The technical view addresses aspects of their implementation. The economic business models and remuneration methods are considered in the economic perspective. Finally, we summarise the factors that are important for upscaling today's – mostly still prototype – telemedicine applications into standard care offerings. The Annex provides an overview of current telemedicine projects.

3.1 The care perspective

Telemedicine applications deliver their benefits by reducing the geographical dependency of healthcare services. The aim is to provide more focused care, enabling the right healthcare service to be delivered by the right provider at the right time. To these ends, TMAs are used to

- implement low-threshold and mobile access to care services,
- strengthen the self-management competence of patients,
- initiate treatment at an early stage,
- bundle competences and strengthen cooperation,
- partially automate care processes and
- introduce technological and process innovation.

As a result, the more effective use of medical resources (personnel, equipment, premises, etc.) should also influence the target parameters of medical care. These parameters are objectively measurable variables of the healthcare system, such as treatment costs per patient (for instance, for hospital stays), mortality or waiting time for treatment. They are also subjective targets for patients, such as increasing patient satisfaction, for instance, through a better healthcare worker to patient ratio and the patients' sense of safety, as well as other targets of health-related quality of life.

Especially in the introductory phase, a TMA should be continuously measured against its goals and adjusted if undesired effects are found. In the early days, for instance, there was a tendency to strengthen existing networks (primarily in radiology, cardiology, neurology), which interconnect a specialist hospital with smaller hospitals, rather than to include other healthcare providers, such as general practitioners – especially in rural regions – and thereby enable comprehensive healthcare provision through telemedicine (se Schnee 2019). This aspect is now being counteracted primarily by corresponding projects that aim to achieve the broadest possible networking of stakeholders (for instance, in the area of teleconsilia, see TELnet@NRW[12]). Another unexpected and detrimental effect may be an increase in the cost of care due to low-threshold access. In this respect, there is a chance that patients and medical service providers could demand services more frequently as part of teleconsilia. Accordingly, more frequent registration

11 The G-BA is the top body of self-administration in the German health system. It represents doctors, dentists, hospitals and health insurance funds through their federal associations, as well as patient representatives without voting rights.
12 TELnet@NRW, an intersectoral, digital health network. URL [https://www.telnet.nrw/]

of indications could trigger treatments that may not require intervention, for example, telemonitoring of patients with heart disease (see GKV-Spitzenverband 2016).

Even if TMAs can provide the aforementioned benefits across the entire chain of the healthcare system, the dominance of telemonitoring and teleconsilia recognised in 2016 (see GKV-Spitzenverband 2016), continues to exist (Schnee, 2019). 55% of the TMAs listed in the vesta information portal in 2019 can be assigned to diagnostics and 48% to therapy (Schnee, 2019). Indications too show a clear trend: 38% of the diseases treated are related to the circulatory system (mainly heart failure and stroke) and 17% to the growing complex of mental illness (Schnee, 2019).

Specific examples of TMAs can be described along the entire healthcare chain. The most prominent examples are video consultations with licenced doctors, which have been remunerated under the statutory health insurance scheme since 2017. Other TMAs, such as AppDoc[13], offer a first telemedicine assessment of dermatological indications via a smartphone app before visiting the doctor, enabling a faster initial diagnosis (usually within 24 hours). Besides several examples of clinics connected to a teleconsilium network, for instance, for the verification of possible stroke cases in the TEMPiS[14] project, other projects show the benefit of consilia for general practitioners: In the TELnet@NRW project, teleconsilia between university clinics, hospitals and licenced doctors specialising in infectious diseases and intensive care medicine are used for early detection and guideline-compliant treatment of blood poisoning and other conditions. This successful concept is now being continued as a virtual hospital[15] and rolled out on a large scale. Increasing nationwide care with the help of telemedicine can also be seen in the emergency medical sector.

Some federal states have already established tele-emergency doctor care (see Landesregierung Nordrhein-Westfalen 2020). Besides reducing the therapy-free time through faster emergency medical care, structured telemedicine guidance ensures guideline-compliant emergency medical care. TMAs also provide benefits in follow-up care, for example, in the NTx360°[16] project, by increasing the chances of transplant survival and reducing concomitant symptoms, such as cardiovascular and immunological risks through case-based care by licenced doctors and follow-up centres (see Pape et al. 2017). Standard operation procedures (SOPs) in telemedicine enable regular risk assessments by the respective experts (nephrologists, psychosomatics, sports physicians, case managers) and initiation of app-supported treatments. A typically prominent field of TMA application is the monitoring of patients with chronic diseases, for instance, in order to reduce their hospital stays and to carry out therapy adjustments as early as possible. Certain telemedicine heart disease care programmes, for instance, use telemonitoring (e.g. Telemed5000) and self-management methods which are in some cases reimbursed by certain health insurance companies (for instance, HerzConnect[17]).

A key challenge of TMAs often lies in their evaluation. In a framework agreement on the review of the uniform assessment scale pursuant to section 87 (2a) eighth sentence of the Fifth Book of the Social Security Code (SGB V, Sozialgesetzbuch (SGB) Fünftes Buch (V)) on the scope of the provision of outpatient services through telemedicine (see Kassenärztliche Bundesvereinigung et al. 2013), Kassenärztliche Bundesvereinigung (KBV) and the German National Association of Statutory Health Insurance Funds emphasise that, compared to conventional care without telemedicine, care with telemedicine must result in an advantage or be at least equivalent to care without telemedicine.

13 Appdoc, the online doctor. URL [https://online-hautarzt.net]
14 TEMPiS, telemedical stroke network Southeast Bavaria. URL [https://tempis.de/]
15 Virtual Hospital NRW. URLhttps://virtuelles-krankenhaus.nrw/
16 NTx360°, innovation project for the further development of care after kidney transplantation. URL [https://ntx360grad.de]
17 HerzConnect, Telemedical Care for Heart Failure in North Rhine-Westphalia and Lower Saxony. URL [https://www.dak.de/dak/kontakt/herzconnect-telemedizinische-versorgung-bei-her-zschwaeche-in-nordrhein-westfalen-und-niedersachsen-2227216.html#/]

- This aspect can be demonstrated in terms of patient-relevant outcomes, such as morbidity, mortality, as well as quality of life and/or improved cost-effectiveness when considering the costs that arise in the case of care with or without telemedicine. Which form of study is required depends on the following categorisation (see GKV-Spitzenverband 2016; Beckers et al. 2015):

- **(I)** TMAs for optimising communications and care processes that support established and already evidence-based medical-therapeutic processes require 'only' proof of economic efficiency (plus feasibility and acceptance studies that may also have to be submitted).

- **(II)** TMAs where existing medical services are to be provided using ICT and which thereby expand or gradually change established medical-therapeutic processes on the basis of an evidence-based medical model, additionally require evidence of medical effectiveness.

- **(III)** TMAs that represent new forms of examination and treatment because they involve significant changes to the previous diagnostic and therapeutic approach additionally require evidence of a positive impact on patient-relevant outcomes in the form of randomised clinical trials.

While teleconsultation and teleconsilium predominantly fall into categories (I) and (II) – depending on the basis and extent of this communication – they must be closely examined, especially in the case of telemonitoring procedures, to ascertain whether these represent new forms of examination and treatment and thus require randomised clinical trials according to category (III). In any case, this categorisation explains why the benefits of TMAs often require separate and robust verification, unless they are less complex, as is the case of video consultation. Clear

differences exist between the different forms of TMAs and their respective fields of application. Especially in the field of heart disease, reliable studies are, for instance, available on the benefits of telemonitoring. Numerous studies have demonstrated a significant reduction in hospital stays for patients with heart failure who receive telemedicine care (see Köhler et al. 2018), as well as a reduction in overall mortality (see Yun et al. 2018). In other areas of application, the study material is not so clear.

Whilst requirements are demanding on the one hand, there is a lack of evaluation data in telemedicine projects on the other (see Lehmann et al. 2018). The interim evaluation of the innovation fund also suggests that there is an increased need for action to ensure the transfer of as many project results as possible to standard care (see Astor et al. 2019). However, the even greater challenge is to develop sustainable care concepts, which is not always possible on the basis of the evaluation results achieved.

Quality assurance and development are central pillars of patient care and must also be ensured by TMA providers and developers (see Szecsenyi et al. 2018). The international ISO/DIS 13131[18] standard is currently being elaborated by experts as a basis for a uniform assessment of the quality of TMAs. This standard contains recommendations for the development of quality objectives and guidelines for telehealth services using a risk management process and is also intended to improve the evaluation situation specifically for TMAs.

The standard pays particular attention to the management of quality processes by healthcare organisations, the management of financial resources to support telehealth services, the processes related to resource planning and defining responsibilities, the provision of required infrastructure and technical resources as well as the availability and management of sufficient (information) technological resources.

18 International Organization for Standardization. URL [https://www.iso.org/standard/75962.html]

3.2 The technical perspective

3.2.1 ICT TOOLS FOR DATA COLLECTION AND TRANSMISSION

The use of TMAs depends on the location-independent availability of digital data. Different information and communication technologies are used to these ends. Software for transmitting video and audio data (for video telephony, video conferencing) is particularly important in this context and is increasingly used in teleconsultation and teleconsilium TMAs.

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IN ADDITION TO VIDEO TELEPHONY, SPECIFIC SOFTWARE AND HARDWARE ARE USED FOR DATA COLLECTION.

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This is software usually developed specifically for telemedicine conditions, such as doccura[19] or jameda[20], and which meet the KBV requirements for video consultation (see Kassenärztliche Bundesvereinigung et al. 2016b). These requirements primarily concern data protection and IT security, but also lay down rules of conduct for participants, doctors and service providers. In order to ensure data security, information security and a trouble-free process, the video consultation must take place in closed rooms that ensure adequate privacy, with recordings of any kind not being permitted during the video consultation. According to the KBV guidelines (see Kassenärztliche Bundesvereinigung et al. 2016b), the video consultation should be transmitted via an end-to-end encrypted peer-to-peer connection between the computers of the participants in the conversation,

without the involvement of a central server. A central server may only be used for call switching. It is important to mention in this context the provision applicable under the General Data Protection Regulation, i.e., that the processing of data, even on behalf of third parties, may only take place in Germany, in a member state of the European Union or in a state equivalent thereto pursuant to section 35(7) of the First Book of the Social Security Code, or, if an adequacy decision pursuant to article 45 of Regulation (EU) 2016/679 exists, in a third country.

Depending on the specific medical services to be provided using a TMA, specific software and devices for data collection are used, often in addition to video telephony. This is especially the case with telemonitoring applications. For this purpose, data is actively entered by users or passively collected by special devices, with these devices ranging from established medical devices and smartphones to novel wearables, such as in-ear sensors (for instance, cosinuss° Two[21]). Mobile ECG recorders, for instance, are also for telemonitoring cardiological risk patients (in the HerzConnect and Telemed5000 projects, for example). In paediatric oncology too, vital signs are recorded by a variety of different medical devices (such as KULT-SH[22]). Accelerometers as motion detectors, which are standard features of common smartphones and wearables and can provide information about the movement activities of patients (for instance, in the Telemed5000 and Active Body Control[23] projects), are also increasingly coming to the fore. The sound recording function of common smartphones is a very effective and efficient way of using speech and voice analysis to identify diseases, for instance, based on changes in speech or voice behaviour, and thus support their diagnosis and possible therapeutic measures (such as Telemed5000 and i PROGNOSIS[24]). The Kinect sensor, originally developed by Microsoft for the gaming sector, is also finding its way into so-called telereha, a subcategory of teletherapy in physiotherapy and rehabilitation. With the integrated combination of video camera and depth measurement sensor technology, patient movements can be recorded and monitored during rehabilitation exercises (for instance, MeineReha[25]).

19 doccura, online video consultation. URL [https://www.doccura.de/]
20 jameda, software for digital patient contact. URL [https://www.jameda.de/fuer-aerzte/]
21 cosinuss°, sensor technology for mobile measuring of vital parameters in the ear. URL [https://www.cosinuss.com/de/]
22 KULT-SH, medical care for children and adolescents with cancer. URL [https://www.uksh.de/paediatrie-kiel/kultsh.html]
23 ABC programme (Active Body Control), an innovative, telemedical and very effective programme for the reduction of overweight. URL [http://www.abcprogramm.de/]
24 i-PROGNOSIS, intelligent, early detection of Parkinson's disease through innovative telemedical applications. URL [http://www.i-prognosis.eu/]
25 MeineReha®, teleassistance system for rehabilitation. URL [https://www.meinereha.de/]

In addition, sensor technology developed specifically for the requirements of TMAs is also being used in individual projects. One example is the TeleSchwindel[26] project of the TEMPiS network that uses special glasses to detect and transmit eye movement to clarify symptoms of dizziness (see Müller-Barna et al. 2019). The GLAUKOM DIGITAL 4.0[27] product continuously measures intraocular pressure using the specially developed, implantable Eyemate[28] microsensor. The wireless stethoscope StethoMe[29] is able to record respiratory data in combination with the associated app. In addition to the monitoring aspect, software-supported data input and/or capture is also used for self-management of chronic diseases, such as diabetes (for instance, Digital Diabetes Clinic[30]) or haemophilia (smart medication™[31]). After all, one third of the TMAs listed in the vesta information portal of gematik GmbH use sensors for data acquisition.

In many projects, patient data acquisition is not limited to a single device. On the contrary, it is important for telemonitoring to keep an eye on the overall condition of patients, especially of those with chronic diseases. For this purpose, all the data captured must first be federated and consolidated in a single system prior to transmission. In most projects, dedicated platforms are implemented for this purpose to which all devices are integrated as an app (such as Telemed5000 and TICURO REPLY[32]).

With all devices so far available, humans interact at both ends – transmission and reception – of the data transmission process. This also corresponds to the constellation currently prevailing in telemedicine. Increasingly, however, intelligent tools, such as chatbots, are coming to the fore that support partially automated processing of incoming requests (see hih – health innovation hub of the Federal Ministry of Health 2020) and/or pre-processing of incoming data (for instance, Telemed5000).

The challenges facing the telemedicine use of ICT tools are related to their use by different target groups, connectivity with other systems, robustness and reliability of data transmission as well as their legally compliant use. In addition to the general relevance of user-friendliness, especially for digital health applications, the needs of different user groups must be taken into account. The use of dedicated applications and devices can be an obstacle. This concerns both telemedicine care, i.e., the transmission and merging of data from different devices and software, as well as integration into other systems of standard care, for instance, in hospital information systems and doctors' office information systems. Regardless of the relevance of data integration issues (see section 3.2.2) in this context, integrated telemedicine care requires the creation of an overall picture of relevant data using suitable software..

3.2.2 DATA MANAGEMENT

Data that has been captured by telemedicine ICT tools must then be sent to the recipient. An encrypted Internet-based transmission method is typically used for this purpose, or a dedicated data transmission infrastructure is set up for the respective project. This is often accomplished using standardised internet technologies, such as the HTTPS protocol, for instance, in the KADIS[33] system, or encrypted e mail transmission, for instance, in the virtual diabetes outpatient clinic ViDiKi[34]. Integrated telemedicine systems that also include dedicated hardware often use secured VPN tunnels (for instance, in the ANNOTeM[35] project). This is where data transmission paths already established in medicine, such as the DICOM transmission protocol, come into play (for instance, in Westdeutscher Teleradiologieverbund[36]). In addition to audio and video data from video telephony, the data transmitted includes structured diagnostic data, such as CT or monitoring data, as well as often unstructured case history and other text data. Except for data that is already standardised, such as the DICOM format for medical images, generic transmission formats, such as JSON and PDF documents, are usually used. The data is usually transferred to software specifically developed for the respective telemedicine application and then processed by qualified medical staff.

26 TeleSchwindel, telemedically supported diagnosis and treatment of patients with acute dizziness. URL [https://tempis.de/teleschwindel/]
27 GLAUKOM DIGITAL 4.0, telemedical care for glaucoma patients. URL [https://talkingeyes.de/loesungen-fuer-privatpersonen/]
28 EyeMate®, intraocular microsensor for telemetric measurement of intraocular pressure. URL [https://implandata.com/mobil/DE/m_eyemate.html]
29 StethoMe®, the wireless, intelligent stethoscope. URL [https://stethome.com/]
30 Digital Diabetes Clinic, diabetes consultation from home. URL [https://digital-diabetes-clinic.de/]
31 smart medicationTM, the digital substitution diary for people with haemophilia. URL [https://www.smart-medication.de/sm/index.cfm]
32 TICURO REPLY, telemedicine solution for behavioural analysis and monitoring of vital bodily functions. URL [https://www.reply.com/ticuro-reply/de/]
33 KADIS, the Karlsburg Diabetes Management System. URL [http://www.kadis-online.de]
34 ViDiKi, Virtual Diabetes Outpatient Clinic for Children and Adolescents. URL [https://www.uksh.de/kinderhormonzentrum-luebeck/vidiki.html]
35 ANNOTeM, Acute Neurological Care in North-East Germany with Telemedical Support. URL [https://www.annotem.de/]
36 West German Teleradiology Network. URL [https://www.medecon-telemedizin.de/]

Integration and documentation in hospital information systems or practice management systems, as is the case with blood pressure monitoring with the SciTIM app[37], are the exception. Even if standard formats for medical data are already established, they will probably only be implemented in response to regulatory requirements. However, some projects, such as NTx360° or TELnet@NRW, already take into account their own electronic case file formats which require standardised connectivity due to their IHE-compliant implementation. Data use following telemedicine care is thus possible to a certain extent, but is not yet generally taken into account. Data is therefore stored in very different ways in telemedicine applications. Project-specific applications often use local storage solutions, whereas established products typically store data in manufacturer-specific databases (for instance, in the KADIS system) or cloud-based solutions (such as MedStage TonoTracker[38]).

Telemedicine applications hence are another source of data for data-driven methods. At present, this source is only seldom used for further telemedicine applications. With the Medical Informatics Initiative[39], the Federal Ministry of Education and Research (BMBF) promotes the exchange and better availability of data from healthcare and research. Although the use cases considered do not yet include any telemedicine applications, clarification and connection to big interconnected data platforms, such as GAIA X[40], could enable big data evaluations in telemedicine. Certain projects in the field of telemonitoring, most notably the Telemed5000 project, are already exploring the use of machine learning methods for data pre-processing. From the totality of the data captured from all patients cared for, models can be trained here that can recognise anomalies in new incoming data. The captured vital data is then pre-sorted using these models and prioritised according to critical indicators. Centralised data evaluation of this type requires large computing and storage capacities on the part of the supervising institution. An alternative to this is a decentralised solution, so-called edge computing, that enables patient data evaluation directly on the data recording devices at the patient end.

For example, early signs of deterioration in a patient's health can be detected and appropriate countermeasures initiated (for instance, with KADIS, StethoMe). The potential of AI-based health applications in the field of telemedicine can generally also be rated as high. The trend here is primarily towards multi-modal procedures (multi-modal big health data) since these can cover the totality of the data collected from one or more patients at the same time, irrespective of how this data was captured.

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TELEMEDICAL APPLICATIONS ARE A FURTHER DATA SOURCE FOR PERSONALIZED MEDICINE. SO FAR, THIS SOURCE IS RARELY INCLUDED.

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37 SciTIM®, platform for blood pressure telemonitoring. URL [https://scitim.de/blutdruckdaten-app/]
38 MedStage® TonoTracker®, cloud-based software for ophthalmic treatment of patients with questionable pathological findings. URL [https://talkingeyes.de/medstage-tonotracker]
39 Medical Informatics Initiative of the BMBF. URL [https://www.medizininformatik-initiative.de/de/]
40 GAIA-X, A networked data structure for a European digital ecosystem. URL [https://www.bmwi.de/Redaktion/DE/Dossier/gaia-x.html]

An all-encompassing picture of a patient can then be created on the basis of all the care data collected (see (no author) 2020) and, in the sense of personalised medicine, diagnostics, therapy and care can be specifically adapted to the needs of individual patients (see Pfannstiel et al. 2020). For this purpose, care and health data of patients are collected from different sources and analysed in the sense of big patient data.

The associated large computational effort can be better distributed using federated methods (see Rieke et al. 2020; Wang et al. 2018). In this process, patient data is not physically brought together in one place, and learning procedures are carried out at the place where the data actually resides. This means that only the learned models have to be transferred to the central system and suitably federated there. This is also conducive to data sovereignty and hence also data protection since it means that personal information in the data sets does not have to leave its original storage location.

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FOR THE DATA GENERATED IN THE CONTEXT OF TELEMEDICINE TO BE MERGED, QUESTIONS OF INTEROPERABILITY MUST BE CLARIFIED.
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The non-technical challenge of data management lies primarily in the regulatory and legal issues of data linkage and use. In order for data generated in telemedicine care to be used together with other patient data, questions of interoperability and standardisation must first be clarified. Nationwide interconnectivity via the telematics infrastructure (TI) and the introduction of an electronic health record (EHR) are a suitable basis for this. The policyholder master data management already introduced as part of the TI improves higher-level patient identification and data allocation. Other services, such as emergency data management and the electronic medication plan, are expected to culminate in an integrated health record in 2021. The structure of the contents is specified by KBV through medical information objects (MIOs)[41], for instance, for the vaccination certificate. The connection to the TI and with it data security pose another challenge for telemedicine applications. The TI, including the 'communication in medicine' (CIM)[42] service, offers a uniform infrastructure, a uniform transmission channel and uniform data encryption for data transmission between the medical service providers connected to it, but also to the associations of panel doctors. Compliance with the GDPR is a challenge due to the use of data for specific purposes, especially in the case of subsequent use of data collected (by telemedicine). In order to enable use of the data generated in standard care for research purposes, the Digital Healthcare Act provides for data transfer to a research data centre, so that defined authorised users can access such data. However, the question regarding the type of data connection has yet to be clarified. A document-based connection to the EHR and its MIOs, as currently envisaged, must be supplemented for this purpose in a research-compatible EHR with further data integration levels. In order for patients to benefit from the advantages of data integration via TMAs, these TMAs must implement the TI specifications for compatible data management.

41 Medical information objects (MIO) are used to document medical data in a standardised manner, i.e. according to a defined format. URL [https://www.kbv.de/html/mio.php]
42 With the communication service KIM (Kommunikation im Medizinwesen) it will be possible in the future for practices to send and receive medical documents electronically and securely via the telematics infrastructure (TI) in the future. URL [https://www.kbv.de/html/kim.php]

⇗ HOW CAN TMA USE THE TI?

The telematics infrastructure (TI) is designed as the digital health network, for the purpose of networking the IT systems of all stakeholders in the health system. The focus is on services for standardised communications in a secure private network (VPN – virtual private network) that can be accessed through a physical connector (similar to a router). Since 2005, gematik GmbH has been responsible for the establishment, operation and further development of the TI. The advantages of the TI primarily come to bear through so-called specialist applications. Directory services (patients, healthcare providers), for example, can identify all participants in a uniform way. These central services also offer TMAs a basis for uniform data integration and other options. However, since the current specification of the electronic health record (EHR) is not designed for raw data integration, this data must first be prepared in a document-based manner, for example, as MIOs41 in the EHR (see 3.2.2). A research-compatible EHR, as envisaged by 2025, could enable further data integration. The TI communication service (KIM) can be used to exchange corresponding documents.

However, the central services of the TI, for instance, for uniform identification of TMA users, can also be accessed by external networks and applications, such as TMAs. The reverse is also true: External applications and networks can also be accessed from within the TI. This implies that two external networks or applications can also communicate via the TI, for instance, in order to use secure channels. The TI network can thus serve as an integrator of other networks (such as the VPN network of a hospital) and applications, such as TMAs. However, the related requirements (see gematik GmbH 2018) can be an obstacle. Use of the TI as a secure channel between TMA users additionally requires participation in the security infrastructure of the TI. Since TMAs are not usually connected to the TI via a physical connector, they must comply with certification guidelines (see gematik GmbH 2019) so that they can be included in the so-called trusted-service status list. The function of the TI as a secure transmission channel is currently achieved by other means, such as dedicated VPN tunnels, which are adapted to the local conditions of the TMAs and use a direct communication channel between TMA users. The necessary security guidelines must be taken into account, similar to a certification of video consultation providers according to the KBV guidelines (see Kassenärztliche Bundesvereinigung et al. 2016b). In order for the TI to be the only network for telemedicine applications, as recommended by GKV (see GKV-Spitzenverband 2016), clear interfaces and services for connecting TMA are important. The data integration function of the TI, for its part, should be the only option for the standardised handling of patient data. Integration of care outcomes from TMAs into the EHR supports integrated patient care and at the same time integration of TMAs into the health system. With a view to TMA scalability, using the TI (with its current specification) as the only communication network for TMAs could therefore pose a challenge; on the other hand, connecting TMAs to the TI to integrate TMAs results may support their dissemination.

3.3   The economic perspective

The most important aspect in business models of the digital health economy is a sustainable revenue model (see Leppert 2016). In principle, various sales channels are open to digital health service providers. First of all, services can be paid for directly by users (self-payers) within the so-called second health market which is subject to significantly less restrictive regulation and therefore has lower barriers to entry. However, it is apparent that comprehensive statutory health insurance coverage has led to a certain amount of reluctance among consumers to pay for private health services. The so-called first healthcare market is hence much more important (with around 73 million insured persons) where a rule-based and transparent system for reimbursement by cost bearers is in place. However, the first health market is highly regulated, which makes market entry difficult.

As a precondition for reimbursement of TMAs, an evaluation of their benefits is essential, unless they only support the care process. Section 3.1 has already highlighted the relevance of the benefits of TMAs with regard to improving health-related care. However, it is only by comparing costs and benefits that an economic assessment of TMAs becomes possible, because economic efficiency considerations must always take both sides into account.

Health economic analyses compare the results of care-related benefits with the cost changes in the system of statutory health insurance funds in conjunction with the intervention compared to established standard therapy. The cost-effectiveness should be at least neutral for the system of statutory health insurance funds, provided that a medical (additional) benefit can be proven in comparison to the previous standard of care.

However, health economic considerations often do not reflect and cover all the expenses of the stakeholders involved that may come to light in the design and implementation of TMAs. On the basis of the literature research and the expert interviews, four 'hidden' cost or expense items became apparent:

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TMA OFTEN REQUIRE INTEGRATION SERVICES. THE ASSOCIATED COSTS ARE NOT ALWAYS FULLY REFLECTED AND REIMBURSED BY THE GKV SYSTEM.

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1. Required ICT equipment in the form of hardware and software: The necessary components vary across the different TMAs as do the associated costs. For example, the equipment necessary for video consultation is much cheaper and easier to implement than that needed for telemonitoring.

2. Costs of organisational integration of a TMA: These are implementation costs resulting from changes in the existing work organisation.

3. Costs of techno-structural integration: On the one hand, insufficient integration into technical and care structures can lead to increased costs due to the creation of parallel structures. On the other hand, holistic integration initially leads to costs for the introduction of TMAs. The software-based costs of connecting TMAs to existing healthcare provider systems involve interoperability costs, for instance, for adapting data exchange standards and data migration procedures. Continuous maintenance and training costs must be expected in addition to these fixed costs.

4. Furthermore, concepts for care models are necessary for socio-economic integration (linkage to reimbursement systems and payment options).

Unlike the necessary ICT equipment, cost items 2. to 4. are difficult to estimate because they cannot be obtained on the market as inputs in the form of products and services which must be provided by the participants themselves during the process of designing and creating the TMAs, involving a considerable amount of manpower time. Such indirect costs, which are incurred by the individual user or the overall system, are often not taken into account because they are difficult to generalise and are also incurred during preparation for a transformation phase and/or during a limited changeover phase. TMAs are often implementations under transformational conditions. Existing structures and technological standards, to which the TMAs are to be linked and/or into which they are to be embedded, sometimes themselves undergo dynamic development processes.

In order to increase the chances of realising TMAs, rationalities at different levels as well as across different groups of stakeholders must also be taken into account as early as possible (during the concept development phase). This is illustrated by the following two examples:

- Licenced doctors: The health policy perspective (objective of/consent to provide a certain service) does not necessarily make the same sense from a microeconomic perspective. However, a medical service provider must take the latter into account if he/she wants to run a practice sustainably. Conversely, a reimbursement option is not always available for every medical service that makes sense in a specific case.

- Benefit and cost changes do not always concern the same entities: This often calls for reconciliation of interests and negotiated solutions. A typical case is also that an of organisation having to make advance payments. If this cannot be borne in purely private-sector settings as a normal entrepreneurial risk, but is negotiated as a public-private-partnership, this must also be considered as part of design development activities and costs.

The concept must hence take into account the different perspectives of stakeholders and the respective underlying incentive structures in which participants operate. Table 1 outlines the different rationalities that providers and designers of TMAs have to take into account.

	IT/device providers	Operators	Politics	Cost bearers	Medical service providers	Patients	Society
	Infrastructure, medical service providers, designers		Framework conditions		Users		Total
Primary perspective/ task	Cost amortisation, revenues	Feasibility, cost recovery	Financial viability, care	Efficiency, cost recovery	Effectiveness, care, cost recovery	Health improvement	Prosperity in the broad sense

Relevance of expenditure items (costs, time):

	IT/device providers	Operators	Politics	Cost bearers	Medical service providers	Patients	Society
Production/ acquisition/ maintenance costs	X	X					X
Price quote	X		X	X	X	(x)	(x)
Change in costs for hospitals	X			X			
Change in costs for outpatient care	X			X			
Expenditure by medical service providers	X	X	X	(x)	X		
Costs for patients	X	X	X	(x)		X	X
Total TMA costs			X				X

Table 1: Different perspectives of the stakeholders involved in a TMA, based on Busse et. al (2013)

Another significant aspect is the changes that accompany the introduction of a TMA with regard to service utilisation. On the one hand, it is conceivable that use will increase as the previous undersupply situation improves. On the other hand, it is also conceivable that the introduction of TMAs will lead to excessive use if groups of people can use TMAs without a corresponding indication.

Particularly in the interest of the community of insured persons, it is the overriding task of cost bearers to estimate the cost situation and trends on a reliable, sound basis and to also consider medium and long-term effects. Evaluations regarding TMAs must therefore take these health economic aspects fully into account. This calls for special instrument sets that expressly enable trial phases and their evaluation as an integral part of these trials, such as the Innovation Fund3. It was introduced in 2015 together with the Act to Strengthen Healthcare Services by Statutory Health Insurance Funds (GKV-Versorgungsstärkungsgesetz) in order to promote new forms of care within the scope of research projects and to enable reliable evaluation in trial operations. Funding in the area of new forms of care, which also includes research into and implementation of TMAs, especially requires that scientific monitoring and evaluation of the projects be part of the funded project (G BA Innovationsausschuss 2020). The evaluation concept should be based on a valid and secure data basis, so that decisions on further procedures for inclusion in general care can then be made on the basis of these results.

The categorisation of a TMA according to GKV-SV specifications (see section 3.1) essentially determines the cost reimbursement review path as well as the existing study requirements in this regard (see Beckers et al. 2015; GKV-Spitzenverband 2016; Szecsenyi et al. 2018). TMAs have the potential to overcome the sector boundaries between outpatient and inpatient treatment and are thus more difficult to map in the existing financing scheme of the statutory health insurance funds (based on special contract forms, see Table 2). In principle, it should be noted that accounting for inpatient services is usually based on diagnosis-related groups (DRGs) or via supplementary services (such as surcharges), while outpatient services are remunerated via the uniform assessment scale. The same healthcare application is therefore reimbursed at different rates and according to different systems in the two sectors (see Knöppler et al. 2017). Furthermore, individual cross-sectoral forms of remuneration exist, such as contracts for integrated care, model projects or disease management programmes. However, these contracts are mostly of a regional nature and limited to the participating health insurance funds and their policyholders. The innovation fund and special funding programmes/initiatives of the federal states (see p. 12) lend themselves as trial instruments and preliminary stages for the development of cross-sectoral care models and reimbursement options.

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TMA MAY HAVE THE POTENTIAL TO OVERCOME THE SECTOR BOUNDARY BETWEEN OUTPATIENT AND INPATIENT CARE. AT THE SAME TIME, HOWEVER, THIS MAKES IT MORE DIFFICULT TO MAP THEM IN THE EXISTING HEALTH CARE INSURANCE FINANCING SYSTEM.

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The reimbursement decision as well as the necessary basis for decision-making with regard to required evidence is again based on the category to which the respective TMA is assigned. Table 2 provides an overview of the different possible reimbursement paths for TMAs, depending on their respective categories.

TMA category according to GKV-SV	Category (I): Optimisation of processes through ICT with a supporting function for established medical procedures Category (II): Expansion to gradual change in established medical procedures through the use of ICT	Category (III): New examination and treatment methods
TMA example	Video consultation, teleconsilia	Telemonitoring
Reimbursement decision	Evaluation committee (KBV, GKV SV)	G-BA
Legal basis	Section 33, 291g of the Fifth Book of the Social Security Code (SGB V, Sozialgesetzbuch (SGB) Fünftes Buch (V))	Section 135, 137c SGB V
Benefit dimension	(Additional) benefits compared to current standard care	
Beneficial effects	- Patient-relevant outcomes (for instance, health-related quality of life, morbidity, mortality) and/or - reduction of costs in terms of hospital time, workload, and - improved equity of care through improved access, for instance, in rural areas and - improved use of resources (specialised medical knowledge)	
Study requirements	No clinical trial necessary, but cost-to-benefit assessment (according to the GKV efficiency principle)	- Clinical trial (RCT, comparison groups) - Cost-to-benefit assessment/evaluation (according to the GKV efficiency principle)
Remuneration	Uniform assessment scale (including outpatient specialist care), supplements	
Examples of remuneration models and forms of financing **(also outside of standard care)**	- Integrated care IV (section 140 a f SGB V), for instance, selective contracts IV (according to section 140 a d SGB V) - Model projects (according to section 63 65 SGB V) - Innovation fund - Federal states and others	

Table 2: Overview of possible reimbursement paths for TMAs

Due to the diversity of TMAs, there is therefore no uniform TMA remuneration model. Instead, the various TMA formats must make their way into the reimbursement system of the statutory health insurance funds along existing reimbursement systems (see Leppert et al. 2016; GKV-Spitzenverband 2016). So far, only a few applications have achieved this[43]. These include monitoring patients with a defibrillator or CRT system, conducting radiological teleconsilia (teleradiology) and holding video consultations (under certain conditions[44]). Furthermore, consiliary case conferences in the sense of teleconsilia via video link have also been billable since 2019[45].

Digital health applications open up another possible avenue for remunerating telemedicine applications. The legislator has now triggered a first step towards broad-based implementation. The reimbursability of digital health applications by statutory health insurers has been regulated by law since 2019 on the basis of the Digital Healthcare Care Act and the Digital Health Applications Ordinance (see Krüger-Brand et al. 2020). Digital applications from the eHealth sector are candidates for digital health applications. One prerequisite for reimbursability, however, is that the applications must successfully pass testing by the Federal Institute for Drugs and Medical Devices (BfArM) and then be listed in a directory of reimbursable digital health applications (DiGA directory[46]). The first tested digital health applications have already been listed in the DiGA directory since October 2020 and in principle can be considered to be reimbursable. The respective reimbursement amount is determined in direct negotiations between the respective of the digital health application and GKV SV. The associations of the health insurance funds and the producers agree on the final factors that are taken into account in pricing. According to the efficiency principle enshrined in the Social Security Code, it will be more a matter of the economic cost-to-benefit ratio of the respective digital health application for these initially extrabudgetary services.

This development is interesting for the prospects for telemedicine in as far as digital health applications show another potential reimbursement path for elements of a TMA. However, telemedicine projects are essentially more complex than a single digital application (see Craig et al. 2008) and therefore often go beyond a digital health application. It should be noted, however, that parts of a TMA can certainly be 'outsourced' as a digital health application (see box on p. 36) in order to achieve interim financing. In addition, the digital health application is intentionally designed as an iterative process "which must also be continued in an agile manner within the scope of future legislative projects" (Federal Ministry of Health). This at least gives hope for further regulatory opening up with regard to TMAs.

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THERE IS NO SINGLE TMA COMPENSATION MODEL DUE TO THE DIVERSITY OF TMA. IN THE CONNECTION WITH THE DIGA, A NEW POSSIBILITY MAY OPEN UP.
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43 Telemedicine, Federal Association of Statutory Health Insurance Physicians. URL [https://www.kbv.de/html/telemedizin.php]
44 The number of exclusive video treatment cases is to be limited to 20% of all treatment cases of a service provider.
45 Case conference according to appendix 27 to the BMV-Ä, EBM fee schedule item 37120. URL [https://www.kbv.de/tools/ebm/html/37120 _2903611856145446092320.html]
46 DiGA directory of the Federal Office for Pharmaceuticals and Medical Devices (BfArM). URL [https://diga.bfarm.de/de/verzeichnis]

⤢ CAN A TMA BE A DIGITAL HEALTH APPLICATION?

The new reimbursement path for digital health applications under the Digital Health Applications Ordinance could be an attractive option for TMAs and a driver for their dissemination due to its short review process adapted to digital applications. However, the extent to which TMAs can use this remuneration path is still unclear. An early assessment of when a TMA might be considered a digital health application is already possible. The basic prerequisite for a digital health application is approval as a class I or IIa medical device and the fulfilment of its corresponding medical purpose via digital functions. Communication tools that do not have a medical purpose are currently not included. For example, certified video consultation applications that follow KBV specifications (see Kassenärztliche Bundesvereinigung et al. 2016b) are by definition not medical devices and hence not digital health applications. However, TMAs can be more than mere communication aids (see section 3.1) and fulfil the basic requirement of digital health applications through their medical benefits. Pursuant to the Digital Health Applications Ordinance, TMAs must demonstrate either positive care effects or structural and procedural improvements. In both cases, the benefit must be demonstrated primarily for patients in their interaction with the digital application. Teleconsilium applications that do not require interaction with patients do not meet this requirement. Even those telemonitoring applications whose primary service is to provide doctors with sensory patient data, for instance, for adjusting treatments, do not fulfil the criteria of a digital health application (see Bundesinstitut für Arzneimittel und Medizinprodukte 2020). However, telemonitoring applications that use telemedicine functions to strengthen the self-management of patients in dealing with their disease and to offer in-treatment support must be distinguished from this. These could hence fulfil the basic requirements for a digital health application. Even if the exchange of data using TMAs is rarely an end in itself, serving only to digitise the communication pathway, the resultant medical benefit or procedural or structural improvement for patients must come directly from the TMA. In addition to this core criterion, the Federal Institute for Drugs and Medical Devices also tests the product with regard to its safety, functional suitability, data protection and security, usability, quality (see Federal Ministry of Health) and interoperability. For the latter, it is sufficient to use standards available in the vesta interoperability directory[47] or as MIOs (see section 3.2.2) or, in the absence of national standards, to use international standards whose inclusion in the directory has been requested.

In conclusion, a quote from the guideline of the Federal Institute for Drugs and Medical Devices reads: "Digital health applications, similar to telemedicine services, can help improve patient access to care and support equal and reliable access to health services regardless of where patients live and other factors" (Bundesinstitut für Arzneimittel und Medizinprodukte 2020). The reverse is also true: TMAs, as digital health applications, can serve their medical purpose in active interaction with patients. This means that TMAs must demonstrate how they use their communication function to deliver their benefits (positive care effect or procedural and structural improvement) for patients. The use of TMAs in teleconsultation, teleconsilia and telemonitoring show a significantly lower potential for compliance with the Digital Health Applications Ordinance than TMAs in teletherapy and telecoaching. The first approved digital health applications (as of 22 October 2020) show that telemedicine functions of a digital health application (for instance, 'somnio'[48]) can be used for monitoring and evaluation by contributing to the performance of a service. Explicit consideration of telemedicine functions as part of the approval process for digital health applications could help to integrate these even better into medical and psychotherapeutic service processes.

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47 The interoperability directory vesta of gematik GmbH consists of an online platform for standards and an information portal. URL [https://www.vesta-gematik.de/standards/]
48 Information for professionals on DiGA somnio (taken from the DiGA directory). URL [https://diga.bfarm.de/de/verzeichnis/508/fachkreise]

04

4 PRECONDITIONS FOR SCALING TELEMEDICINE

The debate regarding the scaling of telemedicine, i.e., the transfer of prototype applications to regular operation on a broad basis, is almost as old as the debate about telemedicine applications itself. Based on existing literature (see Gupta et al. 2016), the term 'scaling' as used there means the quantitative increase of an offering. In the case of TMAs, this is typically linked to a spatial expansion of the service offering and/or the expansion of access to a TMA for as many users as possible at national level or beyond.

The key challenges for TMAs from the perspectives of supply, technology and economics have been outlined in chapter 3 above. In combination with existing studies on success factors and barriers in conjunction with TMAs (see Lehmann et al. 2018; GKV-Spitzenverband 2016; Nolting et al. 2017) and the expert interviews, we have identified five important factors influencing the scalability of TMAs (see Fig. 4). We followed recent studies on implementation barriers for TMAs (see Lehmann et al. 2018) and their success factors (see Nolting et al. 2017), but we went one step further by considering how factors and criteria influence TMA scalability.
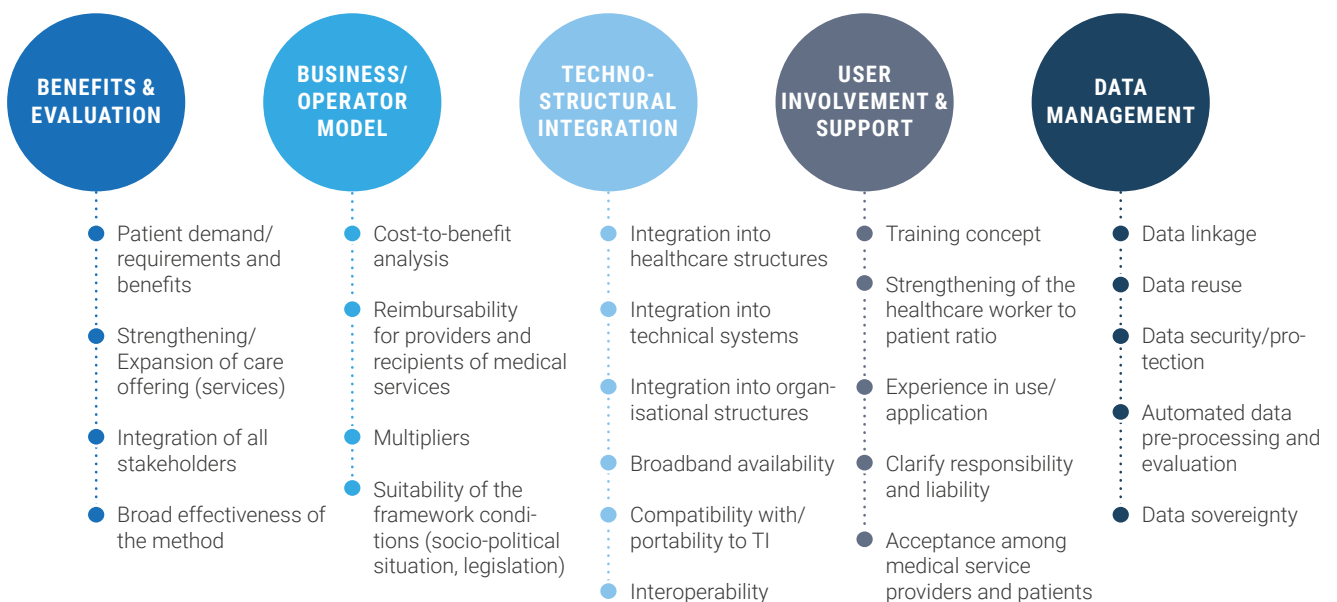
BENEFITS & EVALUATION	**BUSINESS/ OPERATOR MODEL**	**TECHNO- STRUCTURAL INTEGRATION**	**USER INVOLVEMENT & SUPPORT**	**DATA MANAGEMENT**
Patient demand/ requirements and benefits	Cost-to-benefit analysis	Integration into healthcare structures	Training concept	Data linkage
Strengthening/ Expansion of care offering (services)	Reimbursability for providers and recipients of medical services	Integration into technical systems	Strengthening of the healthcare worker to patient ratio	Data reuse
Integration of all stakeholders	Multipliers	Integration into organ- isational structures	Experience in use/ application	Data security/pro- tection
Broad effectiveness of the method	Suitability of the framework condi- tions (socio-political situation, legislation)	Broadband availability	Clarify responsibility and liability	Automated data pre-processing and evaluation
		Compatibility with/ portability to TI	Acceptance among medical service providers and patients	Data sovereignty
		Interoperability		

Fig. 4: Factors influencing the scalability of telemedicine applications

BENEFIT & EVALUATION

Without clarity about the benefits of a TMA for patients and other stakeholders based on their needs and their evaluation, it will not be possible to overcome the most important hurdle facing broad application. This typically requires positive verification. The position paper by GKV SV (see GKV-Spitzenverband 2016) recommends the application of different test criteria for evaluating TMAs depending on their type of use (see section 3.1). The need to expand or strengthen the range of medical care rather than replace existing services is emphasised in this context. The position paper also mentions a possible distortion of evaluations by creating optimal conditions for participants in model projects which cannot be entirely transferred to nationwide medical care by panel doctors. In this sense, the effectiveness of TMAs should also be evaluated on a broad scale by considering representative use under realistic conditions. This aspect makes the evaluation of TMAs, which is often regarded as particularly complex, even more difficult. One of the reasons for this is also the need to view use of some TMAs as complex interventions (see Haring 2020). Recent developments in the field of ecosystems and trial platforms for digital health economy products (such as HLaN[49], AIQNET[50]) could very well provide an interesting option for demonstrating the effectiveness of TMAs.

BUSINESS/OPERATOR MODEL

According to a survey of potentially successful telemedicine projects (see Lehmann et al. 2018), secure funding, the ability to fit into existing framework conditions and the broadest possible support from relevant stakeholders are essential when it comes to mastering the transfer of a TMA from a temporary project context to widespread care. We use the term 'business/operator model' to summarise these aspects. Reimbursability within the statutory health insurance system can be the basis for secure funding. However, reimbursement models within the second health market (private health insurance and self-payers) are also possible. In as far as reimbursement by statutory health insurance funds is possible, this study also considers the required cost-to-benefit analysis to be a prerequisite for the scalability of telemedicine.

TECHNO-STRUCTURAL INTEGRATION

The concept of techno-structural integration emphasises the interdependence and linking of successful integration in technical systems as well as supply and organisational structures. All of these factors must be considered together as a precondition for scaling TMAs. In this context, the final report of the "Studie und Expertengespräch zu Umsetzungshemmnissen telemedizinischer Anwendungen" (Study and Expert Discussion on Implementation Obstacles facing Telemedicine Applications) (see Lehmann et al. 2018) places particular emphasis on the factor of structural integration. The lack of network coverage and/or Internet availability, especially in rural areas, is a lasting obstacle to the implementation of TMAs, even though they have the greatest potential for coverage away from urban areas. The broadband atlas of the Federal Ministry of Transport and Digital Infrastructure (see Federal Ministry of Transport and Digital Infrastructure 2020) clearly shows that there are many regions in Germany where broadband availability is below 30 Mbps. However, even simple TMAs, such as video consultation, require at least this bandwidth for acceptable video quality; more advanced, complex applications that involve data transmission require even significantly more. Successful technical integration always requires an integrative view in both care and organisational structures and vice versa (see eHealth Initiative 2012). Ensuring data interoperability is also conducive to widespread implementation. The GKV SV position paper goes one step further and recommends that "the secure TI be permitted as the only network for telemedicine services and applications in the future" (GKV-Spitzenverband 2016). So far, there has been a discrepancy between aspiration and reality. The TI can hence be a facilitating factor for the technical scalability of TMAs. However, bringing aspiration and reality in line with each other will be extremely difficult (see section 3.2.1). That being said, technical scaling must also consider use of more than a single TMA. The resulting heterogeneity at both data and software level can be a decisive obstacle in the overall view of TMA use which could be defused by the uniform services of a TI. The complications seen up till now in the often parallel use of software in the health sector would also directly reach patients through broad use of TMAs. This factor is often neglected.

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49 HLaN, a real laboratory for German health start-ups. URL [https://www.digitale-technologien.de/DT/Redaktion/DE/Standardartikel/SmartServiceWeltProjekte/Medizin/SSWII_Projekt_HLaN.html]

50 AIQNET, a digital ecosystem for cross-sectoral, secure health data exchange. URL [https://www.digitale-technologien.de/DT/Redaktion/DE/Standardartikel/KuenstlicheIntelligenzProjekte/KuenstlicheIntelligenz_Umsetzungsphase/ki-projekt_AIQNET.html]

For example, one survey (see Lehmann et al. 2018) believes that how TMAs fit into the technical framework is not very relevant. On the whole, the health sector often tends to view technology as an obstacle rather than as a driver. However, for TMAs to be scalable, technical integration may not be treated as a matter of course that can be addressed downstream should complications arise. Instead, it should be considered as early as possible together with integration into care and organisational processes, so that process and technical innovation can go hand in hand.

USER INVOLVEMENT AND SUPPORT

This category encompasses all aspects that ensure broad acceptance of TMAs among all the stakeholders involved. In addition to the early involvement of all user groups during the concept and development phases, this also includes the development of training concepts. In terms of the broadest possible usability of TMAs, it is necessary for patients to be able to use them "without the need for major training" (see Nolting et al. 2017). However, this does not exclude a training concept. On the contrary, this enormously increases the quality of care provided by the attending physician or medical professional, which in turn has a positive impact on acceptance. Furthermore, it is essential that appropriate training concepts be provided, especially for medical service providers. The German Medical Association confirms that telemedicine care models deeply intervene in legal, organisational and financial contexts of medical treatment processes and influence the relationship between patient and doctor (see German Medical Association 2010). It must therefore be ensured that appropriate quality development and assurance, which constitute the central pillars of patient care (see Szecsenyi et al. 2018), are also provided in the implementation of TMAs. In addition to the necessary technical and medical competence for the entire spectrum of possible medical requirements of the respective telemedicine procedure, the medical service provider must also be able to handle the technical components and have knowledge of the processes as well as the communication and documentation protocols of the telemedicine procedure. Imparting such skills goes definitely beyond medical practice guidelines. Although these are science-based recommendations for the treatment of diseases that are constantly being revised by the scientific medical societies according to the current status (see Krupinski et al. 2014), the technical handling of special TMA modules is often widely neglected. However, this needs to be focused on more intensively since technical implementation and use also entail legal questions regarding liability and professional law, which, according to reliable surveys (see Lehmann et al. 2018), are of major importance for broad implementation. In addition, positive user experience on the part of both patients and medical service providers should not be underestimated. It is certainly beneficial if simpler telemedicine applications, such as video consultations, are used by as large a group of people as possible, so that first-time experience can be gained and fear of TMAs generally reduced.

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TELEMEDICAL CARE MODELS INFLUENCE THE RELATIONSHIP BETWEEN PATIENT AND DOCTOR AND THEREFORE REQUIRE APPROPRIATE QUALITY DEVELOPMENT.

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DATA MANAGEMENT

Data management issues were usually neglected in previous studies. Some testing procedures and certifications in the health sector, such as the testing procedure of the Federal Institute for Drugs and Medical Device for digital health applications or the conformity assessment procedures for medical devices, already require the existence of robust data security mechanisms. Unfortunately, however, these have not been sufficiently verified (see Olk 2020) and do not have to be integrated as a requirement into more comprehensive data use concepts.

It is foreseeable, especially in the healthcare sector, that further standardised certifications for data-driven models and systems will become mandatory. This means that secure, transparent data management and guaranteed data protection within the scope of the GDPR already have a major impact on the broad feasibility of telemedicine. This is particularly important to note where patient data is exchanged, i.e., especially in telemonitoring as well as teleconsilia. Furthermore, upscaling the number of patients to be cared for, especially in the area of telemonitoring, is always associated with a rapid increase in the amount of data to be analysed for the individual medical service providers. As described in more detail in section 3.2.2, data must be pre-processed or pre-selected above a certain population size in order to save resources. Clear rules should also be in place for data re-use in addition to a data management plan. Only then can TMAs be used as another data source in the health sector. Future research-compatible interoperability standards, such as the EHR, lend themselves to this, but the trend towards data-intensive TMAs in terms of scalability must also be taken into consideration. The data collected and/or generated within the scope of a TMA should be aggregated and made available to patients after voluntary provision. These aspects of data management require not only interoperable interfaces and quality assurance processes, and suitable core data sets must already be considered in the data modelling stage.

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SEMIAUTOMATED DATA ANALYSIS CAN HELP IN KEEPING THE MULTITUDE OF DATA THAT IS TO BE ANALYSED MANAGEABLE FOR SERVICE PROVIDERS.
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Fig. 4 maps these relevant influencing factors along possible fields of action which TMA developers and their partners should address at an early stage and/or to a greater extent. However, the relevance of influencing factors varies from case to case, so that no blanket statement is possible. Instead, using the identified influencing factors in the following TMA categories, we will show whether and under which conditions these factors inhibit or favour TMA scalability.

05

5   THE ECONOMIC POTENTIAL OF TELEMEDICINE

Teleconsultation
doc2pat

Teleconsilia
doc2doc
+ Data transmission

Telemonitoring
doc2pop
+ Data transmission
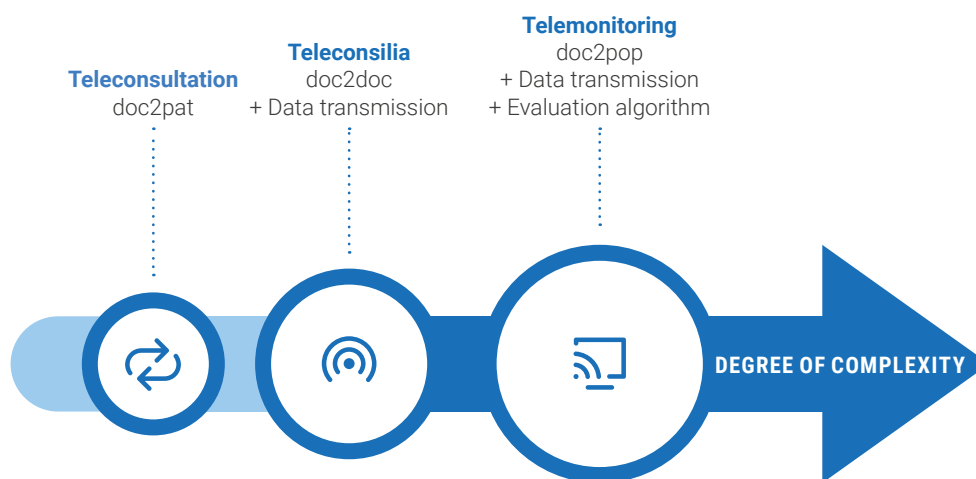+ Evaluation algorithm

DEGREE OF COMPLEXITY

Fig. 5: The TMA categories considered vs. the increasing degree of complexity of their technical implementation

Telemedicine is still in its infancy, so estimating its economic potential is a considerable challenge. Although other studies have dealt with estimates for the digital health economy or for the field of eHealth (see Leppert 2016; Bernnat et al. 2017; El-bel et al. 2019), it is almost impossible to extract telemedicine from these works due to the very different delimitations of the various terms outlined at the beginning of this study as well as considerable inaccuracies. We have therefore chosen a different, bottom-to-top path for our assessment in which we use three broad categories of TMA as a basis, i.e., teleconsultation, teleconsilium and telemonitoring. These cover a large part of present and future telemedicine applications and additionally differ in terms of their respective implementation complexity (see Fig. 5), which is primarily associated with increasing costs for IT infrastructure. Whilst teleconsultation in most cases implements pure video stream communication, teleconsilia additionally involve the exchange of patient data, which goes hand in hand with the need for additional data transmission and associated security mechanisms. Telemonitoring involves the additional challenge of securely transmitting, storing and suitably pre-processing the data of a patient cohort.

We have chosen the year 2030 as the time horizon because the strong dependence of telemedicine on regulatory, economic and technical prerequisites as well as acceptance by patients will foreseeably require longer introduction times. Geographically, the analysis is limited to the German health system. This makes sense because it is the only way to adequately consider the specific national regulatory features of the healthcare system.

We determine the economic potential on the basis of the investments in IT hardware, software and services which medical service providers will have to make to ensure correct provision of the TMAs. This creates a market that can be served by providers from the ICT sector and, to a certain extent, also by manufacturers of medical devices (see Lehberg et al. 2019). The top-down approach for possible savings in the healthcare system is typically adopted in studies on the potential of eHealth applications (see Bernnat et al. 2017; Braun et al. 2012). For telemedicine, however, a bottom-up methodology seems much more appropriate since cost savings are not the primary goal of telemedicine (see Schnee 2019). Although these are theoretically possible by avoiding gaps in care and by providing faster further treatment, they are very difficult to estimate as a whole for the categories considered here.

The bottom-up methodology adopted is based not only on carefully selected primary literature but also on hypotheses and approximate estimates of the investments to be made, which

were carried out in consultation with the experts. The present study is explicitly intended to encourage further development of the chosen methodological framework and to include (even future) analyses and elaborations to sharpen the results presented here.

This estimate obviously neglects the economic consequences of the widespread introduction of telemedicine, such as economies of scale and the possibilities for pooling resources. It also omits non-quantifiable welfare effects, such as an improved attitude to life among patients supported by TMAs. These effects are almost impossible to estimate today and would go beyond the scope of this study. However, the subsection 'Effects of telemedicine on the national economy and society as a whole' (see p. 47) provides at least a quantitative description.

⤢ EFFECTS OF TELEMEDICINE ON THE NATIONAL ECONOMY AND SOCIETY AS A WHOLE

The economic effects of the use of telemedicine, i.e., savings for cost bearers and generated sales in the healthcare sector (especially in the segment of IT solution providers, medical devices), will already be seen in the short and medium term with the establishment and dissemination of the various TMAs (technology diffusion). From a macroeconomic perspective, other positive socio-economic effects will be visible, most of which are only indirect and therefore difficult to quantify:

■ **ECONOMIES OF SCALE:** The economic effects in the form of economies of scale can be realised as techno-structural integration progresses. Most of the resulting revenues are typically siphoned off by IT service providers.

■ **ECONOMIES OF SCOPE:** As structural integration progresses, these effects emerge in the system mainly through cooperation and knowledge transfer between different stakeholders during the course of TMA implementation. This specifically promotes knowledge gains in the system and enhances the quality of care. In less regulated areas, the revenues generated in

this way typically also benefit the private corporate sector. In more tightly regulated sectors, such as the healthcare sector, which does not lose sight of the primary perspective of providing health-related care to citizens, the resulting revenues remain partly in the system in the form of social gains and benefit a large number of stakeholders. Currently, these 'pooling effects' are mainly associated with integrated data use for research, for example, in the Netzwerk Universitätsmedizin[51].

For society as a whole, the above-mentioned effects and other (external) effects that are neither internalised by cost bearers nor appropriated in the corporate sector, such as the subjective perception of improved quality of life by patients, savings in resources at the patient end or by private households (travel and waiting times), relief for employers by reducing shortages of skilled workers and in the case of continued payment of wages for ill employees, potentially higher satisfaction among medical service providers and improved equality of care, and an overall higher level of prosperity in society (impact).

51 The University Medicine Network is a research network of 30 university hospitals with the aim of gaining timely knowledge on the diagnosis and therapy of Covid-19

We estimate the investment volume for each TMA category as follows:

1. Following on from the preconditions analysed in chapter 4, we will first show which character-istics of TMAs in this category and which framework conditions as influencing factors have a positive or negative effect on TMA dissemination

2. This is followed by an estimation of the application potential of the respective TMA category, i.e., the quantitative use of the respective TMA. As far as reasonable and possible, this will be carried out as a quantitative assessment on the basis of the use and dissemination of TMAs so far. Because of the strong dependence on the influencing factors and their development in the coming years, three perspective scenarios with reference to the year 2030 will be used, i.e., S (small), M (medium) and L (large). Even the pessimistic 'S' scenario goes beyond the current status quo as a basis. It is to be expected that increased use of TMAs due to COVID 19 will not decline after the end of the pandemic and will continue to grow at least slightly, either because many patients will have to overcome the first hurdle or because they are still afraid of infection

3. In the next step, the output quantities varying across the different scenarios are multiplied by available or estimated market prices for equipment and software in order to determine the potential sales volume

4. Finally, the respective investment volumes of the three TMA categories considered will be extrapolated to the investment volume for all TMAs, i.e., the entire field of telemedicine.

5.1   Market potential for teleconsultation

The basis of the first calculation is the consultation, which is understood as synchronous video communications between panel doctors and patients known to them. Video consultation can, in principle, help to close gaps in care in rural areas. It saves people from having to travel long distances and can replace time-consuming home visits. It is particularly suitable for patients with limited mobility and for chronically ill patients in need of regular visits. The technical require-ments are relatively low. Most applications only require an Internet connection, a video display with a camera, speakers and a microphone, as well as complementary software. There is already a long list of certified providers (see hih – health innovation hub of the Federal Ministry of Health 2020) from which interested patients and medical service providers can choose. Video consul-tation is already included in the uniform assessment scale and can thus be billed by licenced doctors (see Kassenärztliche Bundesvereinigung 2020), however, with the restriction that only 20% of all treatment cases of a medical service provider may be billed as video consultation. In addition to basic and technical flat rates, the uniform assessment scale also allows for 'start-up financing' to cover investment and implementation costs (up to €500 per quarter for a maximum of four quarters). Reimbursement for patients insured by non-statutory insurers can be made via the German Doctors' Fee Scale (GOÄ, Gebührenordnung für Ärzte).

5.1.1   INFLUENCING FACTORS

COVID 19 in particular has significantly changed the underlying facts and the interest situa-tion since March 2020. It is also a great advantage for medical service providers if only some patients come to the doctor's office and some can also be treated via video consultation. The rule that the number of exclusive video treatment cases is limited to 20% of all treated cases by a medical service provider has been suspended since April 2020 (see Kassenärztliche Bun-desvereinigung 2020). Due to the COVID 19 pandemic, many providers have additionally made use of their services freely available for a limited time. The related positive experience with the application influences the willingness of both user groups to use this service. According to more recent estimates by KBV, around 25,000 medical practices were already using video consul-tation hours in April 2020, which is about a quarter of all practices. One question is how much of this boost from COVID 19 will remain, i.e., become a kind of habit. For the inpatient sector, it is assumed that the implementation of video consultations (doc2pat) will also increase in the broader context of increasingly billable consilia (doc2doc).

The influencing factors from chapter 4 have different effects on the implementation success of video consultation (see Table 3).

Influencing factors	Effect	
	Conducive/Favourable	**Inhibiting/unfavourable**
Benefit, evaluation	- Wide range of applications for many medical indications - Low-complexity TMAs of category (I) or (II) - Manageable effort for verification of benefit/evaluation	Cost-to-benefit evaluation by cost bearers can have a restrictive effect
Business/operator model:	- Reform of the ban on telemedicine and other restrictions in response to COVID 19 - Increased interest on the part of medical service providers - Increased willingness to use among patients/insured persons - Many market-ready offers from IT providers - Service in a regulated environment, but with transparent market entry conditions - Costs incurred by those entities that also participate in revenues; no reconciliation of interests (negotiated solution) required	- Limited reimbursability of expenses (organisation, IT) for medical service providers - Capping of reimbursement to counteract an unexpected increase in utilisation on the part of the cost bearers
Techno-structural integration:	- Simple technical run-up - Limited techno-structural integration	- Integration into practice structures associated with re-organisation efforts - Limited broadband connection, especially in rural regions - Technical effort to ensure data protection and information security during the call
User involvement, support:	- Good information materials from IT providers and KBV - Increased digital competence building (also in response to COVID 19) has a positive effect on acceptance - Possibility of patient health self-management	- Liability issues, also with regard to medical responsibility, have not been finally clarified - Positive use experience not yet widespread
Data management:	- No storage of personal data, therefore simple data security requirements - Certification option for providers according to KBV guidelines entsprechend der KBV-Richtlinien	

Table 3: Inhibiting and facilitating factors for teleconsultation

5.1.2   ESTIMATION OF USE

We have estimated the potential of teleconsultation in three scenarios as shown in Table 4.
The factors influencing the use/application of video consultation are based on the overview in
chapter 4.

Central influencing factors	Use/application of video consultation (Estimate for the year 2030)		
	SCENARIO S	SCENARIO M	SCENARIO L
Demand among patients with statutory health insurance	Steady, slight increase	Significant increase compared to 2020	Very significant increase compared to 2020
Acceptance among medical service providers	Steady, slight increase	Significant increase compared to 2020	Very significant increase compared to 2020
Experience in use/application	Mixed	Mostly good	Usually good to very good
Reimbursability	Billing via uniform assessment scale possible (with cap)	Billing via uniform assessment scale possible (low cap)	Billing via uniform assessment scale possible (without cap)
Broadband connection	2020 situation	Slightly improved compared to 2020	Nationwide
Price/business models of IT providers	Suboptimal	Optimised	Optimally adapted
Degree of use by medical practices (in %)[52]	40	70	90
Use by clinics/hospitals (in %)[53]	40	70	90

Table 4: Scenarios for use of teleconsultation

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52 According to recent surveys, the trend is towards a continuing increase, not only on the supply side, but also on the user side (service providers and patients). URL [https://hih-2025.de/
here-to-stay-digital-health-in-times-of-covid-19-a-german-deep-dive/]
53 If one looks at the "digitisation index" (of the KBV) for the inpatient sector, then initially the assumption seems justified that inpatient doctor-patient communication lags behind that in
the outpatient sector - also for reimbursement reasons. In this respect, a much lower degree of utilisation of video consultation in relation to hospitals/clinics seems appropriate as an
approach. However, it is assumed that in the medium term (here with a view to 2030), scope will be opened up in interaction with teleconsultations and a change in the reimbursement
possibilities.

Scenario S (use rate of 40% by medical practices and clinics/hospitals): This scenario assumes a further increase due to the COVID 19 pandemic, i.e., beyond the current level of 25%. Service providers continue to have reservations (medically justified and due to continuing liability issues), even if patients request video consultations. Users have mixed experiences in use/application, which is mainly due to low use and (still) limited digital competence on both sides, i.e., medical service providers and patients. Video consultation is reimbursable for medical service providers to a limited extent. Insufficient broadband connectivity is not a bottleneck everywhere, but for certain patient groups, especially in rural areas. Business models are largely optimised for users, but suboptimal in terms of economic benefits for individuals and for the economy as a whole due to the lack of economies of scale.

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THE REIMBURSEMENT POSSIBILITY AND AN INCREASE IN USER ACCEPTANCE DETERMINE THE DEGREE OF UTILIZATION OF TELECONSULTATION.

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Scenario M (use rate of 70% by medical practices and clinics/hospitals): This scenario assumes a medium to stronger boost due to the COVID 19 pandemic. Positive use experiences strengthen need and demand among patients and cause increased use, even as an alternative to specialist visits. The slight improvement in broadband coverage (80% area coverage) allows even more patients and providers to access video consultations. The majority of medical service providers decided to offer the video consultation format to their patients, because several years of testing have proven that the range of applications is greater than expected and some of the reservations that were discussed before the start-up phase have proven to be largely unfounded in practice. Business models are optimised, so there is still room for adjustment with regard to certain target groups. Economies of scale can be exploited to some extent on the supplier side.

Scenario L (use rate of 90%[54] by medical practices and clinics/hospitals): In this scenario, a very high level of use has been achieved due to nationwide broadband availability. The pandemic-related push, as well as the progress of digitalisation processes in general, has a very positive effect on the use of video consultations. According to the assessment of cost bearers, the format has proven itself from the point of view of economic efficiency, so that remuneration for the outpatient and inpatient sectors is possible without further restrictions. Suitable incentive-compatible business models are available for all target groups.

54 It is assumed that with a utilisation rate of 90% the maximum possible spread of video consultation in Germany will be achieved. On the one hand, this is due to the fact that not every doctor wants to bear the switching costs at the end of his or her professional life. In addition, medical and other reservations will remain on the part of the service providers. In addition, the value promises made in connection with the business models of the IT providers may - depending on the type of practice - only be partially fulfilled/realised. It is therefore assumed that the status of other countries, which due to their very low EW density and corresponding early or high pressure to act (e.g. Scandinavia, Australia) cannot be reached in the medium term.

5.1.3   ESTIMATING SALES VOLUME

The investments medical service providers must make in order to be able to offer video consultation include user fees for the service as well as costs for the acquisition of hardware needed to use the service.

The portfolio of video consultation offerings underlying this study is based on our research and the list of certified video consultation providers of the health innovation hub (hih – health innovation hub of the Federal Ministry of Health 2020). The at present strongly used Doctolib[55] business model is based on a price of €129 per doctor's practice per month (for up to three users). Another business model from provider sprechstunde.online[56] currently costs €39 per practice and doctor and is thus an alternative for individual practices or up to three service providers[57]. Competition will lead to price pressure in the medium term.

The more doctors use the offer, the more likely it is that unrealistic 'value-added promises' will become apparent as market exploration progresses (for instance, unlimited supply of new patients), for which users tend to be willing to pay when a new service is launched on the market. Price reductions will hence follow. However, the scope for price reductions will be gradually compensated for by video consultation providers through the added value they offer. This translates into an assumed average price of €120 per month and medical practice (for up to three users) or €40 per month and single user (inpatient sector). This results in annual costs of €1.440 for the outpatient sector doctor's practice and €480 for the inpatient sector and individual user in the hospital. The acquisition costs are estimated at €900 per user. One can realistically assume that in most cases the introduction of video consultation in a practice will involve purchasing a new laptop with a camera, microphone and loudspeaker because no such device is available or existing devices do not meet the technical requirements. Considering the total useful life for such hardware of three years[58], this results in annual costs of around €300.

Germany currently counts about 100,000 medical practices[59] and 1,925 clinics/hospitals. Given current use rates in 2020 (25 %), this translates into annual turnover of €10.5 million (25,000 practices x €120 per month) and one-off acquisition costs of €7.5 million (25,000 practices x €300). Our estimates are based on the year 2030.

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INCREASED USE OF TELECONSULTATION WILL LEAD TO PRICE REDUCTIONS AND AN ENHANCEMENT OF THE OFFER THROUGH THE CORRESPONDING ADDED VALUE.

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55 Doctolib, software solution for appointment and patient management. URL [https://info.doctolib.de/]
56 sprechstunde.online, KBV-certified video consultation [https://sprechstunde.online/]
57 The approach used does not take into account any additional scaling effects in pricing. The pricing models currently existing on the market show a very wide range in connection with the Covd 19 pandemic and cannot be regarded entirely as real market prices, but rather as market entry strategies.
58 The depreciation table for generally usable fixed assets (AfA) shows a total useful life of 3 years for such hardware. After this useful life has expired, new hardware can be acquired
59 Excluded are laboratory physicians, nuclear medicine physicians, pathologists and radiologists

Although forecasts indicate a slight reduction in the number of practices and hospitals by 2030 (see Deutsches Ärzteblatt 2016), these have little impact on our estimates of market potential, so that we also use the current figures of around 100,000 medical practices and 1,800 clinics/hospitals for the year 2030.

SCENARIO S

In **SCENARIO S**, 40% of medical practices use teleconsilia. 40% of clinics/hospitals require **5 individual solutions** in each case. Hardware investments are necessary addtionally.

Outpatient: 40,000 x €1,440 = **€57.6 million**

Inpatient: 720 x 5 x €480 = **€1.7 million**

Investment costs:

40,000 x €300 = **€12 million**

720 x 5 x €300 = **€1.1 million**

SCENARIO M

In **SCENARIO M**, 70% of medical practices use teleconsilia. 70% of clinics/hospitals require **10 individual solutions** in each case. Hardware investments are necessary addiontally.

Outpatient: 70,000 x €1,440 = **€100.8 million**

Inpatient: 1,260 x 10 x €480 = **€6 million**

Investment costs:

70,000 x €300 = **€21 million**

1,260 x 10 x €300 = **€3.8 million**

SCENARIO L

In **SCENARIO L**, 90% of medical practices use teleconsilia. 90% of clinics/hospitals require **20 individual solutions** in each case. Hardware investments are necessary additionally.

Outpatient: 90,000 x €1,440 = **€129.6 million**

Inpatient: 1,620 x 20 x €480 = **€15.6 million**

Investment costs:

90,000 x €300 = **€27 million**

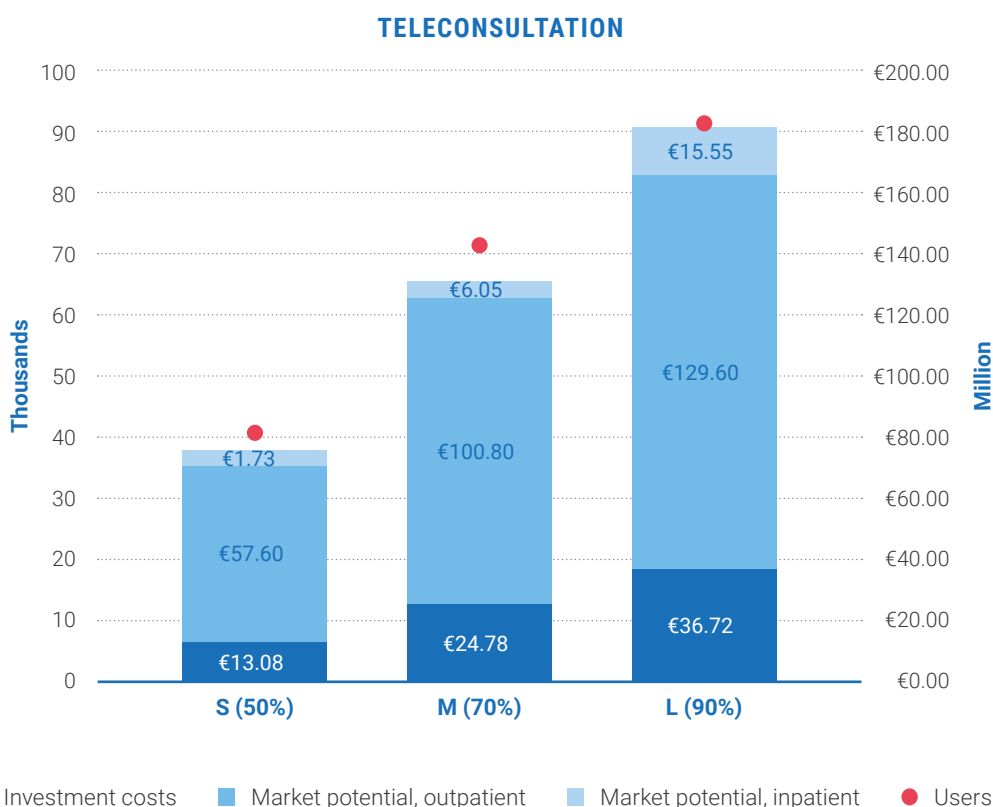1,620 x 20 x €300 = **€9.7 million**

TELECONSULTATION

Fig. 6: Market potential for teleconsultation in Germany in 2030

5.2   Market potential for teleconsilisa

Teleconsilia are specifically used to obtain medical expertise, enable interdisciplinary exchange between medical service providers (doc2doc) and to make use of specialist medical knowledge available in the health system regardless of location. In addition to video consultations, teleconsilia also have the potential to close gaps in care in rural areas.

Demand for such structures has increased significantly, especially in the wake of the COVID 19 pandemic[60]. The technical requirements are comparatively low, although somewhat more complex than for video consultation due to the exchange of patient data. Most applications only require an Internet connection, a video display with a camera, loudspeaker, a microphone and connection to a secure data exchange channel (typically via a connector from the TI, see info box on p. 29). Requirements for the technical procedure have so far only been specified for radiology (Kassenärztliche Bundesvereinigung et al. 2016a).

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60 eHealth.NRW: Bringing digitisation into the system. URL [https://www.ehealthserver.de/ztg/949-ehealth-nrw-digitalisierung-auf-den-weg-in-das-system-bringen]

5.2.1 INFLUENCING FACTORS

Reimbursement options for teleconsilia have improved significantly since October 2020. In addition to the tried-and-tested teleconsilia in radiology (teleradiology), teleconsilia can now also be billed via the uniform assessment scale, especially for complex medical issues. In addition, the Federal Joint Committee's 'centre decision' of December 2019 provides for a number of other indication areas, such as rheumatology as well as stroke, lung, nephrology and paediatric oncology centres and their financing via centre surcharges (see Deutsches Ärzteblatt 2020a). With the Third Digitisation Act, teleconsilia are to be expanded in the inpatient sector, i.e., in hospitals (see Deutsches Ärzteblatt 2020b).

The COVID 19 pandemic had a positive effect on the use of teleconsilia in that the benefits for many medical service providers and society which were achieved with new formats for interregional and interdisciplinary knowledge exchange in medical research and care have increased the importance of mutual consultation among medical professionals, i.e., consultative consilia. This is particularly relevant now, especially for intensive care and infectious disease expertise (for instance, TELnet@ NRW). The possibility of consiliary advice among doctors pays off especially where such expertise is not available. In contrast to what is sometimes the case with video consultation, there are no fundamental reservations on the part of the medical profession.

It can therefore be expected that acceptance will steadily increase with the identified need and positive application experience, assuming practicality in everyday practice and corresponding reimbursement.

The influencing factors referred to in chapter 4 (see p. 40) have different effects on the success of the implementation of teleconsilia. Table 5 provides an overview of the different modes of action.

Influencing factors	Effect	
	Conducive/Favourable	**Inhibiting/unfavourable**
Benefit, evaluation	- Wide range of applications for many medical indications and reasons for consultation - Linking to existing networks and structures possible	- The large number of medical service providers to be involved requires sophisticated implementation models - Evidence of (medical) efficiency and effectiveness for category (II) TMAs (see p. 24)
Business/operator model:	- Suitable IT solution providers available - Increased interest on the part of medical service providers	Reimbursability is not yet regulated for all participating medical service providers
Techno-structural integration:	- Simple technical run-up - TI enables a secure exchange channel for diagnostic data (see box on p. 29)	- Integration into organisational structures is associated with significant effort - Significant structural integration effort
User involvement, support:	- Association of Statutory Health Insurance Physicians and doctors' networks offer training - Integration of training aspects in education (for instance, EVA[61])	-Integration into nursing and physiotherapy training has not yet taken place
Data management:	- Uniform standards exist that also ensure data security - Information security regulated by access rights - Use of electronic case files favour interoperability	- No obligation to connect to a uniform infrastructure - No obligation to use uniform standards - High data protection requirements due to patient data transmission

Table 5: Inhibiting and facilitating factors for teleconsilia

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61 Relieving care assistant (EVA), further training for medical assistants (MFA)

5.2.2   ESTIMATION OF USE

We have estimated the potential of teleconsilia in three scenarios (see Table 6). The factors influencing the use of video consilia are based on chapter 4

Central influencing factors	Use/application of video consilia (Estimate for the year 2030)		
	SCENARIO S	SCENARIO M	SCENARIO L
Acceptance among medical service providers	Good	Increase compared to 2020	Significant increase
Experience in use/application	Mixed	Mostly good	Usually good to very good
Care models/ networks	Suboptimal	Optimised through evaluation	Optimally adapted through continuous evaluation
Data use	Reuse for research purposes within the existing framework	Partial connection to a research-compatible EHR	Connection to national and European data platforms
Data security/protection	Existing standards applied	Standards further improved	Standards further adapted to innovations
Connection to TI, interoperability	Use of TI specialist applications (see box on p. 29) for the exchange of central diagnostic data	Complete data exchange and integration in TI, connection via electronic case file	Low-threshold interoperability through full use of TI services
Reimbursement/remuneration	Retention of existing reimbursement schemes	Extension of reimbursement schemes	Comprehensive reimbursement (including inpatient)
Opening up further indications	As at present	Expansion compared to 2020	Significant expansion compared to 2020
Broadband connection	2020 situation	Slightly improved compared to 2020	Significant improvement compared to 2020 (nationwide)
Degree of use by medical practices (in %)[62]	**50**	**70**	**90**
Use by clinics/hospitals (in %)	**50**	**70**	**90**

Table 6: Scenarios for use of teleconsilia

62 It is difficult to determine the number of teleconsultations already carried out today, because they are not fully reflected in the EBM and the SHI-accredited physician billing. Furthermore, it is not possible to determine the number of (consulting and receiving) practices that carry out teleconsultations from aggregated billing data. A reliable estimate would also have to take into account the teleconsultations embedded in various care concepts, such as in emergency networks (e.g. Telestroke), model projects and projects separately funded by the health insurance funds. However, specialisation and centralisation are irreversible trends that increasingly promote the use of teleconsultation on a broad scale.

Scenario S (use rate of 50% by medical practices and clinics/hospitals): This scenario assumes a constant increase in acceptance on the part of medical service providers. However, the indication areas are limited to those that are already common today. Application experience is mixed, also due to as yet insufficient broadband expansion and the limited number of existing teleconsilia networks available. Care models are suboptimal or only exist in application fields that already exist. Data use for research purposes is limited to the current framework and does not additionally drive openness to application. The interoperability of data exchange for central findings and the electronic doctor's letter is ensured by standards for routine data and the use of specialist applications (see box on p. 29).

Scenario M (use rate of 70% by medical practices and clinics/hospitals): In this scenario, permanent provision of such extensive teleconsilia, with the aim of enabling the best possible use of outstanding expertise and specialist knowledge independent of location, depends on the continuation and creation of suitable forms of remuneration. This possibility is opened up by the Federal Joint Committee's 'centre decision' of December 2019, which is largely exploited within this scenario. This also entails expansion of medical indication areas beyond existing ones. Care models have been optimised through evaluation, and broadband coverage is improved, especially in rural regions. A high degree of interoperability is achieved by connecting to a research-compatible EHR. Use of data for research is thus possible to a certain extent and expands application possibilities. Use of the TI as a communication platform is possible through the electronic case file.

In **scenario L (use rate of 90% of doctors' practices and clinics/hospitals))**, it can be assumed that the reimbursement schemes will approach exhaustion of application possibilities with further progress in testing and recognition of the medical benefits. Care models are optimally adapted through continuous evaluation. Broadband coverage is significantly improved and available almost nationwide. The TI is implemented as a central infrastructure for health telematics and provides corresponding interfaces for easy connection. This also means a very high degree of interoperability. Connection to national and European research data platforms, such as NFDI4Health[63] and the European Health Data Space[64] means that an increased transfer of research findings into TMAs can be offered. Extensive use of data for research is possible and additionally has a clearly positive effect on openness to application.

5.2.3 ESTIMATING SALES VOLUMES

Teleconsilia typically involve costs not only for software or user fees, but also for hardware investments, which is always the case when teleconsilia are required in addition to the exchange of documents. In the TELnet@NRW project, for example, these are ward trolleys that are upgraded to enable telemedicine functions and video conversations between doctors and also with patient participation.

Extrapolating the development of hospital stock from recent years, 1,800 hospitals are expected for the year 2030 and, for simplification, 100,000 doctors' practices. Prices for teleconsilia are calculated according to existing solutions for teleradiology[65], averaged for the outpatient and inpatient sectors, with an average of €300 per month and €3,600 per year and per medical service provider or stand-alone solution.

Acquisition costs are estimated at €2,100 per user and include a laptop with a camera, microphone, loudspeaker and connection to the TI (via appropriate connector) as well as a teleconsilium/ward trolley. Taking into account total useful life according to depreciation tables, this translates into annual costs of €700.

63 NFDI4Health, National Research Data Infrastructure for Personal Health Data - https://www.nfdi4health.de/de/what-is-nfdi4health-deutsch/ [16.11.2020].
64 The European Health Data Space ensures efficient exchange and direct access to different health data (electronic health records, genomics data, data from patient registers, etc.) - not only in healthcare itself (primary use), but also in health research and health policy (secondary use). URL [https://ec.europa.eu/health/ehealth/dataspace_de]
65 Price list of the West German teleradiology network, at the end of October 2020 just under 500 users are shown there. URL [https://www.medecon-telemedizin.de/files/Westdeutscher_Teleradiologieverbund_Preise_%20und_%20Leistungen_20200601.pdf]

SCENARIO S

In **SCENARIO S**, 50% of medical service providers in the outpatient sector will participate in teleconsilium solutions. In addition, 50% of hospitals require 5 single-user solutions in each case. Hardware investments are necessary additionally.

Outpatient: 50,000 x €3,600 = **€180 million**

Inpatient: 900 x 5 x €3,600 = **€16.2 million**

Investment costs:

50,000 x 700 € = **€35 million**

900 x 5 x 700 € = **€3.2 million**

SCENARIO M

In **SCENARIO M**, 70% of medical service providers in the outpatient sector use teleconsultations, as well as in the inpatient sector with 10 solutions per hospital. Hardware investments are necessary additionally.

Outpatient: 70,000 x 3,600 € = **€252 million**

Inpatient: 1,260 x 10 x 3,600 € = **€45.4 million**

Investment costs:

70,000 x 700 € = **€49 million**

1,260 x 10 x 700 € = **€8.8 million**

SCENARIO L

In **SCENARIO L**, 90% of medical service providers in the outpatient sector will participate in teleconsilium solutions. In addition, 90% of hospitals require 20 single-user solutions in each case. Hardware investments are necessary additionally.

Outpatient: 90,000 x 3,600 € = **€324 million**

Inpatient: 1,620 x 20 x 3,600 € = **€116.6 million**

Investment costs:

90,000 x 700 € = **€63 million**

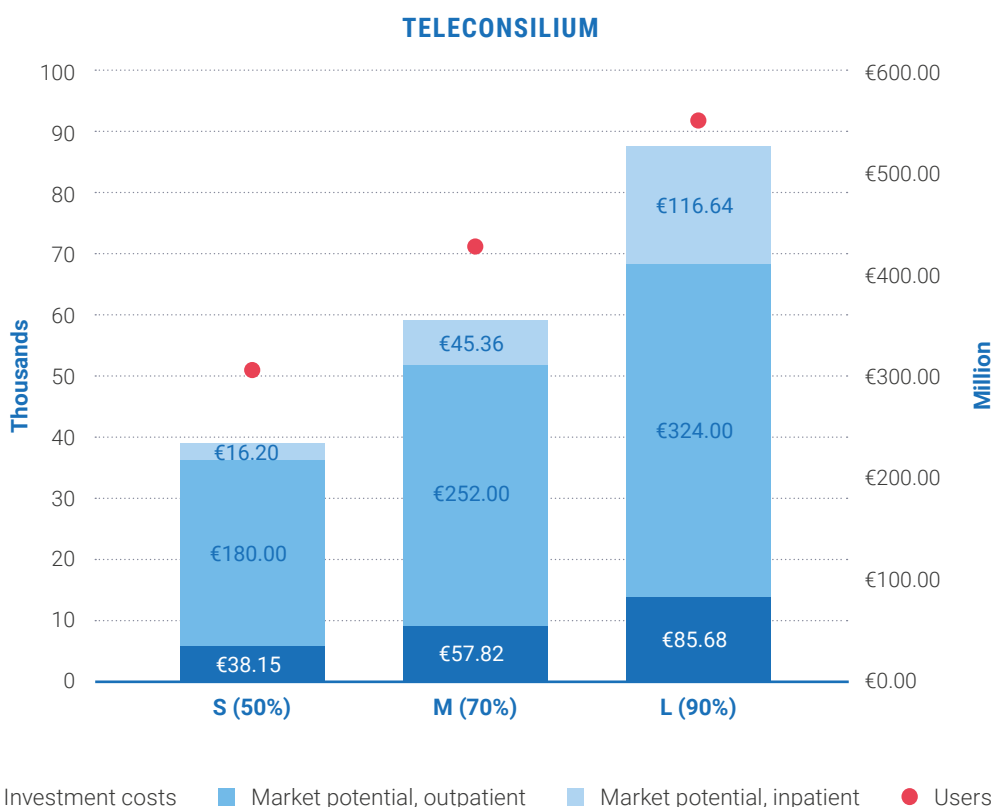1,620 x 20 x 700 € = **€25.7 million**

Figure 7: Market potential for teleconsilia in Germany in 2030

5.3   Market potential for telemonitoring

Telemonitoring typically includes three pillars of telemedicine co-care (see Köhler 2015): Therapy according to care guidelines, patient education as well as daily measurement, transmission and monitoring of vital data (ECG, weight, blood pressure, oxygen saturation) and, if necessary, intervention (contacting patient, emergency call). The elements, details and processes may vary depending on the specific care model. The technological basis consists of measuring and transmitting vital data and other use of sensors. With so-called remote monitoring, patients can actively establish a connection to the telemonitoring centre in order to transmit their data.

Telemonitoring is relatively widespread in Germany. A large number of projects indicate that telemonitoring is already being extensively practised, tested and evaluated. Overview studies (systematic reviews) on telemonitoring, which specifically include both clinical and economic effects (see Heinen Kammerer et al. 2006; Augustin et al. 2012), show a significant improvement in Germany with regard to the quality of life of patients and cost-effectiveness, as well as a certain

improvement with regard to mortality, hospital stays and medication adherence. Basically, it is demographic effects, such as increased multi-morbidity and chronic diseases in general, which make the use of telemonitoring appear sensible. In the mixed-age average, for example, up to 40% of the population are confronted with chronic diseases (see Güthlin et al. 2020). Telemonitoring can be relevant for a relatively wide range of associated indication areas (such as heart failure, COPD, diabetes) as various studies have shown in a broad overview (see Vegesna et al. 2017; Müller et al. ca. 2009).

Data management is a precondition for broad implementation and thus the inclusion of large patient populations. The data must be stored and processed in a data integration server (usually the telemedicine centre). Machine learning and artificial intelligence methods enable efficient and effective pre-analysis. This means that more patients can now be cared for and monitored without overburdening available medical resources (for example, in Telemed5000). This opens up far-reaching possibilities for comprehensive and continuous monitoring of the health of large cohorts, which can provide new insights especially for novel pandemic diseases (see Watson et al. 2020).

Because telemonitoring is carried out on an indication-related, elective basis, i.e., for specific patient groups in each case, remuneration is mostly based on dedicated contracts. Medical service providers are usually a telemedicine centre, licenced specialists (such as cardiologists) and clinics. More complex TMAs in category III (see p. 24), including telemonitoring, are embedded in suitable care models and corresponding forms of remuneration. Helpful in this context are independent moderators who intervene at an early stage and sometimes even in advance. It must be clarified who will take the lead and how the merits are distributed. Binding rules are especially needed to determine who will lead negotiations with cost bearers if extrabudgetary remuneration models (for instance, models based on dedicated contracts) are used.

THE EFFECTS OF TELEMONITORING PRESENT AS VERY POSITIVE, BASED ON SUCCESSFUL EXAMPLE USE CASES .

Especially in telemonitoring, application (usability) experience is very important. It was also found that applications with a minimum of continuous patient cooperation tend to be more sustainable. Overall, it can be said that early involvement of users (patients and medical service providers) is an increasingly important aspect. This is another reason why the chances of more complex TMAs, such as telemonitoring, becoming permanently established are currently estimated at 25 to 30%. Some applications have already reached quite an advanced level. Telemedicine co-management of patients with chronic heart failure has already been covered by a sufficient number of clinical trials and is about to be included in the uniform assessment scale. It seems realistic that these TMA approaches could be adapted to further chronic indication areas.

5.3.1   INFLUENCING FACTORS

The influencing factors from chapter 4 have different effects on the success of the implementation of telemonitoring. Table 7 provides an overview of the different modes of action.

Influencing factors	Effect	
	Conducive/Favourable	**Inhibiting/unfavourable**
Determination of benefit, evaluation	- Increased demand due to demographic effects and the progression of chronic disease prevalence - Efficacy proven by clinical outcomes for some indications - High patient benefit due to controlled self-management	- Proof of medical benefit and economic viability required (See TMA category III) - Permanent patient participation needs stimuli
Business/operator model:	- IT solution providers and the necessary medical devices available - Connectable products can be expected from the field of digital health applications	- Reimbursability not (yet) provided for - Reconciliation of interests (negotiated solution) required since several entities involved in exploitation
Techno-structural integration:	- Technical components available - Specialised centres involved, this includes opportunities for specialisation advantages	- Integration into conventional hospital structures complex - Establishment of a telemedicine centre necessary - Technical implementation as a uniform overall solution very complex
Training, support:	- Acceptance exists because benefits can be experienced by all sides - Supporting measures and training in place	- Intuitive usability of data collection systems requires early user involvement
Data management:	- Uniform standards exist that also ensure data security - Information security regulated by access rights - Use of electronic case files favour interoperability - Integration of machine learning and artificial intelligence methods creates scaling advantages - Establishment of a structured data platform with further possibilities regarding big patient data	- No mandatory connection to TI - No data standards for wearables and medical devices

Table 7: Inhibiting and facilitating factors for telemonitoring

5.3.2 ESTIMATION OF USE

Asked about the possibilities of nationwide expansion of this TMA expression, the following factors that influence the application potential emerged from research and expert discussions and are condensed in three scenarios in Table 8:

Central influencing factors	Use/application of telemonitoring (Estimate for the year 2030)		
	SCENARIO S	SCENARIO M	SCENARIO L
Demand among patients with statutory health insurance	Steady, slight increase	Increase compared to 2020	Significant increase
Acceptance among medical service providers	Steady, slight increase	Increase compared to 2020	Significant increase
Experience in use/application	Mixed	Mostly good	Usually good to very good
Evaluation	Unclear evidence situation	Partially reliable results regarding patient benefits/economic efficiency	Mostly reliable results with regard to patient benefits/economic efficiency
Operator models, care models	Suboptimal	Optimised	Optimally adapted
Data use (care/research); processing algorithms	Use in existing framework, learning procedure for anomaly detection	Partial use for research, integration of big patient data approaches	More extensive use for research, precision medicine
Data security/protection	Existing standards applied	Standards further improved	Standards further adapted to innovations
Reimbursement	Retention of existing remuneration options, such as dedicated contracts	Moderate transfer to standard care	Extensive transfer to standard care
Broadband connection	2020 situation	Slightly improved compared to 2020	Significant improvement compared to 2020 (nationwide)
Use rate by patients/insured persons (in %)	15	20	40

Table 8: Scenarios for use of telemonitoring

Scenario S (use rate of 15% by patients/insured persons): In this scenario, use of telemonitoring is slightly increasing compared to 2020[66], use experience is mixed and acceptance only slightly increased. The evidence situation remains unclear, so that the operator models/care models are likely to be suboptimal solutions. Remuneration continues to take place predominantly within the framework of dedicated contracts. Data is used for research purposes within the framework of existing possibilities. Data protection standards are applied in accordance with the GDPR. Broadband connection that has changed little compared to 2020 proves to be an obstacle to data transmission, especially in rural regions. Telemonitoring will have a major role to play in the medical care of chronically ill insured persons/individuals. The use rate is in the order of 15% for the chronically ill, which corresponds to approximately 5.5 million insured persons.

Scenario M (use rate of 20% by patients/insured persons): In this scenario, demand increases compared to 2020, the use experience is mostly good and acceptance increases. The evidence situation is more reliable, so that the operator models/care models will achieve optimised solutions. Remuneration takes place within the framework of dedicated contracts and to some extent also in standard care. There is some data use for research, but is not yet widely exploited. Data protection standards increase parallel to requirements. Improved nationwide broadband connection compared to 2020 opens up further possibilities. Telemonitoring will be a relevant component in the care of chronically ill insured persons/individuals. The use rate is in the order of 20% for the chronically ill, which corresponds to approximately 7.3 million insured persons.

Scenario L (use rate of 40% by patients/insured persons): In this scenario, demand is up significantly compared to 2020, the use experience is good or very good and acceptance increases strongly. The evidence base is mostly clear and some operator models/care models will achieve optimal solutions. Remuneration is mainly within the framework of standard care, provided that this is the aim of the care models. Data is used for research purposes on a large scale. Data protection standards follow the pace of innovation. In contrast to the 2020 situation, nationwide broadband connection opens up opportunities across almost the entire population. Telemonitoring will be an important component in the care of chronically ill insured persons/individuals. The use rate is in the order of 40%, which corresponds to approximately 14.6 million insured persons.

5.3.3   ESTIMATING SALES VOLUMES

Telemonitoring typically generates costs not only for software or user fees, but hardware investment costs for the data integration centre and data acquisition devices as well as personnel costs for the telemedicine care of patients (training, data evaluation, supervision). In clinical trials and systematic reviews on the topic of heart failure (see Benatar et al. 2003; Heinen-Kammerer et al. 2006), telemonitoring costs (technical equipment and personnel) are calculated separately per patient and day and are reported at $1.87. Converted with the then exchange rate, this translates into a little more than €50 per month and patient.

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66 We assume a current usage rate of about 10% for 2020. This assumption is based on current survey results according to which 20% of the patients surveyed use wearables or measurement apps (cf. Silberzahn et al. 2020). However, this also includes apps that do not allow any monitoring by medical professionals.

This assessment is in line with more recent statements by representatives of the telemedicine industry (Deutsches Ärzteblatt 2013)[67]who estimate a monthly amount of between €50 and €100 per patient (depending on the respective care concept). In total, this corresponds to annual costs of around €600 to €1,200 per patient. With an absolute lower limit of €600 per patient per year and a calculated average model of €900 per patient per year, the latter is taken as a basis. In addition, cost increases, including personnel cost increases, are assumed and final costs of €1,000 per year and patient are assumed. We assume that 10% of this, i.e., €100 per year and patient, is spent on ICT and medical devices[68]. This approach does not yet consider possible cost degression through increased use of AI to pre-evaluate monitoring data.

67 We are not aware of any more recent sources of information on the costs of telemonitoring.
68 The comparability of absolute costs and cost structures is fundamentally limited due to the different survey/transfer/support concepts for telemonitoring. Moreover, available data in studies do not show the IT share separately or only the telephone support (cf. Braun et al. 2012). With the trend towards rising personnel costs and falling average IT costs, the 10% shown there for IT costs is used as a rough orientation. The assumption is reinforced by forecasts that in 2025 approximately 8% of healthcare expenditure will be spent on hardware and IT services (cf. Choueiri et al. 2019). If we assume that the share of the digital health economy in the healthcare market will increase significantly by 2030, the assumption of an increase in this expenditure to 10 % is quite realistic.

SCENARIO S

In **SCENARIO S**, 15% of patients with chronic illnesses will participate in telemonitoring. This translates into a potential turnover of

€5.5 Mio. x €100 = €548 million per year

SCENARIO M

In **SCENARIO M**, 20% of patients with chronic illnesses will participate in telemonitoring. This translates into a potential turnover of

€7.3 Mio. x €100 € = €730 million per year

SCENARIO L

In **SCENARIO L**, 40% of patients with chronic illnesses will participate in telemonitoring. This translates into a potential turnover of

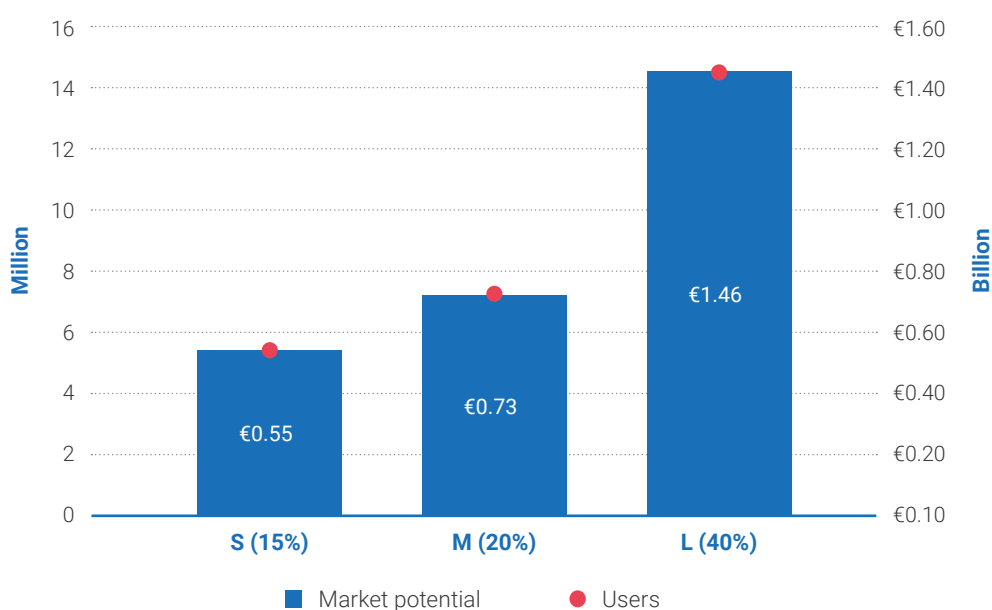**€14.6 Mio. x €100 € = €1.5 billion per year**

TELEMONITORING

Figure 8: Market potential for telemonitoring in Germany in 2030

Our estimates are based on the assumption of 73.0 million citizens in Germany with statutory health insurance. Assuming that around half of all insured persons suffer from a chronic disease (see Deutsches Ärzteblatt 2020), the maximum application potential adds up to 36.5 million insured persons[69].

Beyond the approaches that exist today, the extent to which digital health applications or other health apps could be integrated into telemedicine care concepts is being discussed. This is also related to the increasing general demand for self-measurement devices and/or products on the second health market. Furthermore, pressure is also increasing on medical service providers due to the availability of health app offerings on the second health market. Patients increasingly ask medical service providers whether a particular app can be included in their treatment (the care process) or which of the services are suitable with a view to their illnesses or a healthy lifestyle. At present, however, it is not yet possible to make a detailed assessment of the extent to which telemedicine and health apps overlap.

69 Patients with several chronic illnesses are not considered separately in this estimate, although this entails an increased care effort. On the other hand, this also reduces the acquisition costs.

5.4   Extrapolation: Market potential for telemedicine

In the previous sections, three categories of TMAs were considered in detail and a quantitative assessment of the market potential was made in relation to the year 2030. Combining the individual estimates leads to turnover of around €851 million (scenario S), €1.2 billion (scenario M) and €2.1 billion in the case of scenario L. However, the TMA categories considered in more detail only represent a certain subset. Other fields of application have existed for some time, for example, in the care areas of psychology (for instance, Invirto[70]) and rehabilitation (for instance, MeineReha). Although some of these applications do include telemedicine components, the provision of a medical service is not their main purpose. They should therefore be attributed to the TMA segment of digital health applications, i.e., those digital health applications that include telemedicine components (see box on p. 36) which will become increasingly important in the coming years due to expected regulatory changes. It is very realistic to assume that this convergence will generate further turnover in the billions. According to KBV data[71], expenditure on rehabilitation alone amounted to around €36 billion in 2017, with an upward trend. Assuming that around 3% of these expenses could be supported by telemedicine in the form of telerehab by 2030, this would result in a market potential of a good €1 billion. Another sales market can be expected in emergency medicine. This is mainly due to the fact that rescue services and control centres increasingly have to purchase mobile medical and measuring equipment for teleconsilia (for instance, Tellenotarzt[72]). Since this goes well beyond the implementation complexity of teleconsilia as defined in this study and because investment costs are also very difficult to estimate, the area of emergency medicine was excluded for all TMAs. However, increasing possibilities for using telemedicine components are also foreseeable in care (telecare). In this case too, the main focus is not on medical service, but there is an increased focus on the use of assistance robotics, so that telecare is also not part of the estimated market potential.

According to our estimates, the categories of teleconsultation, teleconsilium and telemonitoring considered above thus cover just 60% of all medically useful and/or economically viable uses of telemedicine. This assessment is roughly in line with similar assumptions in previous studies[73]. If we extrapolate the results of this study to all currently discussed TMA application areas, taking the former to be 60 %, we arrive at a market potential of around €1.4 billion (annual turnover, based on 2030). This scenario is based on a steady trajectory and a rather moderate increase in current utilisation rates and can hence be regarded as rather conservative.

70 Invirto, Angsttherapie per Telemedizin. URL [https://www.invirto.de/]
71 National Association of Statutory Health Insurance Physicians, Health Data. URL [https://gesundheitsdaten.kbv.de/cms/html/17065.php]
72 Telenotarzt. URL [https://www.telenotarzt.de/]
73 Leppert et al. (2016) assigns doc2doc and doc2patient applications a share of approx. 63 % of the total turnover of telemedicine applications for the year 2013.

If scenario M, which describes a significant increase in the use of telemedicine services, is taken as a basis, the estimates lead to approximately €2 billion. Scenario L, which is based on extensive use of telemedicine offers and a favourable development of the various framework conditions that are currently proving to be obstacles, results in turnover of around €3.6 billion for the sectors involved in the provision of services with reference to the year 2030.
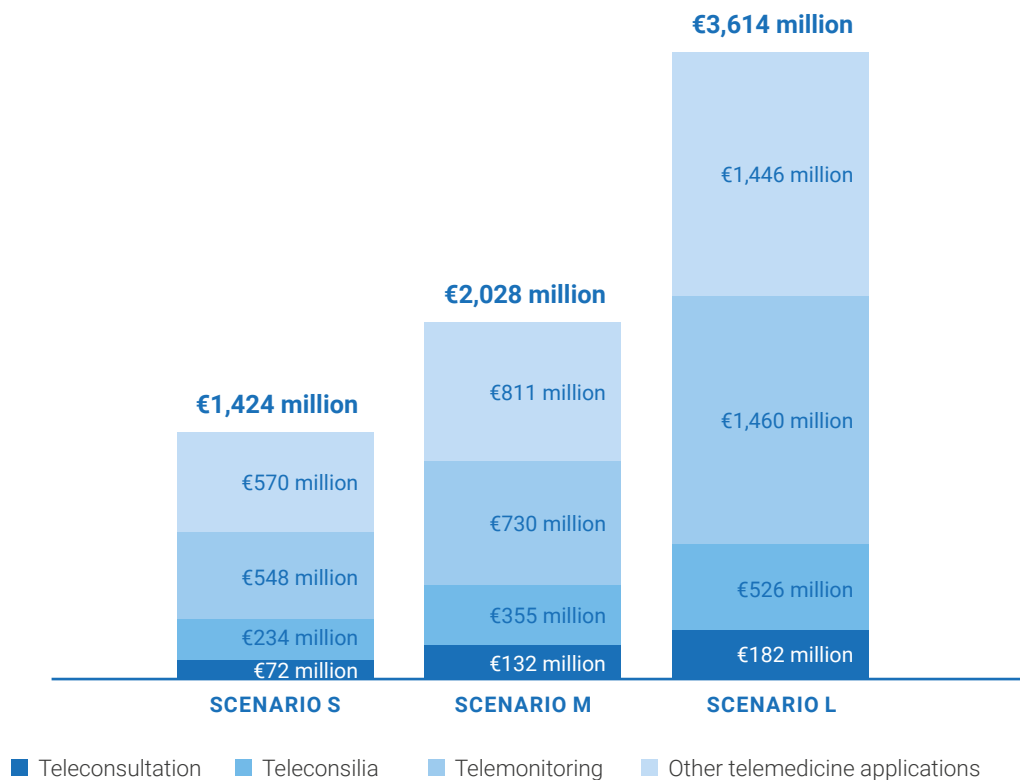

€3,614 million

€1,446 million

€2,028 million

€1,460 million

€811 million

€1,424 million

€730 million

€570 million

€526 million

€548 million

€355 million

€234 million

€182 million

€72 million

€132 million

SCENARIO S   **SCENARIO M**   **SCENARIO L**

■ Teleconsultation   ■ Teleconsilia   ■ Telemonitoring   ■ Other telemedicine applications

Fig. 9: Market potential for telemedicine and selected telemedicine applications in Germany in 2030

06

6 LITERATURE

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APPENDIX

LIST OF THE TELEMEDICINE PROJECTS COVERED IN THIS SHORT STUDY

Here we list all telemedicine projects in Germany that are relevant for our study. Starting points for the research were the vesta information portal, the list of funded projects in the area of "new forms of care" of the Innovation Fund of the Federal Joint Committee (G-BA), the federal government's funding catalogue, and the information websites of some of the initiatives of the states of Länder Baden-Württemberg, Bavaria, North Rhine-Westphalia, Schleswig-Holstein and Saxony. From all websites, only those projects were selected that could be classified according to the definition of this short study (cf. chapter 2) into the TMA categories teleconsultation, teleconsilium or telemonitoring and which are in the project or implementation phase.

PROJECT TITLE	TMA-CATEGORY	PATHOLOGY	FIELD OF APPLICATION
#ealth4Students	Teleconsultation	overlapping	General medicine
ACHT	Telemonitoring	Obesity (Bariatric surgery)	Surgery
Active Body Control	Telemonitoring	Obesity	General medicine, Dietology
AescuLink	Teleconsil		Emergency medicine
Ambulantes Blutdruck-monitoring	Telemonitoring	Hypertension, Hypotension	Cardiology
ANNOTeM	Teleconsilium	overlapping	Neurology
Caterna	Teletherapy, Telemonitoring	Amblyopia	Ophthalmology
Comm4Care SAN	Telemonitoring	geriatric diseases	General medicine
conneCT CF	Telemonitoring	cystic fibrosis	General medicine
DACE	Teleconsilium, Teleconsultation	overlapping	Nephrology
DigiCare Bodensee	overlapping	overlapping	overlapping
Digital Diabetes Clinic	Telemonitoring	Diabetes	General medicine
DMP HI PLUS	Telemonitoring	Heart failure	Cardiology
EHeRversorgt	Telemonitoring	Heart failure	Cardiology
Elektronische Vernetzung von Praxen in der Region Heilbronn	Teleconsilium	overlapping	General medicine
ERIC	Teleconsilium	Rehabilitation	Intensive Care Medicine
HerzConnect	Telemonitoring	chronic heart insufficiency	Cardiology
HerzEffektMV	Telemonitoring	chronic heart disease	Cardiology
invirto	Telemonitoring	Anxiety disorders	Psychiatry
iRescYou	Teleconsilium	Stroke	Emergency medicine
KADIS	Telemonitoring	diabetes mellitus	
KULT-SH	Telemonitoring	Paediatric oncology	Oncology
MeSiB	Teleconsilium, Telemonitoring	Respiratory care	General medicine

WEBSITE
https://www.telemedbw.de/projekte/ealth4students
https://acht-nachsorge.de/
http://www.abcprogramm.de/#
http://www.ghc-tech.de/produktportfolio/produktlinie-aesculink-system
https://www.hdz-nrw.de/kliniken-institute/institute/angewandte-telemedizin/leistungen-programme/ambulantes-blutdruckmonitoring.html
https://www.annotem.de/
https://caterna.de/
https://innovationsfonds.g-ba.de/projekte/neue-versorgungsformen/comm4care-san-versorgung-pflegebeduerftiger-unter-optimi-erung-der-interprofessionellen-kommunikation.350
https://innovationsfonds.g-ba.de/projekte/neue-versorgungsformen/connect-cf-coaching-und-telemonitoring-fuer-patienten-mit-cys-tischer-fibrose.357
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https://www.charite.de/forschung/forschung_an_der_charite/forschungsprojekte/innovationsfonds/eric/
https://www.hdz-nrw.de/kliniken-institute/institute/angewandte-telemedizin/leistungen-programme/herzinsuffizienz-management.html
https://www.herzeffekt-mv.de/herzeffekt-mv
https://www.invirto.de/
https://www.irescyou.de/
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PROJECT TITLE	TMA-CATEGORY	PATHOLOGY	FIELD OF APPLICATION
MiniDefi	Telemonitoring, Teleconsilium	sudden cardiac death	Cardiology
Modellregion OWL	Telemonitoring, Teleconsilium, Teleconsultation, Teletherapy	overlapping	overlapping
NeTKoH	Teleconsilium	Neurological emergencies	Neurology
NEVAS	Teleconsilium	Stroke	Neurology
NTX360°	Teleconsilium	Kidney transplantation	Surgery
OptimalNRW	Teleconsultation	overlapping	Geriatrie
PädExpert	Teleconsilium	overlapping	Paediatrics
pAVK – TeGeCoach	Telecoaching, Telemonitoring	peripheral arterial disease	General medicine
Rheinland-Pfalz atmet durch	Telemonitoring	COPD, Asthma	Pneumology
SALUS	Telemonitoring	Glaucoma	Ophthalmology
Sicher Leben mit Epilepsie	Telemonitoring, Teleconsultation	Epilepsy	Neurology
Smart	Telemonitoring	Obesity	Diabetology
smart medication	Telemonitoring	Haematology, Haemophilia	Haemostaseology
TASC	Teleconsilium	Stroke	Neurology
TeleArzt	Teleconsilium	overlapping	Emergency medicine
Tele-Augenkonsil	Teleconsilium, Telemonitoring	overlapping	Ophthalmology
TeleDerm	Teleconsilium	dermatological diseases	General medicine, Dermatology
TeleDermatologie	Teleconsilium	dermatological diseases	General medicine, Emergency medicine, Dermatology
Telemed5000	Telemonitoring	Heart failure	Cardiology
Telemedizin COPD	Telemonitoring	COPD	Pneumology
Telemedizin Herz	Telemonitoring	chronic heart insufficiency	Cardiology
Telemedizin@NRW	overlapping	overlapping	overlapping
TelemedNetz.SH	Teleconsilium	geriatric diseases	General medicine
Telenotarzt	Teleconsilium	overlapping	Emergency medicine
Telenotarzt.Bayern	Teleconsilium	overlapping	Emergency medicine
TelEp	Teleconsilium	Epilepsy	Neurology
TelePraCMan	Telemonitoring	chronic diseases	General medicine
TeleRad M-V	Teleconsilium	overlapping	Radiology
TeLiPro	Telemonitoring,	diabetes mellitus	General medicine
TELnet@NRW	Teleconsilium	overlapping	Intensive Care Medicine, Infectiology
TEMPiS	Teleconsilium, Teleconsultation	Stroke	Neurology
TESAURUS	Teleconsilium	Stroke	Neurology
TESSA	Teleconsilium	Stroke, cerebral infarction, cerebral haemorrhages	Neurology, Radiology
TIC-PEA	Teleconsilium	oesophageal atresia	General medicine
TRANSIT Stroke	Teleconsilium	Stroke	Neurology
VITAAL	Telemonitoring, Teleconsilium	Geriatrics	Rehabilitation
Westdeutscher Teleradiologieverbund	Teleconsilium	overlapping	Radiologie

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GLOSSARY

GLOSSAR	
AAL	Ambient Assistant Living
DiGA	Digital health applications
DiGAV	Digital Health Applications Regulation
DVG	Digital Supply Act
EBM	Uniform standard of assessment
EFA	Electronic case file
ePA	Electronic patient file
GKV-SV	Statutory Health Insurance - Central Association
GOÄ	Scale of fees for doctors
KBV	National Association of Statutory Health Insurance Physicians
MIO	Medical information object
RPM	Remote patient monitoring
TI	Telematics infrastructure
TMA	Telemedical applications
TMZ	Telemedicine Centre