

Chapter 2

Contextual Background

2.1 A Brief Outline of the Historical Development of eHealth Technologies

Before looking more closely at how Germany's healthcare system works, analyzing what the introduction of the 'eGK' technology in Germany entails and who is responsible for its rollout, this subsection provides a brief overview of the development of eHealth technologies over the past years.

Within the field of eHealth the term telemedicine has in the past been used to describe the "delivery of health care and the exchange of healthcare-information across distance" encompassing "the whole range of medical activities including diagnosis, treatment and prevention of disease, continuing education of health-care providers and consumers, and research and evaluation" (Craig and Patterson 2005, p. 3). Quite possibly the earliest form of eHealth was the use of telemedicine in the form of bonfires to pass on information about the bubonic plague across countries back in the Middle Ages. These forms of messaging have since been continuously developed, first with the rise of postal services, then telegraphy in the mid-19th century, which were eventually replaced by the telephone, and finally the radio.

Thanks to substantive technological development modern telemedicine has evolved away from analogue techniques towards digital forms of communication. Today, services using television, teleconferencing devices or the Internet can be considered a quasi-standard in practices and hospitals across developed countries. In fact, there often is no alternative to using telemedicine these days. By connecting the most remote locations telemedicine allows for better healthcare provision across countries thereby also improving the overall integration of healthcare providers and patients (Craig and Patterson 2005).

More recently, the term eHealth has been introduced to encompass not only telemedicine but add a broader dimension to "an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related

technologies”(Eysenbach 2001). The expression of eHealth has therefore been labeled as the “death of telemedicine because—in the context of a broad availability of medical information systems that can interconnect and communicate—telemedicine will no longer exist as a specific field” (Della Mea 2001).

In Germany, eHealth technologies have been employed for years. In the form of telemedicine the so-called Telemedical Maritime Assistance Service (TMAS) dates back to the early 1930s. In the 1970s in-house emergency call services were increasingly introduced, while in the 1990s retirement homes across the country were equipped with broadband video-communication (Paulus and Romanowski 2009).

The demand for a centralized eHealth technology with functionality beyond pure telemedical communication gained momentum with the so-called “Lipobay scandal” in 2001. The pharmaceutical company, Bayer, was forced to withdraw their medication, Lipobay/Baycol, as it showed severe side effects especially in combination with other subscribed medication (Die Zeit 2002). Due to the lack of electronic patient files these side effects were also hard to trace. A subsequent study published by the consulting firm Roland Berger therefore called for the need for a chip-based health card that would be able to store such information (please refer to Sects. 2.5 and 2.6 for a further description of the development of the ‘eGK’ technology).

2.2 Healthcare in Germany

Germany offers a national healthcare system, wherein every citizen of the state must be either nationally (statutorily) or privately insured. As of 01st January 2014 approximately 70 million of the 82 million German citizens are members of one of 132 statutory health insurance companies (GKV-Spitzenverband). As such, they are entitled by law to receive treatment in order to maintain and restore their personal health according to a catalogue which is collectively agreed upon by payors, providers and the government.

The Ministry of Health assumes the governing body for the healthcare sector and is responsible for all national matters with regards to health, prevention and long-term care. It also regulates European and international health tasks. The provision and financing of public healthcare services is done through self-governing institutions. These are amongst others the statutory health insurance companies and associations of medical doctors. In 2012, expenditure in the healthcare sector was ca. €300 billion which resulted mainly from expenditure of the statutory and private health insurance companies, expenditure of private households and organizations without commercial interest as well as goods and services which were provided in the context of ambulant treatments. This amount corresponds to approximately 11.3 % of the German gross domestic product (Statistisches Bundesamt 2014).

The statutory health insurance system is financed by the statutory health insurance funds. These are public-law corporations and are both financially and organizationally independent. While being assigned tasks by the state, these corporations carry out their tasks on their own responsibility. The statutory health

insurance system is based on the principles of solidarity and benefits in kind. The solidarity principle ensures that each insured person receives the medically necessary benefits regardless of their income. The principle of benefits in kind warrants benefits without the patient having to make up-front payments.

As of January 2009, the statutory health insurance benefits are funded through a national Health Fund based on a uniform contribution rate for all insured citizens. Both employers and employees pay parts of the contributions into this fund via the statutory health insurance.

Thus, while other countries introducing eHealth technologies have tax-financed systems, i.e. the U.K., Germany's overall statutory healthcare system is financed through contributions. The German system also differs considerably from the somewhat mixed system in the U.S. where healthcare provision, for example through the so-called 'medicare' and 'medicaid' systems, can be both provision- and tax-financed.

Importantly, in Germany doctors are not employees of the government or specific payor institutions, unlike in other countries such as the U.K. They therefore have a constitutionally ensured scope for discretion with respect to choosing the appropriate therapy as well as to voicing their opinion towards changes in the system. On the one hand, the German system thus allows providers, payors and patients great liberties in the overall provision and claiming of healthcare services respectively. On the other hand, this set-up adds stakeholder complexity as in the case of the 'eGK' technology whereby payors and providers generally act independently of the government and of one another. As such, each party individually has to be convinced of the benefits of new eHealth systems. Indeed, each stakeholder group aims at maximizing their own utility as the 'eGK' technology implementation project continues.

2.3 The Reasons for Introducing the 'eGK' in Germany

While the so-called "Lipobay scandal" in 2001 is often cited as being the catalyst for why the rollout of a central eHealth system including electronic patient files were demanded, it should be noted that the reasons for introducing the 'eGK' technology are manifold. Indeed, different stakeholders involved in the process are to benefit from the advantages of the 'eGK' technology in different ways and to a different extent. Some of the most prominent advantages can be summarized as follows:

Firstly, there is a general transformation favoring digital technologies in both the public and the private sector that has already penetrated the healthcare industry to a considerable extent. Indeed, countrywide eHealth systems are no longer the exception (please refer to Sect. 3.2 for a detailed discussion of the relevant literature on other national eHealth systems) while patient-focused technologies, such as medical mobile applications, are also increasingly being developed around the world. These eHealth technologies generate substantial overall economic and

technological benefits to patients, doctors and the medical technology industry alike. With its ‘eGK’ technology Germany logically follows this trend.

Secondly, two major cost-benefit analyses commissioned in 2006 and 2011 have suggested that there is a considerable economic benefit associated with the introduction of the ‘eGK’ technology (Gesellschaft für Telematikanwendungen der Gesundheitskarte mbh and Booz Allen Hamilton 2006). According to these reports, the ‘eGK’ technology directly profits both the insurance companies and therefore also the insurant who arguably pay unnecessarily high insurance contributions. The ‘eGK’ may therefore reduce the administrative costs of giving out new cards, for example when an insured person changes their insurance status. Furthermore, with a picture of the insurant printed on the card the insurance companies hope to avoid a considerable amount of fraud whereby an artificer of such fraud would illegally use a stolen insurance card.

Lastly and probably most importantly, a lot of qualitative benefits come along with the ‘eGK’ technology, the value of which goes beyond a simple measurement in monetary terms. Notably patients stand to gain from these qualitative benefits, i.e. medical functions of the ‘eGK’ technology, that are said to enable doctors to deliver more effective and efficient treatment, as explained later in this section.

2.4 Key Stakeholders in the ‘eGK’ Implementation Project

2.4.1 The Health Insurance Companies (Payors)

As mentioned above German citizens can choose amongst 132 statutory healthcare insurance companies whereby healthcare insurance is mandatory for every citizen of the state (GKV-Spitzenverband). Both the citizen and her employer normally pay the insurance contribution. Above a certain annual income threshold a citizen has the option of joining one of the private insurance companies.

In the context of the ‘eGK’ technology implementation the insurance companies are generally referred to as ‘payors’ (‘Kostenträger’) given that they are paying for the whole of the implementation process including the funding of the ‘gematik’ (definition below) as well as the rollout and subsequent maintenance of the hard- and software to be installed in the doctors’ medical practices.

While various healthcare and care insurance companies have employees dedicated to the work on the implementation of the ‘eGK’ technology, they are also centrally represented by an umbrella organization in this matter (Spitzenverband der Gesetzlichen Krankenversicherungen, ‘GKV-SV’). The GKV-SV was founded as part of the law § 217a SGB V in 2007. Overall, it determines general conditions for competitiveness within the health insurance market, both in terms of economic feasibility and the quality of the insurance services provided. It also supports the healthcare insurance providers in terms of meeting their responsibilities and in terms of the representation of their interests. One example of this is their assistance in developing a system for standardized electronic data transmission amongst all

statutory insurance providers. The GKV-SV generally supports the introduction of the 'eGK' and represents the interests of the statutory insurance companies within the 'gematik'.

2.4.2 The Doctors (Providers)

As of 2011, approximately 342,000 doctors practice medical services in Germany. The largest categories of specialization are: 101,000 general practitioners, 101,000 doctors for general, internal and child medicine as well as 36,000 surgeons and orthopedic surgeons. Additionally, 69,000 dentists, 36,000 psychotherapists and 61,000 pharmacists work in Germany (Statistisches Bundesamt 2013a). In 2012, 2017 hospitals operated across the country (Statistisches Bundesamt 2013b).

In the context of implementing the 'eGK' technology the doctors are often referred to as 'providers' ('Leistungserbringer') given that they will be the ones using the 'eGK' technology on a daily basis while providing medical services to their patients.

Overall, all resident doctors no matter their specialization, all hospitals and all dentists will eventually be provided with the 'eGK' technology according to current rollout plans. Furthermore, the 'eGK' technology is also intended to connect pharmacies across the country making use of specific functions such as the ePrescription ('eRezept'), whereby a prescription is electronically wired from doctor to pharmacy.

Within the 'gematik' the interests of the various providers are represented by the German Medical Association (Bundesärztekammer—'BÄK'), the German Dental Association (Bundeszahnärztekammer—'BZÄK'), the German Pharmacists' Association (Deutscher Apothekerverband e.V.—'DAV'), the German Hospital Federation (Deutsche Krankenhausgesellschaft—'DKG'), the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung—'KBV') and the National Association of Statutory Health Insurance Dentists (Kassenzahnärztliche Bundesvereinigung—'KZBV'). These organizations are all, just like the GKV-SV, direct shareholders in the 'gematik'.

2.4.3 The 'Gematik'

In 2002, the lead associations of both payors (health insurers) and providers (doctors) decided to collaborate on the implementation of the 'eGK' technology, which was anchored in the German law to modernize the public German health insurance system (§ 291 (2a) SGB V) in 2004.

In particular, § 291a and § 291b regulate that the conceptual and operational realization of this eHealth program is to be carried out by the Society for Telematics Applications (Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH

—‘gematik’), which was founded in January 2005 as a special purpose vehicle for this task. The organizational structure and governance is described in law § 291a (7) Sentence 1, SGB V and lists the shareholders as mentioned above. The ‘gematik’ is primarily responsible for the specification and certification of the various technical and systemic parts to be installed at doctors’ practices, hospitals and in the backbone. The ‘gematik’ has approximately 180 employees in Berlin (Gesellschaft für Telematikanwendungen der Gesundheitskarte mbh).

The ‘gematik’ is governed to equal parts by both the lead associations of payors and providers, who hold 50 % of the shares respectively. Decision-making is regulated by law and requires 67 % of the votes in a shareholders’ meeting.

Until 01st July 2009 both the statutory and private health insurance companies were involved in the planning and implementation process of the ‘eGK’ technology. However, as of July 2009 the private insurance companies have withdrawn from the ‘gematik’ and have handed over their share to the statutory insurance companies to keep the 50 and 50 % balance in shares between payors and providers. This move therefore means that privately insured citizens are not given the ‘eGK’ for the time being. As long as this remains the case, these patients will also not be able to access their medical data electronically over the countrywide ‘eGK’ system.

2.4.4 The Federal Ministry of Health

The ‘eGK’ implementation project was essentially started by the Federal Ministry of Health (Bundesministerium für Gesundheit—‘BMG’), which was headed by the Social Democratic Party of Germany (Sozialdemokratische Partei Deutschlands—‘SPD’) and the Green Party (BÜNDNIS 90/DIE GRÜNEN) at the time this decision was made. Already in 2003, the BMG contracted a number of companies to form the so-called ‘bIT4health’, a consortium commissioned to determine the general requirements for introducing a nationwide eHealth infrastructure in Germany. In 2004, the BMG subsequently introduced the law to modernize the public German health insurance system, § 291 SGB V. In 2005, it furthermore published an act which regulates the regional testing procedures required prior to the full, nationwide rollout of the ‘eGK’ technology (Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte). Until today, the BMG remains closely involved in the project.

2.4.5 The Federal Office for Information Security and Federal Commissioner for Data Protection and Freedom of Information

Overall, the German government as well as the key stakeholders responsible for the implementation of the ‘eGK’ technology have gone to great lengths to ensure a high

standard of data security. Apart from the Federal Ministry of Health, both the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik—‘BSI’) and Federal Commissioner for Data Protection and Freedom of Information (Bundesbeauftragte für den Datenschutz und die Informationsfreiheit—‘BfDI’) are heavily involved in the realization of this eHealth program. The ‘gematik’ reports closely and directly on the technical specifications of the various technological components as well as the data transmission process as a whole.

The BSI, in charge of data security, has issued clear guidelines for the technological specifications of the ‘eGK’ infrastructure. They are expressed in so-called protection profiles and set the standard for the required data security. As such, these standards affect the configuration of, for example, the key components of the Connector or the card reading terminals (definitions in Sect. 2.5).

In the past, the BfDI, responsible for data privacy, has been critical of the old health insurance cards (Krankenversicherungskarte—‘KVK’) for containing patients’ master data in an unprotected form. It has therefore voiced its general consent to the ‘eGK’ technology while nonetheless underlining the importance of establishing a truly safe connection of the doctors’ medical practices. The BfDI has furthermore recognized that one important benefit of the new technological standard is the introduction of a standardized form of logging. The new ‘eGK’ technology thus allows for informing the patients about which personal data is read and updated on the ‘eGK’.

2.4.6 The Medical Technology Industry

Over the years a significant number of technology providers have been involved in the development of the various technological components for the envisioned ‘eGK’ technology. Companies have focused on and specialized on developing individual products and services, such as the connector, the card reading terminal or the provision of a secure Internet connection (see below for definitions). In previous as well as in future tests of the ‘eGK’ technology, consortia of technology providers have formed to offer a holistic product and service for a test region.

The providers of medical technology produce the components according to the strict functional and technological standards determined by the ‘gematik’. The ‘gematik’ also manages the tendering process for the consortia and is therefore ultimately responsible for selecting the technological solutions employed during the various test phases. In the final rollout physicians will likely be able to acquire the individual components of the ‘eGK’ technology from various providers who produce these according to the final specifications of the ‘gematik’.

2.5 The Technology Behind the ‘eGK’

Compared to the former health insurance card (Krankenversichertenkarte—‘KVK’), the ‘eGK’ itself has a number of important new features (see Fig. 2.1):

1. The most noticeable, physical change to the new ‘eGK’ is a picture of the insured person, which is to guard against misuse of the card, i.e. in case of loss or theft.
2. The new health insurance number, which is issued alongside the new card, is retained also in the case where a patient changes her insurance provider.
3. The microchip is used to store the patient’s so-called master data (Versichertenstammdaten—‘VSDM’) in a protected environment. This includes the name, date of birth, address data, insurance number and data on how the patient is ensured, i.e. whether as member or family insurance policy-holder.
4. The name of the card is now standardized.

Figure 2.2 presents a simplified representation of the envisioned ‘eGK’ technology including its key components:

- *Doctor’s personal computer (‘PC’)*—The doctor’s personal computer encompasses the primary system of the practice or hospital, i.e. the relevant medical software. If not already connected to the Internet, the doctor’s PC will be connected to the Internet during the rollout of the ‘eGK’ technology to permit an online transmission of relevant data.
- *Card reading terminal for ‘eGK’*—The ‘eGK’ card reading terminal is a device specifically designed for the insertion and reading of the ‘eGK’. It can loosely be compared to a credit card reading device as often used in shops or restaurants and is either directly connected to the Connector (definition below) or works as a mobile device, for example in an ambulance.
- *Card reading terminal for ‘HBA’*—Another card reading terminal will be connected to the Connector, which reads the doctor’s Health Professional Card (Heilberufsausweis—‘HBA’). The HBA is the doctor’s own personal ID authorizing her to access a patient’s electronic health data.

Fig. 2.1 Sample picture of the ‘eGK’. Source ‘Kartengrafik: gematik GmbH’



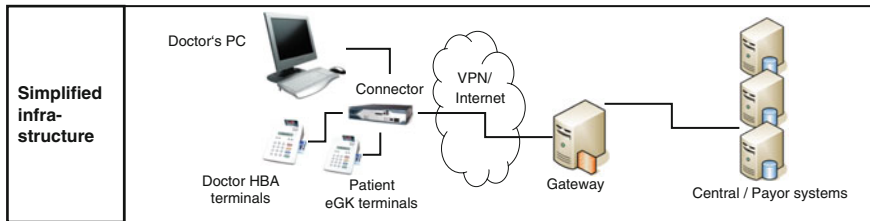


Fig. 2.2 Simplified depiction of 'eGK' technology

- *Connector*—The Connector works as an authentication and encryption device while also protecting the doctor's local computer and primary system from the outside, given that it will be connected to the Internet in the future. Effectively, the Connector establishes a safe Virtual private network ('VPN') between the doctor's personal computer and the Gateway (definition below). The Connector includes an application logic, which triggers the data transmission between the 'eGK' and the central/payor systems (definition below) and furthermore ensures the update of any data on the card itself.
- *Network*—The network can be a standard Internet connection as provided by one of the many telecommunications providers in the country. The doctor's medical practice or a hospital can be connected for example via a Digital Subscriber Line ('DSL') or a Universal Mobile Telecommunications System ('UMTS') common in German households. The type of network used will also depend on whether a stationary or mobile device is being connected.
- *Gateway*—The Gateway concentrates the many VPN protected networks arriving from the doctor's medical practices and connects them with the central/payor systems at the back of the system.
- *Central systems*—The Central systems are part of the back-end of the 'eGK' technology and are responsible for the implementation of relevant data safety requirements. These are particularly relevant as in its final version the 'eGK' technology will transmit a large number of highly sensitive personal medical data.
- *Payor systems*—The Payor systems are also part of the back-end of the 'eGK' technology and encompass a number of systems, for example the Update Flag Service ('UFS'), which consolidates the requests for the update of data saved on the 'eGK'.

From a user perspective and taking a non-technical approach, i.e. without listing all technical transmissions between every single component, the 'eGK' technology works as follows: Assuming a patient's standard visit to their general practitioner, the patient's 'eGK' is inserted into the dedicated card reading terminal, which is directly connected to the Connector. The patient enters her personal pin thus authorizing the doctor to access and store her medical data. The Connector is in turn connected to the doctor's personal computer (see Fig. 2.2). A safe Internet connection is established between the doctor's personal computer and the so-called

backbone, which consists of the Gateway, the Central systems as well as the insurance companies' Payor systems. The 'eGK' therefore works as the key to retrieving the electronic data from the backbone as it initiates the set-up of the connection between the local and the central systems. While the patient's master data is stored on the 'eGK' itself, no other medical data is stored on the card, first and foremost to avoid it being decoded should the card be lost or stolen.

Key to establishing a safe connection between the local system of the doctor and the backbone is the Connector. It also encrypts all data before it leaves the doctor's office. With this in place, the 'eGK' is first checked to determine whether the patient's master data is up to date. For example, should the patient have changed her address and have reported this change to her insurance company, the insurance company will update their data in the payor system. As the 'eGK' is inserted and a connection is established between the doctor's personal computer and the backbone, the new address is updated and saved on the card. The process of updating the patient's master data is the most basic function of the 'eGK' technology.

Once the 'eGK' technology is fully implemented, the patient's actual medical data can be retrieved and exchanged. For this purpose the doctor has to insert her own HBA at the same time that the 'eGK' is inserted. The HBA works as an authorization device signaling to the Central system that the doctor is accredited to retrieve the patient's highly sensitive medical data ('card-to-card authorization'). It furthermore allows the doctor to electronically enter new medical records.

Apart from being able to transmit the patients master data, the 'eGK' technology will in the future also comprise further key functions, as stated in SGB V § 291a. It is important to notice that according to law the patient alone has the right to decide which data is stored on the card and who is granted access to the medical data. The additional functions, described below, are therefore also referred to as 'voluntary' functions:

- **Electronic emergency data (Notfalldaten)**—By choice a patient can have relevant information, such as allergies, chronic diseases, drug intolerances as well as other important diagnoses saved on the 'eGK'. Further, the address of a contact person in case of an emergency as well as the contact information of the primary doctor can be stored. In this case, any doctor can access this relevant information even without the patient's immediate consent. This feature is particularly useful when the doctor has to act quickly and the patient is not able to respond. Besides, if so wanted, the patient's provision as well as information on their willingness to donate organs can be saved.
- **Electronic doctor letter (eArztbrief /KOM-LE)**—Today, doctors mostly communicate via post. One drawback of this is that information can sometimes not be shared on time between two doctors simultaneously treating the same patient. Furthermore, doctors already working with digital patient files also need to transfer the relevant information into the computer system of their medical practice which can be unnecessarily time consuming. The electronic doctor letter allows doctors to quickly share diagnostic findings in a legally binding, safe and compatible manner.

- Data for checking the drug therapy safety (AMTS)—On a voluntary basis, patients can choose to have data on medications, drug prescriptions or suggestions for therapy electronically documented. As such, a doctor or pharmacist can get an overview over the different drugs a patient is taking. A key advantage of this feature is that it should reduce the risk of prescribing or selling drugs which cause interactions with negative consequences.
- Electronic case file (eFallakte)—In the future, all doctors involved in a certain treatment process can be permitted access to the documentation of this treatment case. This data will be saved in the electronic case file and should enable a better harmonization of individual medical cases.
- Electronic patient file (Patientenfach)—This function enables the storage of data provided by the patients themselves.
- Electronic patient receipt (Patientenquittung)—Patients will be able to ask their doctor for a patient receipt which can be issued on the very day of the treatment or on a quarterly basis.

To sum up, while the 'eGK' technology is transforming the use of technology in German medical practices and therefore also the way patients will be treated in the future, it does not require the total dismantlement of currently used hard- and software within the various medical practices and hospitals. This is important to notice and a key difference to other information systems implementations observed in some of the existing literature on eHealth technologies (Aanestad and Jensen 2011; Hanseth and Monteiro 1998). As such, only the interfaces to the doctor's PC and the payor systems will have to be adjusted to accommodate the use of the 'eGK' technology. Other components such as the card-reading terminals, the Internet connection and most of the backbone infrastructure will be independently developed, installed and configured. Indeed, this is an important prerequisite in order to be able to operate a safe and autonomous system that cannot be breached from the outside. Many of the existing data privacy concerns and corresponding strict regulation could otherwise not be met.

Furthermore, the newly developed and installed components of the 'eGK's' technology are mostly purpose-built. An "adaptability problem", which should, according to Hanseth and Lyytinen (2010), be avoided by making simple, modularized information infrastructures, therefore only partially applies to the 'eGK' technology.

2.6 The Implementation Process of the 'eGK' Technology

2.6.1 The Implementation Process of the 'eGK' Technology Until Today

Puzzlingly, despite the implementation process of the 'eGK' being clearly regulated by law, despite the set-up of a special-purpose vehicle to steer the process, i.e. the

‘gematik’, despite the general support of the relevant governmental bodies and despite a general willingness by technology providers to develop and produce the technical components according to the strict specifications, the rollout of the ‘eGK’ technology has been difficult right from the outset.

Initial plans as stated by law (§ 291 (1) SGB V) envisioned a rollout of the ‘eGK’ technology by January 2006. However, difficulties were already encountered early on: Technical and functional demands continuously increased as the stakeholders involved in the implementation process struggled to agree on a number of points, amongst them concerns about the functionality of the technology and how it would be used on a daily basis. Further points of disagreement evolved around the timing of the rollout, details on the planned testing procedures and data privacy concerns.

In 2006, the ‘gematik’ consequently commissioned a cost-benefit analysis of the program, which mapped the costs of the rollout and day-to-day operations of hard- and software against the saving potentials encompassed in the new technology. Savings were therefore calculated to result from avoiding unnecessary administrative costs. These were often associated with the issuing of new cards whenever certain data was manually updated that could instead be electronically updated making use of the ‘eGK’. Better medical treatment would further augment these savings effects. The results emphasized the benefits of the technology to payors and providers alike.

In 2007, the ‘eGK’ technology was tested amongst 10,000 patients in six designated areas in Germany to get representative feedback from doctors across the country. At the same time, the regions were chosen for their general political support of the new technology. However, results were mixed in terms of the technological success as well as user acceptance. This was partially due to cards not being comprehensively rolled out as well as due to technical issues, such as problems with the interoperability of components produced by different suppliers. A heavy reliance on a strong and supportive lobby within the test regions, which could mediate between the different stakeholders involved, also proved an obstacle.

In 2009, in a position paper, the umbrella organization of the payors, the GKV-SV, called for the disentanglement of the technological complexity. The idea was to reduce the dependency of the various technical components on one another, leverage the immediate economic benefits as well as increase the planning reliability for the various stakeholders involved in the rollout process. This was welcomed by the private industry, i.e. the medical technology providers. Indeed, the latter were, on the one hand, hoping to profitably supply new technologies as part of the ‘eGK’ solution, but, on the other hand, had previously been developing ‘eGK’-related technologies that were becoming obsolete as requirements changed over time. One example of this are the so-called dual ‘eGK’ card reading terminals, which could also be used as payment devices in connection with credit and debit cards. As of 2004 patients were required by law to pay a quarterly charge for registration with their doctor. However, this charge was suspended in late 2012 therefore also defying the purpose of a dual card reading terminal.

Finally, in late 2010, the GKV-SV ordered yet another re-evaluation of the costs and benefits of the projects with the aim of quickly introducing a technologically simplified solution. Again, the aim was to speed up the nationwide rollout process while quickly offering the first benefits to payors, providers and patients alike. Furthermore, by then a number of risks had evolved which urgently needed to be addressed, especially from the standpoint of the payor organizations: Firstly, the rollout process of the 'eGK' had turned into a loss-making project over the years. The qualitative as well as the economic benefits of the technology, as described in earlier position papers, were becoming harder and harder to realize. Secondly, the prolonged rollout process had led to an establishment of isolated stakeholder-specific solutions. Thereby, doctors would employ competing alternative technologies to the 'eGK', such as the online payment tool KV-SafeNet or a card-based solution used by dentists, "Zahnärzte Online Deutschland", in order to electronically share patient data within their local networks. The risk of the 'eGK' technology becoming obsolete was therefore increasing. Thirdly, while the 'eGK' itself was to replace the KVK as of October 2011, the patient's master data would only be saved on the protected area of the 'eGK' once the 'eGK' technology as a whole was fully rolled out and actually connected online. Otherwise, data would be stored on an unprotected area of the microchip of the card as already the case with the KVK. Indeed, this meant that the BSI and BfDI, which had previously criticized the KVK as unsafe, could be inclined to stop the overall project for non-compliance with the required data safety and data security standards.

2.6.2 The Implementation Process of the 'eGK' Technology as of Today and as Currently Envisioned for the Future

As a reaction to the complications in the rollout process and the substantially prolonged implementation, the government decided to force the payor organizations to exchange the old KVK with the new 'eGK', not at least as a symbolic gesture that the implementation of the 'eGK' technology was moving ahead. The exchange of the cards was to be carried out by 31st January 2013. The insurant were hence asked to send in a mug shot to be printed onto the new cards. Those statutory health insurance companies that would not comply were to be economically penalized. Despite smaller difficulties, because some of the insurant sent fake photos of themselves, the 'eGK' itself has been handed out to basically all citizens who are statutorily insured. Current estimates suggest that only around 2 million insurant still use the KVK which approximates to 3 % of the statutorily insured (Spiegel Online 2014). Although doctors are still entitled to accept the KVK until 01st October 2014, the 'eGK' has officially replaced the KVK as the main proof of a legible insurance status between patient and doctor as of 01st January 2014.

Prior to the actual 'eGK' being handed out, doctors had already been encouraged to purchase a card reading terminal in 2011. During the period of April–September

2011 these were also fully subsidized by the payor organizations. Doctors were therefore reimbursed for buying from one of a number of technology providers that produce these terminals according to the technical specifications defined by the ‘gematik’.

Despite these important stepping-stones, the ‘eGK’ technology is far from delivering on its supposed potential as of January 2014. Indeed, none of the doctors are actually connected online via the ‘eGK’ technology as described in Sect. 2.5. While patients can now show their ‘eGK’, the doctors’ practices cannot make any use of it as they have not been provided with the rest of the technology required.

At the time of writing, two consortia commissioned by the ‘gematik’ in December 2013 are working on the implementation of a new round of field tests in two designated areas, one in the counties of Schleswig-Holstein, North Rhine-Westphalia and Rhineland-Palatinate (test region Northwest), the other in Saxony and Bavaria (test region Southeast). The tendering process of the technology used in the tests incorporated three lots: two lots for the decentralized components in one of each of the test regions, i.e. all components within the doctors’ medical practices necessary for the execution of the testing, and a third lot for the centralized parts of the ‘eGK’ technology equally applicable to both test regions, i.e. the backbone. During the field tests at least 500 doctors, dentists, psychotherapists as well as five hospitals will be connected online using the ‘eGK’ technology. The tests focus on assessing the functionality of mainly three features: the updating of the patients’ master data, the QES (definition below) as well as the safe online connection of dental practices. The test procedure is divided into three phases: the development, the installation and the service of an actionable version of the ‘eGK’ technology. The tests are set to start in 2014 and will immediately be followed by the countrywide rollout.

An important milestone during this rollout process is the introduction of the so-called qualified electronic signature (Qualifizierte Elektronische Signatur—‘QES’). The QES is the technical precondition for many further medical features the ‘eGK’ shall encompass in the future. Just as the different technological parts within the ‘eGK’ technology, i.e. the card reading terminal and Connector, are certified to allow for the specific and safe electronic transmission of data among them, each doctor will be issued a qualified electronic signature. This will allow them to authorize themselves and safely communicate with one another. As such, this technical function constitutes the basis for introducing features such as the electronic doctor letter, as described above.

2.6.3 Resistance to the ‘eGK’ Technology Implementation Process

Finally, at this point it is important to notice that throughout the implementation process, German doctors have repeatedly voiced their concerns in reaction to

further advancements to roll out the 'eGK' technology, for example at the Congresses for Physicians (Ärztetag) in 2007, 2008, 2009, 2010, 2012 and 2013. Among other reasons, concerns were voiced that the 'eGK' technology would not be able to provide a modern, safe and user-friendly platform for the exchange of medical data.

2.7 Summary of the Contextual Background

Overall, the lengthy, costly as well as technically and logistically complicated implementation process of the 'eGK' technology, which has required the attention of many key stakeholders in the German healthcare sector since 2003, demonstrates the complexity of this national eHealth project. It also highlights, from a practical standpoint, some of the key characteristics or issues of such an implementation program:

- Involvement of many stakeholders—Given that healthcare is a sector that is both of great national interest as well as highly structured and regulated, it is not surprising that a lot of stakeholders are directly involved in the implementation of a national eHealth program such as the 'eGK' project. This alone is sufficient to cause delays, as coordination amongst them can be time-consuming.
- Different goals of these stakeholders—In addition to the previous point, individual parties will aim to maximize their personal utility from any project. This is particularly the case when there are numerous parties engaged in a project with potentially very high costs, both monetary as well as in terms of time and labor. Often this can also be at the expense of the utility of other parties and can further be nurtured by discrepancies surrounding the power of the stakeholders. For example, in the case of the 'eGK' implementation, the payors bear the financial costs of the project, while the providers bear the cost of having to adapt to the new system at a potential loss of their acquired working practices. Hence, their goals during the technology implementation process might differ considerably.
- Technological and logistical complexity—Generally, implementing new technology can be very complex. For example new technological standards have to be developed, subsequently local hard- and software has to be adapted and users have to be trained. In the case of a mega project, such as the implementation of the 'eGK' technology, which is to connect thousands of healthcare providers across the country with standardized eHealth technology, the complexity takes on even greater proportions.
- Data privacy and data security concerns—As medical data is some of the most sensitive out there, general concerns for data privacy and data security are naturally very high amongst patients and doctors alike. An eHealth technology required to handle such data has to be of the highest security standards. In the case of the 'eGK' technology this is clearly reflected by the involvement of

several government bodies cooperating with the ‘gematik’ and the medical technology industry to develop customized technology according to tailored functional and technical requirements.

With the practical background of the case established, this thesis goes on to review the relevant academic literature on national eHealth programs to get an overview on how other academics have approached the introduction of eHealth technologies from a theoretical standpoint.

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Klöcker, P.

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