

## Country Brief: Germany

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## About the *eHealth Strategies* study

The eHealth Strategies study analyses policy development and planning, implementation measures as well as progress achieved with respect to national and regional eHealth solutions in EU and EEA Member States, with emphasis on barriers and enablers beyond technology. The focus is on infrastructure elements and selected solutions emphasised in the European eHealth Action Plan of 2004.

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## Executive summary

Efforts at introducing an Electronic Health Record and other eHealth services have a long history in Germany. The official German eHealth policy as well as implementation measures were already included in the Law for the Modernisation of Statutory Health Insurance of November 2003. This law contained amendments to the 5th Book of the Social Law on Statutory Health Insurance and provided for the introduction of electronic health cards for patients (“Elektronische Gesundheitskarte”) as the core element of the strategy, electronic health professionals cards (“Elektronischer Heilsberufsausweis”), core and voluntary applications to be supported by these cards, the establishment of a health telematic infrastructure, the establishment of institutions deemed necessary for its successful implementation as well as rules for financing these activities. Various factors related to the federal structure of Germany have so far made progress difficult.

Following a change of federal government in autumn of 2009, a reappraisal of the entire eHealth infrastructure and eCard project in Germany was undertaken, focusing particularly on security and confidentiality issues. A key outcome of this was a restructuring of the implementation process by assigning responsibility for certain implementation topics to specific stakeholder associations. Mandatory applications for the German eCard are now the online verification of the insurance status of patients and the online update of insurance data, including the data set of the European Health Insurance Card (EHIC). Technically feasible further services which are however not mandatory include an emergency care data-set for the patient. Future services should include doctor-doctor communication (electronic discharge information). With regard to ePrescription services, discussions on deployment have been put on hold according to the ministry of health, until proven solutions responding to highest data-protection requirements are found.

A recent effort on the level of telemedicine services focussed on stakeholder mobilisation. In mid 2010, the Federal Ministry of Health therefore launched the “eHealth-Initiative”, uniting key players of the German healthcare system (doctors, insurers together with the Fraunhofer Gesellschaft and key industry players) around the goal of identifying existing barriers to telemedicine deployment. A set of measures to address these barriers were agreed upon in late 2010. Their implementation will be addressed in the course of 2011.

In sum, eHealth is now gaining new momentum in Germany, albeit on a less ambitious scale than previously planned. The restructuring of the governance mechanisms to give an active role to the key stakeholders, is now forcing the corporatist system to act jointly or risk further delays.

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# 1 Introduction to the report

## 1.1 Motivation of the eHealth Strategies study

Following the *Communication* of the European Commission (EC) on “eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area”<sup>1</sup> Member States of the European Union (EU) have committed themselves to develop and issue national roadmaps – national strategies and plans for the deployment of eHealth applications addressing policy actions identified in the European eHealth Action Plan.

The *2004 eHealth Action Plan* required the Commission to *regularly monitor* the state of the art in deployment of eHealth, the progress made in agreeing on and updating national eHealth Roadmaps, and to facilitate the exchange of good practices. Furthermore, in December 2006 the EU Competitiveness Council agreed to launch the *Lead Market Initiative*<sup>2</sup> as a new policy approach aiming at the creation of markets with high economic and social value, in which European companies could develop a globally leading role. Following this impetus, the Roadmap for implementation of the “eHealth Task Force Lead Market Initiative” also identified better coordination and exchange of good practices in eHealth as a way to reduce market fragmentation and lack of interoperability.<sup>3</sup>

On the more specific aspects of electronic health record (EHR) systems, the recent *EC Recommendation on cross-border interoperability of electronic health record systems*<sup>4</sup> notes under “Monitoring and Evaluation”, that “in order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should: consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems.” The present study certainly is a contribution to monitoring the progress made in establishing national/regional EHR systems in Member States. It also provides analytical information and support to current efforts by the European Large Scale Pilot (LSP) on cross-border Patient Summary and ePrescription services, the epSOS - European patients Smart Open Services - project.<sup>5</sup> With the involvement of almost all Member States, its goal is to define and implement a European wide standard for such applications at the interface between national health systems.

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<sup>1</sup> European Commission (2004), e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area

<sup>2</sup> European Commission Communication. “Lead Market Initiative for Europe”. COM(2007) 860 final, 21.12.2007.

<sup>3</sup> “Accelerating the Development of the eHealth market in Europe”, eHealth task force report, European Communities, 2007.  
[http://ec.europa.eu/information\\_society/activities/health/policy/lmi\\_ehealth/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm)

<sup>4</sup> European Commission (2008), Commission Recommendation on cross-border interoperability of electronic health record systems

<sup>5</sup> Smart Open Services for European Patients epSOS, [www.epsos.eu](http://www.epsos.eu)

Earlier, in line with the requirement to “regularly monitor the state of the art in deployment of eHealth”, the EC already funded a first project to map national eHealth strategies – the eHealth ERA "Towards the establishment of a European eHealth Research Area" (FP6 Coordination Action)<sup>6</sup> - and a project on "Good eHealth: Study on the exchange of good practices in eHealth"<sup>7</sup> mapping good practices in Europe - both of which provided valuable input to the present *eHealth Strategies* work and its reports. Member States' representatives and eHealth stakeholders, e.g. in the context of the *i2010 Subgroup on eHealth*<sup>8</sup> and the annual European High Level eHealth Conferences<sup>9</sup> have underlined the importance of this work and the need to maintain it updated to continue to benefit from it.

This country report on Germany summarises main findings and an assessment of progress made towards realising key objectives of the eHealth Action Plan. It presents lessons learned from the national eHealth programme, planning and implementation efforts and provides an outlook on future developments.

## 1.2 Survey methodology

After developing an overall conceptual approach and establishing a comprehensive analytical framework, national level information was collected through a long-standing Europe-wide network of national correspondents commanding an impressive experience in such work. In addition, a handbook containing definitions of key concepts was distributed among the correspondents to guarantee a certain consistency in reporting. For Germany, relevant information on policy contexts and health system situation, policies and initiatives as well as examples for specific applications was collected by the overall project lead - empirica in Bonn, Germany.

The key tool to collect this information from the correspondents was an online survey template containing six main sections:

- A. National eHealth Strategy
- B. eHealth Implementations
- C. Legal and Regulatory Facilitators
- D. Administrative and Process Support
- E. Financing and Reimbursement Issues
- F. Evaluation

Under each section, specific questions were formulated and combined with free text fields and drop-down menus. The drop-down menus were designed to capture dates and stages of development (planning/implementation/routine operation). In addition, drop-

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<sup>6</sup> [www.ehealth-era.org](http://www.ehealth-era.org) (2007). For country reports, references and national documents see <http://www.ehealth-era.org/database/database.html>

<sup>7</sup> [www.good-ehealth.org](http://www.good-ehealth.org)

<sup>8</sup> The i2010 subgroup on eHealth was recently followed by the eHealth Governance Initiative: [http://ec.europa.eu/information\\_society/activities/health/policy/ehealth\\_governance\\_initiative/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/ehealth_governance_initiative/index_en.htm)

<sup>9</sup> See an overview of the conferences at [http://ec.europa.eu/information\\_society/activities/health/policy/ehealth\\_conf/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/ehealth_conf/index_en.htm)

down menus were designed to limit the number of possible answering options, for example with regard to specific telemedicine services or issues included in a strategy document. The overall purpose was to assure as much consistency as reasonably possible when comparing developments in different countries, in spite of the well-known disparity of European national and regional health system structures and services.

Under Section B on eHealth implementation, questions regarding the following applications were formulated: existence and deployment of patient and healthcare provider identifiers, eCards, patient summary, ePrescription, standards as well as telemonitoring and telecare.

The data and information gathering followed a multi-stage approach. In order to create a *baseline* for the progress assessment, the empirica team filled in those parts of the respective questions dealing with the state of affairs about 3 to 4 years ago, thereby drawing on data from earlier eHealth ERA reports, case studies, etc. to the extent meaningfully possible. In the next step, national correspondents respectively partners from the study team filled in the template on recent developments in the healthcare sector of the corresponding country. These results were checked, further improved and validated by independent experts whenever possible.

Progress of eHealth in Germany is described in chapter 3 of this report in the respective thematic subsections. The graphical illustrations presented there deliberately focus on key items on the progress timeline and cannot reflect all activities undertaken.

This report was subjected to both an internal and an external quality review process. Nevertheless, the document may not fully reflect the real situation and the analysis may not be exhaustive due to focusing on European policy priorities as well as due to limited study resources, and the consequent need for preferentially describing certain activities over others. Also, the views of those who helped to collect, interpret and validate contents may have had an impact.

## 1.3 Outline

At the outset and as an introduction, the report provides in chapter 2 general background information on the *German* healthcare system. It is concerned with the overall system setting, such as decision making bodies, healthcare service providers and health indicator data.

Chapter 3 presents the current situation of selected key eHealth developments based on detailed analyses of available documents and other information by national correspondents and data gathered by them through a well-structured online questionnaire. It touches on issues and challenges around eHealth policy activities, administrative and organisational structure, the deployment of selected eHealth applications, technical aspects of their implementation, legal and regulatory facilitators, financing and reimbursement issues, and finally evaluation results, plans, and activities

The report finishes with a short outlook.

## 2 Healthcare system setting

This chapter summarises key performance data and the most important political reforms of the last five to ten years that have shaped the organisation of healthcare processes and the financing of the healthcare system. It highlights governance arrangements and political priorities with regard to the restructuring of healthcare processes.

### 2.1 Country introduction<sup>10</sup>

The box below summarises the key facts about the German healthcare system:

<b>Key facts about the German healthcare system:<sup>11</sup></b>		
Population:	81.8 million	(GBE <sup>12</sup> 2009)
Life expectancy at birth:	80 years	(OECD 2006)
Healthcare expenditure as % of GDP:	10.4 %	(WHO 2008)
Public sector healthcare expenditure as % of total healthcare expenditure:	76.8 %	(WHO 2008)

### 2.2 Healthcare governance

The following subchapter briefly sketches the governance arrangements in the German healthcare system, which is characterised by a high degree of autonomy of the individual actors (insurers, hospitals, physicians).

#### 2.2.1 Decision making bodies, responsibilities, sharing of power

Germany is a federal state with three major levels of government: The Federation (Bund), 16 States (Länder), and several hundreds of local governments (municipalities and counties). A fundamental characteristic of the German political system in general and the health care system in particular is the sharing of decision-making powers between the Länder and the federal government. Legislation takes place at the federal and the Länder level; implementation of legislation is mostly through the various bodies of health system self-administration (cooperation of social health insurance associations, statutory medical and dentists associations, pharmacy association, patient representatives) and, with respect to hospitals, at Länder level.

<sup>10</sup> Data from Evidence-based support for the design and delivery of user-centred online public services eUser, [www.euser-eu.org](http://www.euser-eu.org)

<sup>11</sup> World Health Organization (2000), The World Health Organization's ranking of the world's health systems, Health Consumer Powerhouse (2008), Eurohealth Consumer Index, Data from World Health Organization (2009), European health for all database (HFA-DB)

<sup>12</sup> GBE Gesundheitsberichterstattung des Bundes (Federal health reporting)

## 2.2.2 Main healthcare service delivery systems in Germany

*Social insurance:* For more than 120 years (in fact since 1883), the health system in Germany has been based on social health insurance, “social” meaning that it is organised by the state and supposed to cover, on a mandatory basis up to a certain level of income, the whole of the population.<sup>13</sup> Health related law is codified in the 5<sup>th</sup> book of the Social Law Book (Sozialgesetzbuch, 5. Buch). The system is financed by three co-existing schemes: statutory health insurance based on salary or wage-based income with contributions equally by employers and employees and free coverage of dependants (spouse and children), private health insurance, and governmental schemes. In 2009 circa 52 million Germans were members of the statutory health insurance, 4 million of which on a voluntary basis.<sup>1</sup> There is no single insurance fund but presently still around 155 public sickness funds<sup>14</sup> that collect the contributions to the statutory insurances for health and long-term care. They negotiate contracts with health care providers and the Statutory Physician Associations (Kassenärztliche Vereinigungen – KV) at the regional level.<sup>15</sup> In addition, about 50 private health insurance companies operate in the market.

*Corporatism:* The German health care system is highly decentralised, with the most striking component being the delegation of executive rights to non-governmental corporatist bodies. They are the main actors in the social health system: the hospitals’ (through the “Deutsche Krankenhausgesellschaft), physicians’ and dentists’ associations on the providers’ side and the sickness funds and their associations on the purchasers’ side. The Federal Ministry of Health proposes the health acts that – when passed by parliament – define the legislative framework of the social health system. It also supervises the corporatist bodies and – with the assistance of a number of subordinate authorities – fulfils licensing and supervisory functions, performs scientific consultancy work and provides information services.<sup>16</sup>

*Ambulatory healthcare:* Ambulatory healthcare is mainly delivered by general practitioners and specialists in private practice. Patients have a time- and location-wise unrestricted choice of physicians, dentists, pharmacies and emergency care, also at hospitals’ outpatient departments.

*Hospital care:* Acute and planned inpatient care is delivered by a mix of public, private and independent non-profit hospitals. Hospitals are financed on a dual basis: investment plans are centrally coordinated by the respective government of the 16 Länder and subsequently co-financed by the Länder and the federal government, while sickness funds finance recurrent expenditures and maintenance costs. Since January 2004, the German adaptation of the Australian system of Diagnosis-Related Groups (DRG) has been introduced as the main system of paying for recurring hospital expenditures, except

<sup>13</sup> Except for those with a high income or business owners and freelancers who opt for private insurance coverage..

<sup>14</sup> As of 1 December 2010 according to the GKV Spitzenverband, the head organisation of the statutory health insurance funds (see: [https://www.gkv-spitzenverband.de/upload/Krankenkassen\\_Fusionenverlauf\\_1970-2010\\_11155.pdf](https://www.gkv-spitzenverband.de/upload/Krankenkassen_Fusionenverlauf_1970-2010_11155.pdf)).

<sup>15</sup> See Grosse-Tebbe (2004) Healthcare Systems in Transition, Germany, WHO Europe report, p. 26.

<sup>16</sup> See Grosse-Tebbe (2004), p. 25.

for certain cases and for psychiatric care.<sup>17</sup> In 2009, it became mandatory for all hospitals.

*Funding:* In 2008, health expenditure in Germany comprised 10.4% of Gross Domestic Product (GDP), ranking fifth among countries in the Organisation for Economic Co-operation and Development (OECD).<sup>18</sup> High expenditures are accompanied by high quality: In international comparison, the population enjoys equal and easy access to a health care system offering very comprehensive benefits at all levels of care.<sup>19</sup>

The below table illustrates in a summary fashion the most important characteristics of primary care in Germany.

**Table 1: Characteristics of primary care in Germany**

<b>Political/administrative unit responsible for primary healthcare</b>	Primary care (as all other key features) is subject to the corporatist “self-administration” between payers and service providers
<b>Consumer Choice</b>	Patients have the free choice of healthcare providers, while access to specialists is conditioned upon referral through the GP or a copayment of 10€ per quarter.
<b>Financing</b>	The healthcare system is mainly financed through health insurance contributions by citizens, co-payments and direct State-funding through taxes.
<b>Public or private providers</b>	GPs and specialists are usually practising privately. The hospital landscape shows a mix of privately run and publicly run institutions, including charitable ownership (by the churches for example).
<b>Gate keeping function of the GP</b>	Through the mandatory €10 fee that patients pay every quarter for a visit to the GP, there is a weak “gate-keeping” function because additional visits to specialists (if not indicated by the GP) are also subject to the €10 copayment.
<b>Integrating health: initiatives for coordination</b>	Integrated care is now a priority topic for the health insurers and has been made possible through changes in legislation

## 2.3 Recent reforms and priorities of health system/public health

### 2.3.1 ***Main issues and strategic targets of national healthcare policy and implementation in Germany***

*Financing issue:* The main health policy issue in Germany concerns the sustained financing of the system, particularly how to stabilise its financial situation without further increasing the cost of labour (insurance payments are a percentage levy on employee

<sup>17</sup> See Grosse-Tebbe (2004), p. 26. Op. cit.

<sup>18</sup> see WHO health for all database on the GDP figure and OECD 2010, Frequently requested healthdata. Germany is outranked by the United States, France, Belgium and Switzerland.

<sup>19</sup> Cf. Patient powerhouse report (2009) ranked Germany’s healthcare system sixth in Europe; see <http://www.healthpowerhouse.com/files/Germany.pdf>:

salaries borne partly – around 45% - by the employer). Cost constraints arise for various reasons. As the German Minister of Health put it in a speech in early 2006: “Developments in medicine, pharmacology and medical technology along with demographic and economic changes will put further pressure for rationalisation measures on our health care system.”<sup>20</sup> As regards the ageing population, the Old Age Dependency Ratio, which is the population above 64 divided by the population aged 15-64, is predicted to double from 0.23 in 2000 to 0.47 in 2050 in Germany.

*Funding schemes:* Presently the German health system is mainly financed by a levy of around 15.5 % on all employment income – up to a monthly income of around € 4,000 – and shared among employer and employee. Various options are under discussion how to deal with the finance challenge, such as a fixed *per capita* charge paid by all who are presently insured, with children and persons on welfare covered from general tax sources, or a levy based on *all* types of income by *all* citizens independent of their employment status. As an initial step, in 2009 a central health fund (Gesundheitsfond) was established which collects all statutory health insurance payments; it distributes its income to the various public health insurance companies according to the morbidity structure of their insured. Additional funding is obtained from private insurances for those not partaking in the public schemes, private co-insurances for selective health services like special treatment in hospitals, and from co-payments for medications or hospital stays. In addition, a slowly increasing share of healthcare expenditures is by now covered from the budget of the federal government for children, persons on welfare and the unemployed. The above mentioned “Gesundheitsfond” receives a direct tax-financed subsidy from the federal government on an annual basis. These payments will increase from €2.5 billion in 2007 and 2008 by 1.5 billion each year until the federal subsidy has reached €14 billion.<sup>21</sup>

*Efficiency improvements:* To further improve quality and at the same time efficiency of service provision, a reimbursement system mainly based on Diagnostic Related Groups (DRGs) is now mandatory in the hospital sector. Quality improvement schemes, such as minimum annual numbers for specified (surgical) interventions per hospital, publishing of data on hospital activities, outcomes and the like are underway. A new federal institute for quality and economic efficiency of health service provision was established in 2004. Presently, its main obligation is to undertake scientific reviews and assessments on the (incremental) benefits of (innovative) drugs in order to determine whether the public system should reimburse them. Health technology assessment (HTA) is another line of activities. In 2010, it was furthermore charged with an initial, short term benefits assessment of new, innovative drugs as a precondition for public reimbursement.

### ***Major currently running national programmes for public health and healthcare system development***

The main strategy for healthcare system development was set down in the 2004 Law for the Modernisation of Statutory Health Insurance (Gesetz zur Modernisierung der Gesetzlichen Krankenversicherung - GKV-Modernisierungsgesetz - GMG) which was

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<sup>20</sup> German Health Minister Ulla Schmidt on “Health Policy and Health Economics in Germany”, 27 January 2006.

<sup>21</sup> See „Stichworte zum Gesundheitsfonds“ by the DAK (German health insurer) available at <http://www.presse.dak.de/ps.nsf/sblArchiv/D0220CCD4BAA56CFC12574FD0051C0C4?Open>

initiated by the Federal Ministry of Health. This Law revised and "modernised" the 5th Book of the "Social Code Book"; dealing with Statutory Health Insurance topics. Main objectives set forward are the following:

- improve efficiency and quality of care for chronically ill patients ("Volkskrankheiten" - diseases affecting large parts of the population),
- restructure the statutory health insurance sector,
- reorganise the financing of the health system

in order to improve the quality of care and at the same time, reduce the insurance premium as well as strengthen patient sovereignty. A particular emphasis was put on reorganising healthcare processes. The law made important steps towards truly integrated care by introducing an optional GP gatekeeper contract model that health insurers can offer to their patients. In addition, the 2004 reform allowed insurances contracting with management organizations which set up integrated care networks. Contracting parties can be institutions or individuals fitting the legal definition of care providers.<sup>22</sup>

More recently, in 2007 the above efforts on promoting integrated care were reinforced by allowing for the inclusion of long term care services (which are subject to a separate insurance regime) in the integrated care contracts. Also, the scope of eligible care providers was widened to include non-medical professions such as occupational and physical therapists. These developments were accompanied by changes in the professional regulations on doctors (Vertragsarztrecht) to allow physicians to contract with polyclinics.<sup>23</sup> These developments towards more integrated care schemes were not welcomed by all providers, but seem to be increasingly accepted by doctors.<sup>24</sup>

The GMG also codified the modernisation of the health system through electronic applications, to be detailed below.

## 2.4 ICT use in the German healthcare system: GPs and hospitals

### Overview

Most physicians in private practice already have some kind of patient administration system. However, quite a few of these systems focus on optimising reimbursement requests and not on clinical documentation, and are outdated by contemporary standards. The requirements that derive from the new eHealth infrastructure will force management to replace many, if not all of these legacy systems with new software installations. Those doctors already running very up-to-date patient administration and clinical record systems will have to upgrade their software to the requirements that result from the specifications for the connector and the mandatory and voluntary applications outlined below.

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<sup>22</sup> Information drawn from Hesse, S. (2005) "Integration of care after 2004 reform act", Health Policy Monitor 6/2005, Bertelsmann Foundation: Gütersloh.

<sup>23</sup> Information drawn from Blum, K. (2007) "Care coordination gaining momentum in Germany", Health Policy Monitor 9/2007, Bertelsmann Foundation: Gütersloh.

<sup>24</sup> See Ärzte Zeitung, 24.02.2011, "Gesetz öffnet Türen für neue Geschäftsmodelle"

*Mutatis mutandis*, the situation is similar in most hospitals, albeit at a much more complex level. The introduction of the Disease-Related Group system as a basis for reimbursement in the hospital sector has forced many hospitals to invest anew, to upgrade or to revive the dormant implementation of comprehensive hospital information systems including complex cost accounting and controlling software. The introduction of the electronic patient and health professional cards will reinforce these trends.

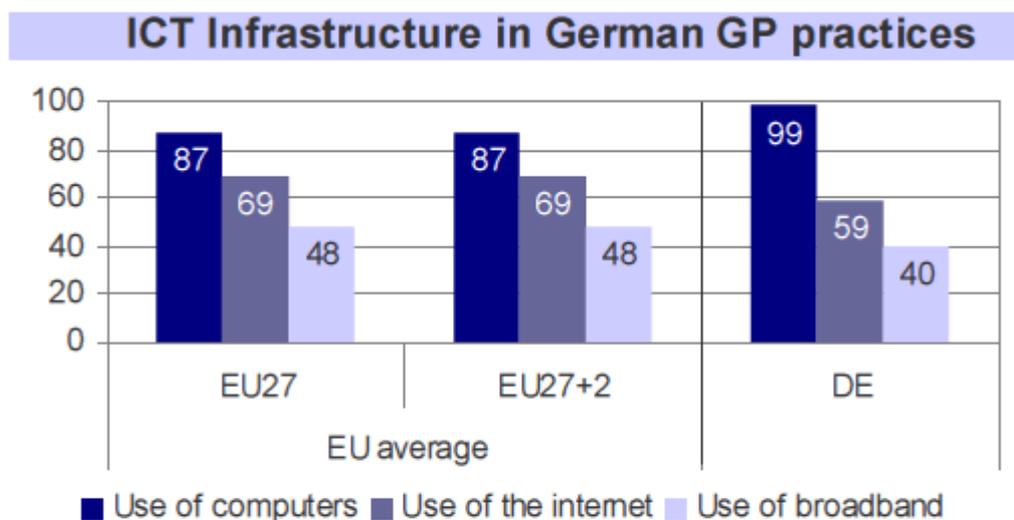
### Use of ICT systems by General practitioners

This section provides a brief overview of important ICT related infrastructure and services data. It draws on a European wide survey of GPs in 2007.

Germany is among the average eHealth performers in the EU27. This concerns both the availability of ICT infrastructure components and the use of ICT for different eHealth related purposes.

In terms of basic IT equipment, 99% of German GP practices use a computer. This puts Germany on a par with 13 other EU countries where a computer availability rate of nearly 100% has been reached. However, in 2007 only 59% of the German GP practices were connected to the Internet. This result is considerably below the EU average of 69%. Broadband connections can be found in only 40% of the GP practices, as compared to about 50% on average in the EU27. This is illustrated in Figure 1 below.

**Figure 1: ICT Infrastructure in German GP practices**



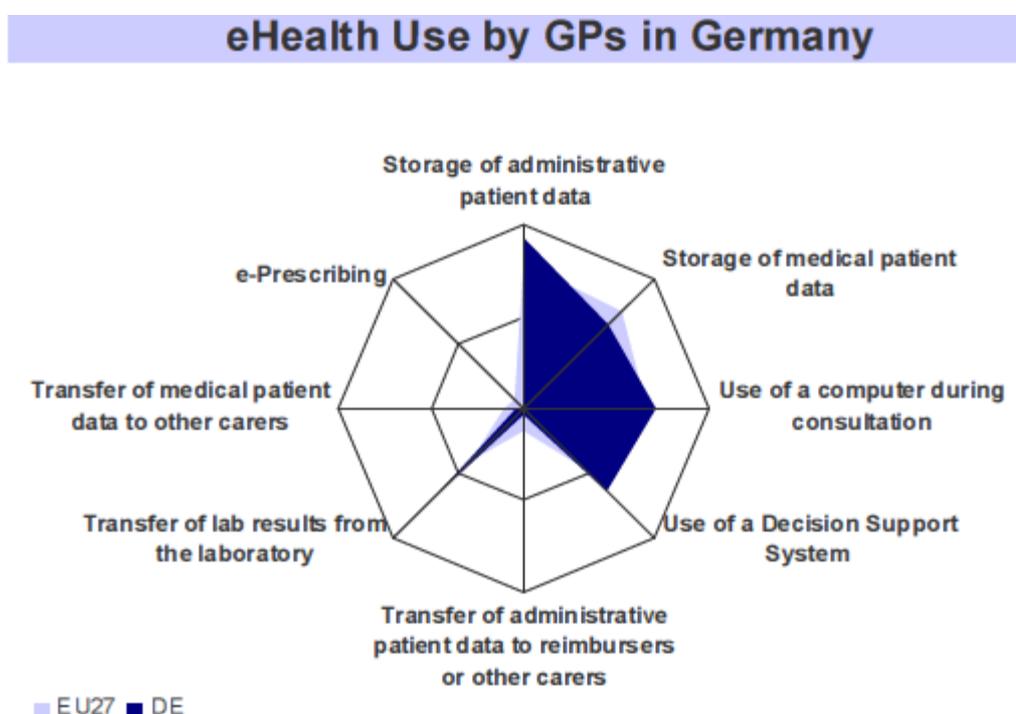
**Base: All GPs. Indicators: R4, C1, C2 (cf. annex for more information), % values. Source: empirica, Pilot on eHealth Indicators, 2007.**

In terms of applications used (see Figure 2 below), the storage of electronic medical patient data is quite common in Germany. At least one type of such data is stored by 96% of GP practices. A computer is available in the consultation room in 85% of German GP practices. It is actually used for consultation purposes with the patients (e.g. to display a patient's file to the practitioner, to explain medical issues to the patient by means of a photo or animation or to run a Decision Support System) by 72% of the German GP

practices. 77% of the German GP practices use a Decision Support System either for diagnosis or prescribing (50% on average in the EU27).

In Germany the transfer of electronic patient data via networks or the Internet is not very common. Only 3% of German GPs exchange administrative data with other care providers. With only 4% of the GP practices exchanging administrative data with reimbursers, Germany also scores below the EU average of 15%. 4% of the GP practices in Germany exchange medical data with other health care providers compared to an average rate of 10%. On the other hand, already 63% of the GP practices receive results from laboratories, a result that exceeds the EU27 average of 40%. In Germany, not even 1% of the GP practices reported making use of ePrescribing. However, apart from the three frontrunners Denmark, Sweden and the Netherlands, adoption levels of ePrescribing are never higher than 5%.

**Figure 2<sup>25</sup>: eHealth use by GPs in Germany**



**Indicators:** Compound indicators of eHealth use (cf. annex for more information), % values. **Source:** empirica, Pilot on eHealth Indicators, 2007.

#### Recent survey results by the Allensbach Institute

In a representative survey of both GPs and hospital physicians a surprisingly positive assessment of the benefits from health telematics and telehealth by these groups was

<sup>25</sup> The notion of „compound indicator“ designates an indicator build from a set of other indicators/survey questions regarding the same topic. The compound indicator reflects an average calculated from different values. (see Annex) The final results of the study on eHealth Indicators is available at [www.ehealth-indicators.eu](http://www.ehealth-indicators.eu).

recorded.<sup>26</sup> The recording of an emergency data-set of patients, an electronic drug interaction check and the electronic transmission of discharge/transfer summaries are welcomed by over two thirds of doctors. However, support for the emergency data-set is highest with hospital doctors (ca. 90%) whereas only 50% of GPs support it. The introduction of an electronic drug prescription service meets with scepticism.

In terms of infrastructure and existing IT connections in the healthcare system, 44% of GPs and 45% of hospital departments are already connected to other actors in the system. With GPs, the electronic connection to the association of statutory doctors (Kassenärztliche Vereinigung) is predominant. Only 15% are connected to other GP practices. While 32% of hospitals are connected with other hospitals, the communication between hospital and primary care doctors is still underdeveloped (only 10% of hospital doctors and GPs make use of it).

In terms of current eHealth projects under development by the eHealth infrastructure organisation *gematik*, the survey results show the highest level of support for the emergency care data-set.

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<sup>26</sup> Institut für Demoskopie Allensbach. (2010) Der Einsatz von Telematik und Telemedizin im Gesundheitswesen aus Sicht der Ärzteschaft - Die wichtigsten Ergebnisse im Überblick

## 3 eHealth Strategies survey results

The following section briefly reviews the eHealth policy development process in Germany, strategy elements and status quo of implementation. This is followed by a description of administrative and organisational measures taken. Section 3.3 summarises results on key eHealth applications. Section 3.4 focuses on the technical and infrastructural side of eHealth, namely the role of patient and healthcare provider identifiers, the role of eCards and standards. Legal and regulatory facilitators as well as financing and reimbursement issues are presented in the following sections 3.5 and 3.6. The chapter concludes with reporting on evaluation activities.

### 3.1 eHealth policy development process

The official eHealth strategies of EU and EEA countries are not always labelled as such. Some countries indeed publish a specific policy document which refers to the ICT strategy in the healthcare sector only; others may include it into a comprehensive eGovernment or Information Society Programme document. Germany has enshrined central eHealth priorities, infrastructure elements and specific applications in legislation governing the healthcare sector in general.

#### 3.1.1 Towards a national eHealth infrastructure

**Actors:** The core actor in defining and setting the framework conditions of the national eHealth policy is the Federal Parliament, and on the administrative side the Ministry of Health (Bundesgesundheitsministerium). At the Länder level, there are Ministries of Health in every Land, often combined with responsibilities for social affairs or other policy fields.

Execution rests with the so-called self-administration bodies of the public health system medical doctors, dentists, insurances, hospitals, pharmacies and others. In the event that they cannot agree on details how to implement certain legal requirements and rules, the Federal Ministry of Health may set a final date for agreement, and afterwards specify itself the execution details ("Ersatzvornahme").

**History:** The present German situation is characterised by a quite long history of planning, preparation for and undertaking implementation work towards realising a comprehensive national eHealth roadmap. The steps towards the present state of affairs can be briefly summarised as follows:

Initial consensual development of key concepts and planning was accomplished by a so-called "Working group on Telematics Applications in the Health Sector" as part of the German national initiative "Forum Info 2000", 1996 to 1998.<sup>27</sup> Its results were further detailed and specified by the "Action Forum Telematics in the Health Sector" (Aktionsforum Telematik im Gesundheitswesen, ATG)<sup>28</sup> 1999 to 2004; which became in

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<sup>27</sup> The results of this working group were published in a report on "Telematics Applications in the Health Sector: Priority Utilisation Fields, Potential for Improvement and Recommendations for Actions"; Nomos Publishing Company, May 1998.

<sup>28</sup> See <http://ehealth.gvg-koeln.de/>.

2005 the GVG-Committee "Health Telematics" (GVG-Ausschuss „Telematik im Gesundheitswesen").

The Action Programme of the Federal Government "Innovation and New Jobs in the Information Society of the 21st Century" (Aktionsprogramm der Bundesregierung für "Innovation und Arbeitsplätze in der Informationsgesellschaft des 21. Jahrhunderts") of 1999 had already described, among many other fields of activities, various measures planned to promote and implement eHealth applications.<sup>29</sup>

This programme was updated and extended in the Action Programme of the Federal Government "Information Society Germany 2006" of 2003 (Aktionsprogramm der Bundesregierung "Informationsgesellschaft Deutschland 2006")<sup>30</sup> which detailed for the first time in considerable depth eHealth strategic aspects, stakeholders to become involved, measures to be implemented and projects to be initiated. Towards the end of 2003, all of this was codified in the Modernising Health Insurance law.

### 3.1.2 eHealth strategy and roadmap - legal base, target applications, development process

#### Legal base

The official German eHealth policy as well as implementation measures are included in the Law for the Modernisation of Statutory Health Insurance of November 2003. This law contains amendments to the 5<sup>th</sup> Book of the Social Law on Statutory Health Insurance and provides for the introduction of electronic health cards for patients ("Elektronische Gesundheitskarte") as the core element of the strategy, electronic health professionals cards ("Elektronischer Heilsberufsausweis"), core and voluntary applications to be supported by these cards, the establishment of a health telematic infrastructure, the establishment of institutions deemed necessary for its successful implementation as well as rules for financing these activities. Together with later amendments and clarifications, it provides for the following elements:<sup>31</sup>

#### Strategy components

**Goal:** The health policy goal is stated in a rather generic form as "improvement of efficiency, quality and transparency of treatment" ("Zur Verbesserung von Wirtschaftlichkeit, Qualität und Transparenz der Behandlung" - § 291a (1))

**Patient identifier:** All insurance funds have to maintain a register of their insurees. Details on patient identifiers can be found in section 3.4.1 unterhalb

**Electronic health card for patients:** The introduction of an electronic patient card is foreseen with details about its mandatory *insurance* application as well as requiring capabilities for further (voluntary) eHealth services, also specifying patient and other rights and obligations (§ 291a).

<sup>29</sup> The trigger was a Federal Government Information Society policy statement of 10 November 1998.

<sup>30</sup> See [http://www.bmbf.de/pub/informationsgesellschaft\\_deutschland.pdf](http://www.bmbf.de/pub/informationsgesellschaft_deutschland.pdf).

<sup>31</sup> See particularly section "Information basis for health insurances" ("Informationsgrundlagen der Krankenkassen"), §§ 288 – 293, available at [http://dejure.org/gesetze/SGB\\_V](http://dejure.org/gesetze/SGB_V)

*Mandatory applications* concern the eventual online update of insurance status, recording of mandatory co-payment status, and the data set of the European Health Insurance Card (EHIC).

*Voluntary applications* describe a number of features the Electronic Health Card also “must be able to support” if a citizen gives informed consent to this.

**Electronic health professional card:** It is regulated that access to electronic patient data stored on the patient card or elsewhere in the public infrastructure is, except for patients themselves, only permitted via an electronic health professional card equipped with qualified electronic signature and secure authentication functionalities (§ 291a (5)).

**Telematic infrastructure:** The implementation of the necessary information, communications services and security infrastructure is stipulated (§ 291a 5a)).

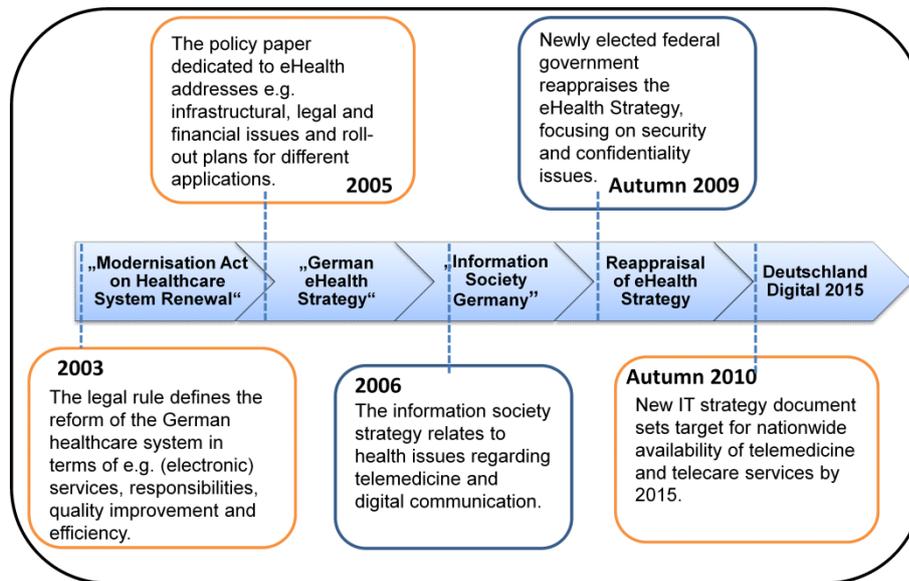
**Competence Centre:** The law also initiated the establishment of a Society for [Health] Telematics (gematik - "Gesellschaft für Telematik") to plan, implement and manage the necessary eHealth infrastructure services (§ 291b).

**Time line:** In spite of its full functionality expected by now only for 2013, the law still explicitly states that at the latest by January 01, 2006, the electronic patient card must be available (§ 291a (1)).

#### **eHealth strategy paper**

In addition to the legal details outlined, in July 2005 the Federal Ministry of Health and Social Security summarised its overall position concerning strategic eHealth developments in a paper entitled “The German eHealth Strategy”. It formulated the policy intentions and perspectives of the above mentioned legal provisions implicit in Germany’s eHealth strategy in a non-judicial way and describes the target of the strategy as follows: “The healthcare system in Germany is a system with a pressing demand for intensive communication between the different actors with the aim of achieving better collaboration and thus numerous positive results for the health of the citizens, the healthcare system and the State’s economic situation.” The overall goal of the German eHealth strategy is the modernisation of the healthcare system using information and communications technology, with the following objectives: establish more citizen-oriented services, support patient-centred care, improve quality and services, reduce costs, and provide better data for health system management.

*Two pillars of modernisation:* The strategy for achieving the modernisation targets built on two pillars. The *first* pillar was to establish an ICT infrastructure financed by one or a few applications, so that other applications can build on this infrastructure without having to carry those basic costs. Besides the online verification of insurance status (mandatory for all citizens insured in the public system – important for reimbursement, e.g., when a patient takes part in a disease management programme, or for co-payments), the transmission of (drug) prescriptions – initially a mandatory, by now only a future voluntary application - was considered a priority with a positive benefit/cost ratio. The *second* pillar was to provide for a voluntary private electronic patient record and other applications, step by step, using the established infrastructure.

**Figure 3: German policy documents related to eHealth**

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**Progress review and “Germany Digital 2015”**

Following a change of federal government in autumn of 2009, a reappraisal of the entire eHealth infrastructure and eCard project in Germany was undertaken, focusing particularly on security and confidentiality issues.<sup>32</sup> A key outcome of this was a restructuring of the implementation process by assigning responsibility for certain implementation topics to specific stakeholder associations. In addition, the online verification of the insurance status of patients and the online update of insurance data is now enshrined in §219, Abs. 2b of the Social Code Book V.<sup>33</sup>

Furthermore, also in the autumn of 2010, the government issued an updated strategy for the digital future of Germany called "Deutschland Digital 2015" (Germany Digital 2015), foreseeing improved support for small and medium-sized companies and the availability of high-speed broadband connections also in rural areas. It stipulates that, based on the eHealth infrastructure, telehealth, telecare and other ICT-based solutions, particularly also for older people, should become available everywhere by 2015.<sup>34</sup>

<sup>32</sup> See Hoeksma, J. (2010) “Germany suspends e-health Card project” in eHealth Insider, January 18<sup>th</sup> 2010, available at <http://www.ehi.co.uk/news/primary-care/5551>

<sup>33</sup> See “Übersicht Gesundheitskarte” version of October 2010, a summary dossier published by the German Hospital Association (Deutsche Krankenhausgesellschaft)

<sup>34</sup> <http://www.bmwi.de/BMWi/Navigation/Technologie-und-Innovation/Digitale-Welt/IKT-Strategie-Nationaler-IT-Gipfel/deutschland-digital-2015.html>

## 3.2 Administrative and organisational structure

**Shared self-administration:** The 2003 “Law for Modernisation of the German Healthcare System” entrusted the deployment of the eHealth infrastructure to the health system self-administration (Selbstverwaltung) composed of the national associations of the major health system actors as detailed in Table 2 below. They are also shareholders and responsible for funding and oversight of the Society for [Health] Telematics (gematik - "Gesellschaft für Telematik") located in Berlin. Its main tasks are the specification, establishment and operation of an interoperable eHealth infrastructure. gematik has to define the technical framework and the security concept, the content and structure of data records, the test and certification procedures for hard and software products or components, if these are necessary for an interoperable and compatible infrastructure.

The gematik was founded in January 2005 to create an interoperable IT infrastructure for Germany with the key component of an electronic health card.<sup>35</sup> It has the tasks of planning, overseeing calls for tender to implement, and managing the eHealth infrastructure and related services.

**Table 2: National health system self-administration member associations**

GKV-Spitzenverband (Gesetzliche Krankenversicherung) Federal Umbrella Organisation of Statutory Health insurance and Social Care Associations]
DAV – Deutscher Apothekerverband e.V. [National Pharmacy Association]
Bundesärztekammer/ Arbeitsgemeinschaft der deutschen Ärztekammer [Federal Chamber of Physicians]
Bundeszahnärztekammer [Federal Chamber of Dentists]
Deutsche Krankenhausgesellschaft e.V. [German Hospital Federation]
Kassenärztliche Bundesvereinigung [National Association of Statutory Health Insurance Physicians]
Kassenzahnärztliche Bundesvereinigung [National Association of Statutory Health Insurance Dentists]
Verband der privaten Krankenversicherungen [Association of private health insurances]

**Stakeholder involvement:** Within the framework of the so-called IT framework Summit by the Chancellor a working group was introduced, which has the goal of finding cooperative structures for the health sector in form of stakeholder involvement through joint initiatives.

**Administrative Challenges:** With a five-year experience of the gematik structure, it can be said: 1) gematik was usually blamed for what went wrong; 2) shareholding organizations tended to block each other quite often in decision-making processes. By now, it has been recognised that this type of self-management failed to some extent, and

<sup>35</sup>[http://www.gematik.de/cms/de/spezifikation/wirkbetrieb/release\\_0\\_5\\_3/release\\_0\\_5\\_3\\_egk/dokumente\\_egk\\_r053.jsp](http://www.gematik.de/cms/de/spezifikation/wirkbetrieb/release_0_5_3/release_0_5_3_egk/dokumente_egk_r053.jsp)

the Ministry of Health is now taking partly the lead, and responsibilities are given back to specific health system organisations.<sup>36</sup>

**Challenges:** Stakeholder involvement, especially on GP side, has been mostly neglected – this seems to be one of the reasons why many, if not most healthcare professionals are still against certain developments, such as the introduction of eCards for professionals and patients.

#### **New structure of responsibilities in 2010**

To faster advance the eCard project through easier decision taking and to avoid further roadblocks, in 2010 a new structure and responsibilities for the respective applications was introduced. This so-called project leader model („Projektleiter-Modell“) transferred responsibility for the development of individual applications to be facilitated by the eCard to one or two of the self-administration associations. These responsibilities are detailed in Table 3 below:

**Table 3: eCard facilitated applications and association responsible**

<b>Application</b>	<b>Association(s) responsible</b>
Telematics infrastructure base	Federal Umbrella Organisation of Statutory Health Insurance and Social Care Associations and National Association of Statutory Health Insurance Physicians
Management of basic administrative data of insurees	Federal Umbrella Organisation of Statutory Health Insurance and Social Care Associations
Emergency data set	Federal Chamber of Physicians
“Addressed” communication – transfer of patient data via ePhysicianLetter	National Association of Statutory Health Insurance Physicians
Electronic care record (Elektronische Fallakte)	German hospital association (Deutsche Krankenhausgesellschaft)

To gematik the general task of supporting these organisations and facilitating the successful implementation of the project leader model was entrusted.

If decisions to be taken are not supported by all relevant associations, a newly introduced ombudsman or referee must mitigate across divergent interests. The former health ministry Secretary of State Dr. Klaus Theo Schröder was entrusted with this task.

### **3.3 Deployment of eHealth infrastructure applications**

The eHealth services to be deployed in the German eHealth infrastructure are determined by law in the Social Code Book V. It distinguishes between mandatory applications, which must be introduced for all patients, and optional ones which depend on the choice of the patient, but which must also be supported by the eHealth infrastructure.

<sup>36</sup> Mau, J. (2010). Die elektronische Gesundheitskarte: Willkommen in der Vergangenheit. kma Gesundheitswirtschaftsmagazin (15), p. 44-49.

### 3.3.1 Legal base

The law defines applications and data that can be managed by using the Electronic Patient Card as an access tool. The mandatory applications will be introduced as a first step; the voluntary applications will become available later. The mandatory applications are [see § 291a (2) of Social Code Book V]:

- Administrative data (identifying the citizen and his or her health insurance status, address, etc.)
- Information about the status concerning private co-payments
- provision of data required by European regulations<sup>37</sup> for having access to medical treatment in the Member States of the EU (in Germany the data will not only be visible but also stored on the chip, thereby creating an “Electronic European Health Insurance Card” - e-EHIC).

The earlier mandatory application of facilitating the transmission of electronic prescriptions to a pharmacy was later declared a voluntary application because no agreement on how to realise this in the short term could be achieved. As prescriptions account for about 50% of all paper transactions in the health system, this was initially considered a key application to achieve early and sizeable benefits to justify the infrastructure investment.

In 2010, two further requirements were introduced by law:

a) In future, when the system becomes operational, physicians will be required to check online and, if necessary, update the administrative insurance data on the card once per calendar quarter if a patient visits the office.

b) No one will be required to integrate this online check into the physician administrative or patient system, i.e. its functionality must allow for a separate, isolated online checking process.

### 3.3.2 Patient summary and electronic health record (EHR)

In this study, the epSOS project's definition<sup>38</sup> of a patient summary was used as a general guideline. There a patient summary is defined as a minimum set of a patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency, accident), but also in case of planned care (e.g. after a relocation, cross-organisational care path).

Lacking a standard definition, a patient's electronic health record (EHR) is here understood as an integrated or also interlinked (virtual) record of ALL his/her health-related data independent of when, where and by whom the data were recorded. In other words, it is an account of his diverse encounters with the health system as recorded in patient or medical records (EPM or EMR) maintained by various providers like GP, specialists, hospitals, laboratories, pharmacies etc. Such records may contain a patient summary as a subset. As of yet, fully-fledged EHR systems rarely exist, e.g. in regional

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<sup>37</sup> See Regulation 1408/71 on the coordination of social security systems in the EU and related documents.

<sup>38</sup> European Patients Glossary: Patient Summary Smart Open Services, <http://www.epsos.eu/glossary.html>

health systems like Andalucía in Spain or Kronoberg in Sweden, or in HMOs (health maintenance organisations) like Kaiser Permanente in the USA.

It should be noted that in most policy documents reference is made simply to an "EHR" without any explanation of what is meant by it, thereby in reality even a single, basic electronic clinical record of a few recent health data may qualify. As a consequence, this section can only report on national activities connected to this wide variety of health-related records without being able to clearly pinpoint what (final) development stage is actually aimed for or has been reached so far.

*Electronic Health Record:* Beyond the eCard discussed above, a basic underlying concept of the German eHealth strategy is a voluntary "citizen-managed, personal electronic health record". This personal electronic health record will eventually be offered and operated by the healthcare system. It was generically defined by law and will be further detailed by the self-administered healthcare system at the federal level. The data will usually be provided and used by healthcare professionals in the form of electronic copies of original documentation. For access to the personal electronic health record, the eCard will be used as the citizen's tool to access and manage data in a trustworthy and secure way. This card must not be used for non-health related purposes.

For information flows between infrastructure components, cryptographic techniques will be applied, including for authentication, and (qualified) digital signatures. It will be assured that a patient's data can only be used with his or her consent. A private key stored on the Electronic Health Card must be used by the citizen himself to read the decrypted data or to have them read by a care provider.<sup>39</sup>

*Mandatory applications* concern the eventual online update of insurance status, recording of mandatory co-payment status, and the data set of the European Health Insurance Card (EHIC)<sup>40</sup>.

*Voluntary applications* describe a number of features the Electronic Health Card also "must be able to support" if a citizen gives informed consent to this. These concern

- so-called emergency data set (minimum data set)
- electronic physician letter (elektronischer Arztbrief): transfer of various messages on test results, diagnoses, suggested therapies, treatment reports and similar to support patient-centric services of providers
- facilitating the transmission of electronic prescriptions to a pharmacy
- full documentation on all prescribed or otherwise bought or taken drugs
- electronic patient record (elektronische Patientenakte): integrated documentation of data on test results, diagnoses, therapies, treatments and immunisations covering all interventions across all service providers

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<sup>39</sup> Bundesministerium für Gesundheit und Soziale Sicherung (2005): The German eHealth Strategy. Berlin/Bonn, July.

<sup>40</sup> This refers to the proof of authority for the claim for benefits in the area of application of the European Union regulation no. 1408/71 of the 14th of July 1971 for the application of the Social Security System to employees and their families, who immigrate and migrate within the Community

- integration of data supplied by the patient or third parties (e.g., on blood sugar level, patient testament and similar).

### 3.3.3 ePrescription

*In the framework of this study and following work in epSOS<sup>41</sup>, ePrescription is understood as the process of the electronic transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the drug by the patient. In this strict sense, only few European countries can claim to have implemented a fully operational ePrescription service.*

In general, German ePrescription planning is linked to the roll-out of the eCard and thereby also dependent on data, security and other implementation issues under way. Baseline at the moment is that as discussions on the eCard are ongoing, further considerations on ePrescription deployment have been postponed to 2011. As mentioned above, ePrescription was demoted from a mandatory to a voluntary application.

Nevertheless, various ePrescription Pilots were already undertaken. Pilot Regions were Bochum-Essen (Nordrhein-Westfalen), Flensburg (Schleswig-Holstein), Heilbronn (Baden-Württemberg), Ingolstadt (Bayern), Löbau-Zittau (Sachsen), Trier (Rheinland-Pfalz), Wolfsburg (Niedersachsen). The ePrescription functionality as part of the electronic Health Card was initially planned to be obligatory for all pilot regions.

#### **Use Case Schleswig-Holstein: 'Flensburg Model'**

Within the framework of the Schleswig-Holstein Health Initiative, the electronic Health Card was tested since 2001. The use case included the practical realisation of ePrescription in 2003 with 1200 Health Cards.

During the test phase, both paper-based and electronic prescriptions were used, but only patients who possessed both, an ePrescription and a paper prescription, were able to fill their ePrescription. Bottom line of the use case concerning ePrescription was that administration challenges were considerable, but differed markedly from case to case.

#### **Use Case Heilbronn: First Hospital Use**

In Heilbronn, around 10,000 insured persons, all five hospitals of the SLK chain of hospitals<sup>42</sup>, 14 doctors and ten pharmacies were part of the pilot project in 2007, which included ePrescription.

The evaluation of the use cases led to these observations:

- More operational steps were needed to create the ePrescription and receive the medicine than with a paper prescription
- If ePrescriptions can be prepared by the doctor's assistant, saved in the electronic patient administrative or clinical system and signed later on, whereas the process of storing the data on the eHealth Card is done separately, preliminary orders can be issued as usual. Another important challenge for the mass use of the ePrescriptions

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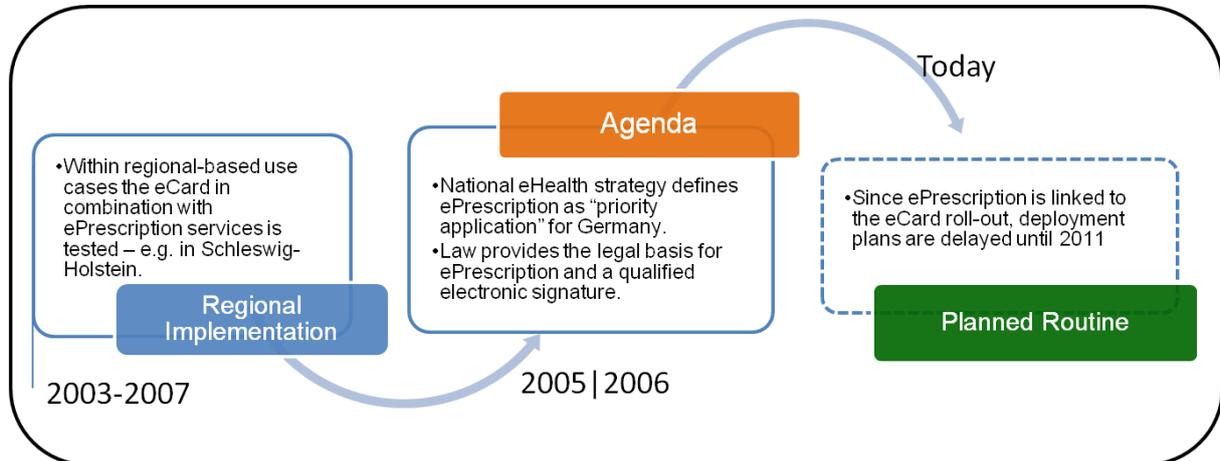
<sup>41</sup> European Patients Glossary: ePrescription Smart Open Services, <http://www.epsos.eu/glossary.html>

<sup>42</sup> SLK stands for "Sozial, Leistungsstark, Kommunal", a regional hospital group, <http://www.slk-kliniken.de/>

was the batch signature of prescriptions for doctors – this was not yet realised by software providers.

- Especially doctors were very sceptical about the positive effects of the eHealth Card

**Figure 4: ePrescription progress in Germany**



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### 3.3.4 Piloting the implementation

The initial roadmap foresaw the electronic health card with its supporting infrastructure to be introduced in five steps:

Step 1: Tests in central test laboratory.

Step 2: Practical user tests with test data

Step 3: Tests with 10,000 users in test regions with real data

Step 4: Tests with 100,000 users in test regions with real data

Step 5: Country-wide rollout

In mid-December 2005, a usability laboratory for testing the electronic health card and its applications was established at gematik. Laboratory tests of the basic functionality of the smart card were undertaken in 2006, allowing the “real” tests to begin early in 2007.<sup>43</sup> Seven test regions undertook step 2 and 3 tests, at least to some extent. This initial phase, which concluded in June 2009, involved in each region up to 25 physician offices, 15 pharmacies, 1 – 2 hospitals and 10,000 insurees testing the so-called Release 1 of the specifications. A preliminary evaluation of these tests identified various challenges to be

<sup>43</sup> Details on test objectives, components, functionalities etc to be tested, including an evaluation of acceptance by users as well as organisational and economic impacts, were regulated initially in the “Regulation on test measures for the implementation of the electronic health card” (Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte (EGKTestV)) of 09.11.2005, which has several times been adapted to concrete test developments and policy needs arising. Available at <http://www.buzer.de/gesetz/9601/index.htm>

further pursued.<sup>44</sup> These included too long a time period necessary to read the basic insurree data from the card when compared to the earlier health insurance card<sup>45</sup> - which seems partly due to higher security standards, interoperability issues when reading and transferring the data into the electronic medical record (EMR) system used in the office, significantly more time required to issue and store an ePrescription than a paper document in the physician's office, and more time needed by the pharmacist to readout the ePrescription. The test of the emergency data set showed a low usage rate, partly obviously due to the considerable time needed to initiate it (up to 30 minutes), considerable problems of patients when required to enter their PIN (a six digit Personal Identification Number) – particularly by older and disabled people. Nevertheless, about 80% of physicians valued in principle the potential availability of emergency data, but required optimisation of the PIN procedure, better interoperability of systems and devices as well as of the data set itself. Finally, whereas voluntarily participating patients expected a better treatment quality and improved availability of their medical data, non-participating patients mentioned both data security concerns and bureaucratic overhead (like the process of recording their consent required for voluntary applications or the PIN procedure) as deterrents.

Further tests are foreseen of newer releases with extended and optimised functionalities, but step 4 tests with 100,000 patients are no longer required.

### 3.3.5 Telehealth

*The use of telehealth applications may enable access to care from a distance, thereby potentially reducing the number of GP visits or even inpatient admissions. Commission services defined telemedicine as “the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location”<sup>46</sup>. In its recent communication on telemedicine for the benefit of patients, healthcare systems and society, the Commission re-emphasised the value of this technology for health system efficiency and the improvement of healthcare delivery<sup>47</sup>. It is therefore of great interest to this study to identify, which telemedicine applications are already available in Germany.*

When published in 2007, the eHealth ERA report for Germany noted that telehealth services had been initiated only in the form of pilots, without scaling up and spreading at the national level. A focus on integrated care, foreseen by legislation and described

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<sup>44</sup> Universität Bayreuth et al. (2009) Wissenschaftliche Evaluation der Feldtests von Release 1 – Evaluationsbericht im Rahmen der Testregionen übergreifenden Evaluation der 10.000er Tests bei der Einführung der elektronischen Gesundheitskarte. Bayreuth, Frankfurt, den 4. Juni 2009. Available at:  
[http://www.dkgev.de/media/file/7105.RS487-09\\_Anlage\\_gematik\\_EvalBericht\\_5231.pdf](http://www.dkgev.de/media/file/7105.RS487-09_Anlage_gematik_EvalBericht_5231.pdf)

<sup>45</sup> It was introduced in 1993/1994 and started full operations on 01.01.1995. It contained already a smart chip (256 bytes), which however was never used for more than transferring insurree data onto a paper form in the physician's office. By substituting for a cumbersome bureaucratic, paper-based process of the patient obtaining and providing to the treating physician a new so-called “sickness” or health insurance certificate every quarter, it supposedly amortised its investment costs within 2 years.

<sup>46</sup> Europe's Information Society Thematic Portal: Telemedicine works ,  
[http://ec.europa.eu/information\\_society/activities/health/policy/telemedicine/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm)

<sup>47</sup> European Commission (2008), On telemedicine for the benefit of patients, healthcare systems and society

above, had helped to kick-start these projects.<sup>48</sup> This analysis still seemed to hold true in early 2009, when *Rüdiger Klar* observed in an article on “Telemedicine in Germany: status, chances and limits”, that although “many successful special applications of telemedicine [exist], these projects are not extendable to the whole nation because of the highly complex German health care system, limited funding, heterogeneous IT standards in ambulatory and hospital care, insufficient official electronic health card use, the different data protection and privacy regulations of the federal and state governments, doubts of physicians and patients as well as unequal costs and benefits for the various persons involved in telemedicine.”<sup>49</sup>

In the meantime, the telemedicine landscape in Germany has gained in political momentum. The Ministry of Health, while recognizing the important potential of telemedicine, also openly acknowledged the failure of these services to reach the level of the “Regelversorgung” (standard level of care available across the country).<sup>50</sup> In mid 2010, the Federal Ministry of Health therefore launched the “eHealth-Initiative”, uniting key players of the German healthcare system (doctors, insurers together with the Fraunhofer Gesellschaft and key industry players) around the goal of identifying existing barriers to telemedicine deployment. A set of measures to address these barriers were agreed upon in late 2010. Their implementation will be addressed in the course of 2011.<sup>51</sup> Examples for measures include an agreement on semantic and technical interoperability standards as well as a scalable information system structure. Finally, existing pilot projects aimed at the treatment of chronic diseases shall benefit from an accelerated transfer into the already mentioned integrated care schemes.<sup>52</sup>

Examples of locally successful telemedicine projects are numerous and documented, among other places, in the Good eHealth database.<sup>53</sup> Telemedicine projects that address chronic diseases are for example the large scale project by the “Institut für angewandte Telemedizin” (IFAT) at the “Heart und Diabetes Centre Bad Oeynhausen” in North Rhine-Westphalia. Together with partners in Luxembourg, from which key results are used, the centre implements a telemedical application to treat heart failure patients. This project will apply results gained from the LuHF (Luxembourg Heart Failure) project in the field of heart transplantation (HTX). New competencies will be built up in the field of tele-monitoring patients with heart valve disease under blood anticoagulation therapy.

The application at the heart of the LUHS project (with a patent protected in Luxembourg) communicates with the patient and collects automatically standardised data to be used in a disease management programme. Pulse Transit Time (PTT) is collected in the home-

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<sup>48</sup> See eHealth ERA report on Germany, published on [www.ehealth-era.org](http://www.ehealth-era.org)

<sup>49</sup> Klar R., Pelikan E. (2009) Telemedicine in Germany: status, chances and limits, *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2009 Mar;52(3):263-9.

<sup>50</sup> Federal Ministry of Health (2011) IT-Gipfelprozess – eHealth/Gesundheitstelematik, article available at <http://www.bmg.bund.de/krankenversicherung/elektronische-gesundheitskarte/informations-und-kommunikationstechnologie.html>

<sup>51</sup> Federal Ministry of Health (2010) “Anwendungen der Telemedizin flächendeckend nutzbar machen”, press release no. 67, dated November 18th 2010, available at <http://www.bmg.bund.de/ministerium/presse/pressemitteilungen/2010-04/ausbau-der-telemedizin.html>

<sup>52</sup> Federal Ministry of Health (2011) IT-Gipfelprozess – eHealth/Gesundheitstelematik (op. Cit.)

<sup>53</sup> available at <http://www.good-ehealth.org/>

monitoring service<sup>54</sup>. This is a unique feature, which allows an early detection of decompensation status. The service was evaluated in a cross-border cooperation together with the university hospitals of Saarbrücken and Nancy. Following this evaluation, cooperation with the “Herzzentrum Bad Oeyenhausen” was set-up. Target groups are pre-implantation patients and post-implantation patients. The telemonitoring service allows for a targeted selection of patients who should be moving upwards on a waiting list for heart transplants. The Bad Oeyenhausen heart centre provides anti-coagulation treatment surveillance services. The INR value (measuring the thinning of the blood) is measured with patients in Luxembourg and then transferred to Bad Oeyenhausen, where treatment advice is provided.<sup>55</sup>

Another example of dealing successfully with a disease (stroke) through telemedicine can be found in Bavaria. In 2003 two specialized stroke centres and 12 (meanwhile 15) regional hospitals founded a telemedical network in eastern Bavaria/Germany with the aim to provide modern stroke management and advanced stroke expertise in non-urban-areas. More than 6,000 patients suffering from stroke are treated in the 15 hospitals of the TEMPiS-network every year. Physicians in the regional hospitals are able to contact the stroke centres in Munich-Harlaching or at the University of Regensburg 24 hours a day. The telemedical system consists of a digital network including a 2-way video conference and CT/MRI-image transfer using high-speed-data transmission (transferring the pictures of the CT-scan within seconds). Stroke experts are contacted while the patient is still in the emergency department. The expert, using the 2-way video conference, can take a look at the patient, talk to the patient directly and examine the patient with the help of the local physician. Within minutes the expert decides whether or not a thrombolysis therapy is indicated. Due to the TEMPiS-network, patients in rural areas now receive a highly specialized stroke treatment that used to be the privilege of patients living in larger cities with stroke centres. The TEMPiS-network not only provides telemedical advice. It also assists the regional hospitals in establishing specialized stroke wards and offers regular education programmes for the staff - nurses, therapists, doctors. Since 2003, more than 21,000 teleconsultations have been performed and more than 1,800 patients received thrombolysis (data from July 2010). Regarding this data, TEMPiS is the largest telemedical stroke network in the world. In a study with 3,100 patients the benefit of this project was shown: the treatment in a TEMPiS-connected hospital significantly improved the chance of a patient with a stroke to leave the hospital without severe disability.<sup>56</sup> TEMPiS is a prime example of an efficient stroke care easily accessible to the rural population. It has gained international appreciation and has received several awards.<sup>57</sup>

Finally, the AGNES project (Arztentlastende, GemeindeNahe, E-healthgestützte, Systemische Intervention) supports general practitioners with qualified medical practice

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<sup>54</sup> Wagner D. ; Rösch N. et al (2010). "Relationship between pulse transit time and blood pressure is impaired in patients with chronic heart failure,Clin Res Cardiol

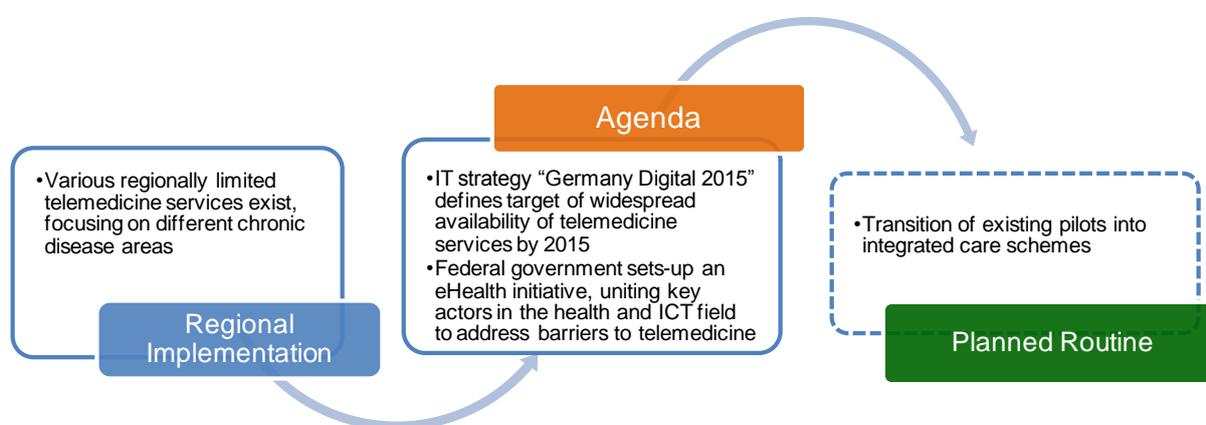
<sup>55</sup> N. Rösch et al (2008), Cross-border home-monitoring of heart failure patients in Luxembourg and North Rhine-Westphalia

<sup>56</sup> Audebert et al (2006) Effects of the implementation of a telemedical stroke network: the Telemedic Pilot Project for Integrative Stroke Care (TEMPiS) in Bavaria, Germany, Lancet Neurology Volume 5, Issue 9, Pages 742 - 748

<sup>57</sup> Taken from the English project summary of the Tempis project, available at <http://www.tempis.de>

personnel who in turn rely on telehealth applications to support patients. AGNES is a project under the auspices of the Institute of Community Medicine at Greifswald university, where doctors, nurses, patients and scientists cooperate intensively with the aim to introduce new methods for delivering primary care in rural areas. The family doctor is supported by a specially trained nurse (Telehealth nurse), who is using the latest communication technology. The telehealth nurse takes over home visits to patients, with preventive, consulting and guiding therapy supervision activities as a priority. An important task of these telehealth nurses is the supportive supervision (monitoring) of the health status of patients at home. For suitable patients telecare devices are used, such as heart rhythm cards, blood pressure and blood glucose meters and electronic scales. Other tasks include drug control and prevention of falls in the home.<sup>58</sup>

**Figure 5: Telemedicine services in Germany**



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## 3.4 Technical aspects of implementation

*A key prerequisite for the establishment of an eHealth infrastructure is the ability to uniquely identify citizens/patients and healthcare professionals. This part of the survey deals with identifiers and how they are stored. This section does not deal with the tokens through which identification can or will take place. One such possibility would be via an eCard. This topic is dealt with in the following section. The current section focuses solely on whether or not unique identifiers are in place in Germany and for which purpose.*

### 3.4.1 Unique identification of patients

For the unique electronic identification of German residents when availing themselves of public healthcare services, a special health insurance ID number has been introduced. This ID is based on the social insurance number (Rentenversicherungsnummer), which now every newborn baby receives. Using a specific mathematical algorithm, the health

<sup>58</sup> Further information (in German) on the "Projekt – AgnES" at <http://www.mezizin.uni-greifswald.de/icm/index.php?id=347>

insurance ID is generated from this number, but does not allow reconnecting to the initial social insurance number – this was a data protection requirement.

This national electronic registry of statutory health insurance IDs is managed by the health insurance companies through their “Vertrauensstelle Krankenversicherer-nummer”<sup>59</sup> (trust agency health insurance number), which creates the IDs on the basis of the social insurance IDs. The trust agency is closely linked to the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnologie<sup>60</sup>). Every German citizen receives this health insurance ID from its statutory health insurance company.

In future, it is anticipated that his number, electronically readable from the eCard, will become the patient’s key to connect to all its health data. The data will be stored in an encrypted form, and only the patient will have access, via its card, to the key.

### 3.4.2 Unique identification of healthcare professionals

Similarly, all healthcare professionals will be identified through a unique electronic ID. For all so-called “verkammerte” (associated with and registered at a health professional association or chamber) professionals (doctors, dentists, pharmacists and psychotherapists), as defined in § 291a SGB V, it will be provided by their respective regional chamber/association.

A challenge is the great diversity of allied health professional groups respectively of persons involved in providing health services which can be charged to the public health insurance system. For the electronic identification of such professions, which are not registered at a chamber (around 40 professions and occupations), such as midwives, speech therapists, physiotherapists, rescue workers, clerks of medical homes or caregivers, optometrists etc., a new “Elektronisches Beruferegister für Gesundheitsfachberufe der Länder” (Electronic register of occupations for health professionals in the Länder) will be established in Bochum. This will be a necessary condition to allow them to access, e.g., electronic patient documents or prescriptions necessary for performing their services. It is estimated that about 2m persons will need such an ID.

### 3.4.3 The role of eCards

#### *Health insurance cards*

For more than 15 years, German citizens who are a member of a public, statutory health insurance fund have had to carry an electronic insurance card which contains on a chip all their administrative insurance data. When receiving health services, they must present it to the health provider once per quarter. The card is used to transfer these electronic insurance data in a clearly legible and reliable manner onto paper documents and, if available, the electronic system of the provider, thus allowing for more efficient bureaucratic processes. The electronic chip has, however, so far not been used for

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<sup>59</sup> Informationstechnische Servicestelle der gesetzlichen Krankenversicherung (Information-technology service provider of social health insurance providers) <http://www.itsg.de/%28S%28qx2s0uayj3mjw555ch2vqybu%29%29/VST.ITSG>

<sup>60</sup> [https://www.bsi.bund.de/cln\\_174/DE/Home/home\\_node.html](https://www.bsi.bund.de/cln_174/DE/Home/home_node.html)

medical purposes. It does not have specific security features that uniquely identify the owner and it is open to misuse to a certain extent.<sup>61</sup>

It is planned to start replacing the old eCard by a new generation of cards finally in 2011. The law of 2003 providing the legal base of the new generation of eCards covers the various functionalities mentioned earlier. Detailed "basic" specifications for the planned tests for piloting the implementation were finalised already in February 2006<sup>62</sup> and covered initially:

- a) base commands, operating system and security functions
- b) specification of mandatory applications and data elements including those needed for ePrescription and qualified electronic signature
- c) external card design including location of a patient picture and the ink signature of the card owner; the back side functions as the European Health Insurance Card (EHIC).<sup>63</sup>

During recent years, reacting to political discussions as well as results from various tests, the initial set of data to be made available on the card has changed; it will now comprise administrative information, clinical emergency data (optional), clinical prescription data (optional) and the possibility to chose the option of organ donation. Its definite implementation is expected now via a two-step process:

1) "**Basis-rollout**": In 2011, at least 10% of all insurees must receive a new generation card, and all others are to follow in 2012. Initially, not the full functionality will be used; rather, only the same capabilities which the old insurance card already had will be activated. However, already through this exchange, the following advantages are predicted:

- with the new, unique life-long health insurance number on the new electronic health (insurance) card, insurance and treatment information can at any time be clearly assigned to a particular patient – whether on paper or in an electronic system;
- the storage space of the new card allows the unabridged recording of even very long street and other names;
- the photograph of the insuree on the new card is expected to reduce fraudulent use.

2) "**Online-rollout**": As a next step, the so-called online-rollout will follow in coming years; it consists of three important steps connected to patient data and their exchange:

- a. *Updating of insurance data on the card*: In future, during an initial visit to a practice/hospital or once per quarter, the following functionalities will become available through the online-rollout of the infrastructure:
  - data (e.g. a new address) can be updated quickly and efficiently and lost or stolen cards can be easily blocked;
  - a change in co-payment status will become immediately evident and financial loads for no longer exempt patients will be avoided;
  - physician billing data is current, and rejection by health insurance funds in the settlement process a thing of the past.

<sup>61</sup> E.g., it is well known from surveys that some cards have been used by tens of people in the same quarter.

<sup>62</sup> For details, see <http://www.bundesaerztekammer.de/page.asp?his=1.134.3416>

<sup>63</sup> See <http://www.dimdi.de/static/de/ehealth/karte/index.htm>.

- b. *Exchange of data between physicians:* The so-called MWK-LE (Mehrwertkommunikation Leistungserbringer – value-added provider communication) functionality will later offer the possibility to exchange medical data. This replaces, e.g., paper, fax or e-mail communication by a secured telematic infrastructure. Thereby, doctors can – after authentication through their health professional card – exchange discharge letters, laboratory results and other notes. Anticipated benefits connected to this infrastructure are the following:
- security mechanism for data transfer
  - almost instant transfer of data
  - exchange of image-based material such as x-rays
  - assistance through simplified acquisition of information and the integration into their practice management and patient systems
  - an easy recipient identification through a central, constantly updated electronic directory
- c. *emergency data on the card:* These data include information on diagnoses, allergies, intolerances, medications, organ donation and contact details of treating physician and a family member. Access to such information can be critical in a first aid treatment by an emergency doctor and avoid complications. The use of this application is optional - only if the insured person agrees to it, a doctor can store the emergency data on the card. With this application:
- complications during an emergency treatment can be avoided - e.g. paramedics get an instant overview of all relevant emergency data of the patient;
  - information that the patient is an organ donator is immediately available

*Security mechanism:* All access to clinical data, except administrative and in certain cases emergency data, depends fully on the patient's consent, and it will be only available to a health professional authorised to see the specific data and who has identified himself through the electronic health professional ID card. Card readers having slots for both the patient and the professional eCard need to be used. Generally, access is secured through authorisation, encryption<sup>64</sup> and data customisation.

It is anticipated that such functionalities and applications, including later also ePrescriptions, may become implemented stepwise only after the basis-rollout has been completed, i.e. in 2013 and the following years.

Another feature is that, also for security reasons, many of these functionalities will be available, via a so-called connector, also as stand-alone solutions, i.e. without direct connections to the patient administrative or clinical management system of the treating doctor.

### **Healthcare professional cards**

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<sup>64</sup> mixed encryption system

*Development/Functionalities of the eCard for healthcare professionals.*<sup>65</sup> It is planned that, based on the electronic registers of all health professionals as detailed earlier, all professionals will receive an electronic ID card in coming years. This health professional card (HPC) is a personal ID card in the format of a credit card. For the time being, the old doctor (paper-based) certificate remains a valid form of identification. The electronic identity card holds the unique physician number, the expiry date and a passport photo. Analogous to the electronic health (insurance) card, the HPC contains a microchip, which is linked to authentication services (electronic identity), allows supporting encryption and provides the service of an electronic signature. With help of this card, a physician has access to the electronic health card of the patient. Furthermore, the physician can electronically sign documents in a legally binding form. Through this procedure, documents or data can also be safely encrypted and decrypted. Currently a special application and registration procedure is being developed in order to supply health professionals with such a card. The card will soon become mandatory for so-called "verkammerte" (associated with and registered at a health professional association or chamber) professionals (doctors, dentists, pharmacists and psychotherapists), as defined in § 291a SGB V.

#### Security Mechanisms:

Technical guidelines have been published by the Federal Office for Information Security in 2009 ("BSI TR-03116 Technische Richtlinie für eCard-Projekte der Bundesregierung"<sup>66</sup>), which mainly describe security mechanisms connected to the planned eCard. These guidelines were developed for the gematik, private producers of eHealth components and the issuers of the eCard for patients and professionals. The set rules are binding, when choosing cryptographic algorithms.

**Figure 6: Timeline of eCard deployment in Germany**

November 2003	The law on the modernization of public health insurance of 14 November 2003 determined the introduction of the electronic health cards for January, 2006 (§ 291a SGB V).
2003	In 2003, the Ministry of Health and Social Security launched a European wide tender for the project consortium "bIT4health" (= better IT for better health), consisting of the companies IBM Germany, the Fraunhofer Institute for Industrial Organization (ILO), SAP Germany, InterComponentWare and ORGA Card Systems (now Sagem Orga) with the goal to analyse the best conditions and prerequisites for the nationwide introduction of the electronic health card. The focus of the work of the project "bIT4health" was the definition of a telematics architectural framework and security infrastructure. The project consortium is planned to accompany the introduction of the electronic health card during the development phase of the framework architecture as well as during the test phase up to the introduction and the first year of operation

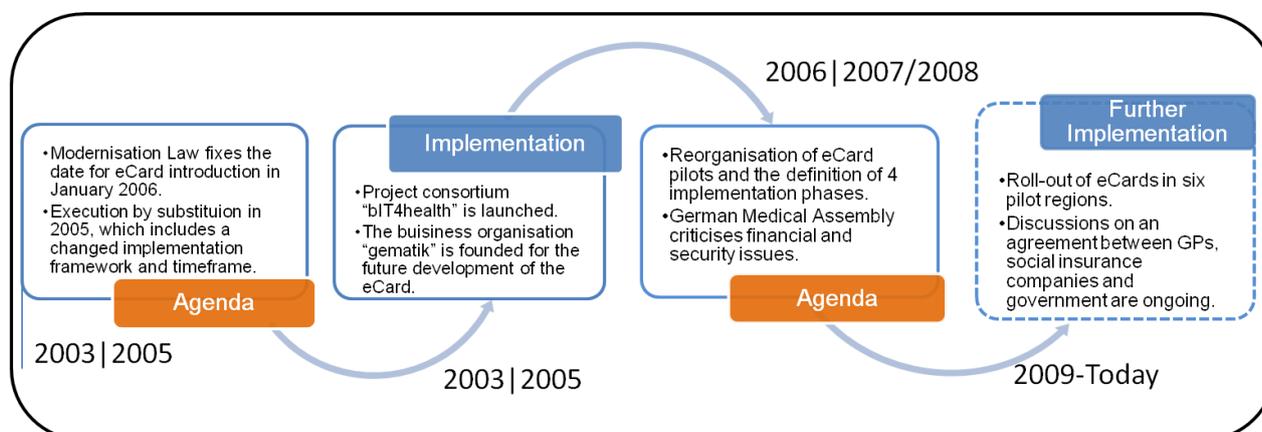
<sup>65</sup> Stüwe U., Möhrle K. (2005) „Elektronischer Heilberufsausweis (Health Professional Card/HPC) und elektronische Gesundheitskarte, in Hessisches Ärzteblatt 2/2005 available at [http://www.laekh.de/upload/Hess.\\_Aerzteblatt/2005/2005\\_02/2005\\_02\\_04.pdf](http://www.laekh.de/upload/Hess._Aerzteblatt/2005/2005_02/2005_02_04.pdf)

<sup>66</sup> Technische Richtlinie für eCard Projekte der Bundesregierung, Federal Office of Information Security, BSI-TR-03116 available at [https://www.bsi.bund.de/cae/servlet/contentblob/477230/publicationFile/30613/BSI-TR-03116\\_pdf.pdf](https://www.bsi.bund.de/cae/servlet/contentblob/477230/publicationFile/30613/BSI-TR-03116_pdf.pdf)

<b>January 2005</b>	For the introduction and future development of the health card, the business organisation gematik (Society for telematics applications of the health card mbH) was founded by the central associations of self-government in January 2005.
<b>September 2005</b>	The planned deadline of January 2006 could not be met. Therefore, the Ministry of Health planned an execution by substitution in September 2005. Afterwards, the implementation framework was changed and administrative tasks newly structured. This was related to the fact that several votings failed and the timeframes of the Ministry of Health and the gematik seemed to be incompatible.
<b>October 2006</b>	In the course of this reorganisation in 2005, the regulation for eCard pilots in Germany was changed in October 2006 („Neufassung der Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte“ <sup>67</sup> ). This regulation defines for implementation phases: 1) under laboratory conditions, 2) with access of healthcare professionals to test data, 3) with access of healthcare professionals to real patient data and finally 4) regional pilots for national roll-out.
<b>2007/2008</b>	The German Medical Assembly decided – with a majority of 111 to 94 votes – against the eCard framework established up to this point. The Assembly demanded more security mechanisms and detailed reimbursement schemes. These demands and tasks were again evaluated at the German Medical Assembly in May 2008.
<b>May 2008</b>	The German Medical Assembly in 2008 renewed its criticism concerning security and financing aspects of the German eCard.
<b>2009- Today</b>	In 2009, preparations for a comprehensive pilot roll-out were started. First pilot region for the release of pilot eCard was North Rhine-Westphalia.
<b>2010 - 2013</b>	New <b>developments in 2010</b> concerning the deployment of the German eCard include: <ul style="list-style-type: none"> <li>- GP advisory board accompanies the eCard pilots in Bochum and Essen – thereby also ideas from stakeholder side will be included</li> <li>- For more acceptance on physician side, the Ministry of Health insists on the involvement of social insurance companies – especially to satisfy financial concerns of doctors</li> <li>- Planned statutory basis of online master data exchange between GP practices and central server</li> <li>- Basis-rollout to start fully in 2011</li> <li>- Online-rollout to start in 2013, with further functionalities to follow in later years</li> </ul>

<sup>67</sup> Bekanntmachung der Neufassung der Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte, Bundesgesetzblatt 2006, Teil I, Nr. 45, available at <http://www.dkgev.de/pdf/1459.pdf>

Figure 7: eCards in Germany



### 3.4.4 Standards

Standards are not only crucial to enable interoperable exchange of meaningful information in the healthcare system; they also ensure secure access to patient records by healthcare providers and citizens. This study aims to identify, among other usage, standards related to the domain of health informatics, such as the SNOMED Clinical Terms or the LOINC terminology. SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) is considered to be the most comprehensive, multilingual clinical healthcare terminology in the world. The organisation developing SNOMED is called the International Health Terminology Standardisation Organisation (IHTSDO<sup>68</sup>).

**Technical health ICT standards:** There will be established – as required by law – a dedicated eHealth infrastructure to be organised by the above mentioned gematik corporation through open calls for tender; implementation will be through private companies. This includes security features like a "black box" (the connector) allowing every health care provider to connect securely to the infrastructure without the need for technical expertise, and to perform all mandatory and voluntary nation-wide eHealth applications. All commercial hardware (e.g. card readers) and software providers will have to comply and implement the technical standards and specifications as defined by gematik, and to up-date their systems to allow their clients to communicate with this central infrastructure and with each other, i.e. they will have to adhere to these standards and specifications set and published by gematik.

**Semantic standards:** Responsible for maintenance and facilitating the use of semantic standards is the German Institute of Medical Documentation and Information<sup>69</sup> (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI): "DIMDI provides with LOINC (Logical Observation Identifiers Names and Codes - Dataset of universal identifiers for laboratory and other clinical observations to facilitate exchange

<sup>68</sup> International Health Terminology Standards Development Organisation About IHTSDO, <http://www.ihtsdo.org/about-ihtsdo/>

<sup>69</sup> <http://www.dimdi.de/dynamic/en/index.html>

and storage of clinical results or vital signs), OID (Object indicators) and ICD-10-GM/Alpha-ID important instruments for semantic interoperability in Germany. Internationally comprehensible standardised terminology systems are essential for electronic data exchange in medicine, e.g. in integrated patient care. As expert for medical classifications, nomenclatures and thesauri, DIMDI is also charge of the above mentioned applications.”

But the widespread use of such standards poses still a great challenge for the German health system. In a statement of the “Gesellschaft für Medizinische Informatik” (society for medical computer science) it is noted that the use of standards in Germany is a chicken and egg problem: the self-organising health system structure behind the *gematik* has to be convinced that the use of standards is indispensable, but the investment into e.g. Snomed CT is only profitable, when these standards, e.g. facilitated via the widespread usage of the voluntary eCard applications, is used nationwide on a regular basis.

**Certification procedures for eHealth systems:** Within the regional associations of statutory health insurance physicians (Kassenärztliche Vereinigungen), certification processes for electronic accounting systems and software to electronically transfer reimbursement data have been in place for more than a decade.

It has been recognised that such certification procedures are a necessity for other eHealth applications as well. For example, the *gematik* has specified certification procedures not only for interoperability, but specifically also for security. These procedures are specific to the respective product. Also, an interoperability testing laboratory was established.

### 3.5 Legal and regulatory facilitators

*Legal and regulatory issues are among the most challenging aspects of eHealth: privacy and unclear confidentiality, liability and data-protection all need to be addressed in order to make eHealth applications possible. Rarely does a country have a coherent set of laws specifically designed to address eHealth. Instead, the eHealth phenomenon has to be addressed within the existing laws on professional liability, data protection etc.*

The Modernisation Act for Public Health Insurance (Gesetz zur Modernisierung der gesetzlichen Krankenversicherung) of November 2003 established the basic guide for the modernisation of information processing in German healthcare. It was decided to establish a dedicated infrastructure for healthcare telematics in Germany. The strategic orientation and the basic infrastructure elements were codified in § 291a (electronic health card) of the Social Security Code V with recognisable effect for all other service areas. Also private health insurers and the industry promised full support.<sup>70</sup>

The legal framework for the Electronic Health Card is defined on the federal level in the Social Code V (§§ 290-291). The law provides for a new lifelong patient identifier which identifies the citizen, independent of where he or she is insured, for purposes of the healthcare system, and the introduction of an Electronic Health Card (Gesundheitskarte).

<sup>70</sup> Goetz, C. (2010) Gesundheitstelematik im Spannungsfeld zwischen Konvergenz und Atomisierung, Missverständnisse und Perspektiven einer großen deutschen Infrastrukturmaßnahme. TeleTrusT Deutschland e.V. Berlin.

The Card functions as the citizen's tool for managing applications and personal medical data. The law defines mandatory and voluntary applications that can be managed using the Electronic Health Card as an access but also data carrying tool.

To protect citizens' private data, the law describes citizens' rights and means of protecting their data. Citizens' rights and data privacy are legally ensured by the citizen's consent (to be documented on the Electronic Health Card) to who may or may not have access to his or her data, regulations for logging access (at a minimum the last 50 accesses have to be logged), prohibition of non-care related utilization, and prohibition of confiscation of health-related personal data.<sup>71</sup>

The online verification of insurance status of citizens through the planned electronic healthcard is enshrined in § 291 Section 2b of the law on the modernisation of statutory health insurance (GKV Modernisierungsgesetz).

Complementary to this, in Germany, comprehensive national legislation exists addressing in detail data protection issues, telecommunications services (with regard to data protection and confidentiality), digital signatures, and product liability of health IT. Also, discussions on a special law to further specify patients' rights have been started recently. For further legal details, please see also section 3.3.1 Legal base and organisational support.

### 3.6 Financing and reimbursement issues

The infrastructure organisation *gematik* is owned by all the contractual partners of the self-administered healthcare system at the federal level. As required by the 2005 addendum to the law, there had to be a contract signed among them about how to finance *gematik*,<sup>72</sup> the initial set-up (definition, test, roll-out) of the infrastructure, and the operational phase of the infrastructure, including some special rules on how to finance infrastructure investments in hospitals. The financial regulations are complex, but follow these general rules:

a) During the initial definition and test phase, lump sums were paid to the participating healthcare providers (€ 6,200 for doctors who are in private practice; € 56,000 for hospitals; and € 5,750 for pharmacies to cover the expenditures for new equipment, training and running costs).

Also during later, more recent test phases, the responsibility for financing remained with *gematik*; it provided funding for project office space, costs of participating service providers, scientists etc. based on lump sums as well as to reimburse for productivity losses during testing.

b) During the operating phase, physicians may receive a lump sum of up to € 850 for acquiring card readers, including charges for initial installation. Hospitals can add two supplements to each bill for inpatients, one as a contribution to the costs of the *gematik*,

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<sup>71</sup> ERA Report 2007

<sup>72</sup> On September 23rd 2008, the Ministry for Health (Bundesministerium für Gesundheit) ruled that the Network for Health Insurance (Spitzenverband Bund der Krankenkassen, GKV) must pay € 0.26 per patient to the Establishment of a Society for Health Telematics (*gematik* - "Gesellschaft für Telematik") for the test phase of the electronic Health Card, including ePrescription.

another one (telematics surcharge) to cover their own additional eHealth-related costs. All other providers are allowed to charge an extra fee to the health insurance funds every time the infrastructure services are used (transaction charges).

gematik's equity is financed in equal parts by health insurance funds (45% statutory, 5% private) and healthcare providers. For decisions, a majority of 67% of the shares is required. The Law provides for an Advisory Board comprised of four representatives of the federal states ('Länder'), three from patient organisations, three from scientific organisations, three from industry, as well as the Federal Commissioner for Data Privacy and the Federal Commissioner for Patients' Affairs.

The Federal Ministry of Health has the right to demand the elimination of identified shortcomings in gematik's implementation decisions and to set deadlines. If such deadlines are not met, the Ministry is entitled to make all necessary specifications by ordinance.

In the future, there will be more medical documentation necessary than was usual in Germany in the past, in order to, e.g., allow third-party providers to treat an unknown patient. There will have to be more structure in and more standardisation of data, implying that medical personnel may need more time in this respect while the benefits may occur in the future and for other participants (for example in Public Health or research). Accordingly, the Law allows the re-negotiation of operational or transaction-related charges on an annual basis.

There are no particular eHealth services yet that are eligible for reimbursement (beyond payments for telephone or similar contacts after initial examination in the physician's office). They are under discussion and may be introduced as appropriate in the course of implementing on a broader level the various functions to be supported by the Electronic Health Card. New services must always prove – within the limits of overall economic considerations – that they are affordable and efficient. It is crucial that projects and re-financing models fit into the overall system.<sup>73</sup>

### 3.7 Evaluation results/plans/activities

*From a public policy perspective, evaluation is a key activity in the policy-cycle. It provides insights into the success or failure of a policy or project and leads to new policy goals and new methods of implementation. The need for evaluation of eHealth policies and projects has been stressed time and again by the EC, not least in order to further the spread of eHealth in the process of healthcare delivery. However, the innovative nature of most eHealth projects and the political risks associated with a systematic policy of evaluation, often lead to a relative disregard for evaluation. In addition, a set of methodological problems present themselves on the policy level: Success or failure judgments about policy depend on clearly imputable government intentions. Intentions however are often (intentionally) vague, ambiguous or even outright contradictory (to meet the expectations of different groups). Evaluation is in itself a political tool, used differently according to who carries out the evaluation and in which context. Finally, policy*

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<sup>73</sup> Goetz, C. (2010), op. cit.

*learning as a result of policy evaluation can be more important than the direct results delivered by the evaluation.*

As stated in the European eHealth Action Plan, “eHealth should be supported by the widespread dissemination of best practices. These should include the impact on access to healthcare and on its quality, assessments of cost benefits and productivity gains.”<sup>74</sup> Germany has not (yet) subscribed to a formal Regulatory Impact Assessment (RIA) of pending or already introduced eHealth legislation, but it has regulated in considerable detail the testing, piloting and assessment of acceptance of core elements of its eHealth strategy in a “Regulation on test measures for the implementation of the electronic health card” (Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte (EGKTestV)) of 09.11.2005, which has several times been adapted to concrete test developments and policy needs arising.<sup>75</sup>

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<sup>74</sup> European Commission (2004). e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area. Brussels.

<sup>75</sup> Available at <http://www.buzer.de/gesetz/9601/index.htm>

## 4 Outlook

Germany is a prime example for the multi-faceted challenges and issues arising when attempting to introduce a nation-wide eHealth infrastructure in a quite large (more than 80m citizens), federally structured country with a highly diverse and complex health system. Discussions on eHealth started in the early 90's of the last century, initial concepts and plans were drafted around 1995 already, a law was adopted in 2003 to establish a basic infrastructure based on eCards for both patients and professionals by 2006, and in 2010 the country is still struggling to roll these applications out to all actors in the health system.

Nevertheless, there is great optimism that by 2012/13 the basic system will become fully operational, and that in the following years more advanced applications will be possible. One may expect that such an infrastructure will, in due time, greatly facilitate the widespread diffusion of advanced eHealth systems across healthcare providers and health professionals, and allow at least for the easy exchange, perhaps even the controlled, secure common access to patient data by all involved in the care of a specific person.

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