The German Electronic Patient's Card

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***Abstract*—The German Electronic Patient's Card (eGK) will be a major step towards a future IT supported health system. It will allow for the storage of electronic prescriptions, the access to an electronic health record and several other applications. In this paper we will introduce those and give an overview of the actual state of affairs.**

***Index Terms*— Health Insurance Card, Health Professional Card, Telematics Infrastructure, eGK, Electronic Patient's Card**

I. Introduction

Introducing the "elektronische Gesundheitskarte" (electronic patient's card, eGK) is one of the biggest ongoing IT projects in Germany. It is going to lastingly change the German healthcare system, affecting over 80 million insurants, 123.000 doctors, 65.000 dentists, 21.000 pharmacists, 2.200 hospitals and 300 health insurance companies [1].

In this lecture we want to outline the reasons that led to the decision to interconnect the participants in the German healthcare system, illustrate the goals pursued, depict the actual state of affairs, introduce the IT architecture and, in the last part, comment on the risks and criticisms.

II. History

In the course of the "Lipobay Scandal" [2], were several people died because of a not well documented interaction with another medicine, voices were being raised to increase the quality of the healthcare system and make it more transparent by the use of modern IT systems. In 1998, a study by Roland Berger concluded, that in order to finance a system to centrally document a patient's medication and thus prevent dangerous or even deadly interactions with other medicaments, only the prescription process had to be changed from a paper based approach to an electronic based solution [3]. In 2001, Debold and Lux did a cost benefit analysis for the "Bundesvereinigung Deutscher Apothekerverbände" (Federal Union of German Associations of Pharmacists) and the "Verband der Angestellten-Krankenkassen" (Association of Employees' Health Insurances), concluding that the introduction of a new health insurance card in combination with an electronic prescription system would yield an extraordinary cost benefit ratio. They calculated that the system would amortize within 12 months [4]. In June 2002, the Conference of State Ministers of Health ("Gesundheitsministerkonferenz", GMK) demanded to support and coordinate model projects for the introduction of electronic health records, electronic doctor's letters and the electronic prescription [5].

This led to the "Gesetz zur Modernisierung der gesetzlichen Krankenversicherung" (SHI Modernization Act, GMG) which passed Bundestag and Bundesrat in 2003 and came into effect on January 1st 2004. It regularizes the eGK project, specifying which applications have to be supported and, most notably, that the eGK has to be introduced by January 1st 2006. It also gave over the responsibility for creating the necessary infrastructure to the joint self-government[1] and an organization of pharmacists [6]. Shortly before, in August 2003, the "bIT4health" consortium under the direction of IBM Germany won the contract for creating the architecture for the eGK after a pan-European bid invitation [7].

The "bIT4health" consortium delivered the framework architecture in time in March 2004 but collapsed in mid-2004 when it came to specifying the detailed solution [8]. In October 2004, the joint self-government and the "Bundesministerium für Gesundheit" (federal ministry of health, BMG) agreed to commission the Fraunhofer Gesellschaft to develop the solution architecture based on the framework architecture which they delivered in March 2005 [7]. Because the involved parties couldn't agree on the further course of action, the BMG threatened them with an execution by substitution. This led to the formation of the Gematik in January 2005, a company whose sole purpose is to invite tenders for the required hardware and software and to test the components [8].

III. Applications and Goals

As defined by law, the eGK consists of three mandatory applications, i.e. applications that have to be used by the patient, and six optional applications where the patient can give and revoke his agreement to store his personal data at any time [9].

A. Mandatory Applications

1) Insurant's master data

The most basic mandatory application is the storage of the

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[1] the joint self-government consists of representatives of doctors, dentists and the compulsory health insurance funds

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insurant's master data, i.e. his name, sex, address, insurance, insurance policy number, additional payment status, etc. Additionally the card has to show a photograph of the insured to make it harder to forge [9, 10]. When the patient wants to claim health insurance benefits, e.g. in a doctor's practice, the card is validated against a central system and the holder's photograph is checked by the doctor's personnel in order to prevent insurance fraud, thus reducing costs [10].

2) eRezept

The second application is the eRezept/eVerordnung (electronic prescription) [9]. Momentarily, when the doctor prescribes a medicament or a treatment, in most cases he enters the prescription into his IT system, prints out the prescription and hands it over to the patient. The patient takes the prescription to his pharmacist who enters the prescription into his computer in order to look up the price and check the stock. Afterwards the pharmacist sends the prescription to a special data center, where the prescription is again entered into an IT system in order to bill it to the respective health insurance company and to archive it. With the eGK, the prescription is stored on a central server system or on the card itself. Instead of printing the prescription, the doctor stores it in the infrastructure or on the card and the patient carries the card to his pharmacist. There the prescription is read in directly into the pharmacist's system and can directly be billed to the insurance company. The need for paperwork and the tedious and error prone task of typing in the prescription at three different locations will then be obsolete. With a continuous electronic data transfer, costs can be saved by facilitating administrative tasks like billing and digitally archiving the prescriptions [10].

3) EHIC

The last mandatory application is the EHIC (European Health Insurance Card). In resolutions 189, 190 and 191, the European Commission decided to introduce a European Health Insurance Card for patients claiming health care benefits in other EU countries then their own [11]. For insurants of the compulsory health insurance fund the eGK will have the necessary data printed on the back.

B. Optional Applications

Contrary to the mandatory applications, the patient can chose whether or not to use the optional applications and has to explicitly give his agreement to store his data for each of the optional applications. Currently there are six optional applications defined by law which will now be introduced.

1) Emergency data

With the emergency data application, data about the patient, e.g. blood type and allergies, is stored so that in case of an emergency, medical personnel can access the data and thus speed up rescue measures or avoid medication intolerances [10]. The law demands that the data has to be accessible even without a network connection [9]. Therefore it is currently planned to store the emergency data on the patient's card itself [12].

2) eArztbrief

The eArztbrief (electronic doctor's letter) provides means of *case-related* electronic communication of a patient's findings, diagnoses, therapy recommendations and treatment reports between the parties involved in the patient's treatment [9]. It is hoped that this will speed up the exchange of information between cooperating health care providers and thus optimize certain work processes. Additionally, the improved availability of information should also improve the quality of the therapy and in turn reduce the time needed for the treatment, thus reducing costs [10].

3) Pharmaceuticals documentation

The pharmaceuticals documentation documents a patient's medication. In order to avoid the prescription of the same medicament by two doctors and in order to avoid interactions with other medicines that could lead to sequelae or even death, thus increasing costs, the patient can allow the doctor to document the patient's medication with the help of the eGK [10].

4) ePatientenatkte

The ePatientenakte (electronic health record, ePA), in contrary to the eArztbrief, provides means of *cross-case* electronic communication of a patient's findings, diagnoses, therapy recommendations and treatment reports between the parties involved in the patient's treatment [9]. It is hoped that this will yield an improvement of the treatment quality, thus reducing the time needed for the therapy and in turn reducing costs. The ePA should also prevent multiple examinations on the same subject because previous examination results are always available [10].

5) Patient's compartment

The patient's compartment is an application where the patient can store his own data. These could be for example a diabetic's journal or an advance directive and shall encourage the patient to contribute to his treatment.

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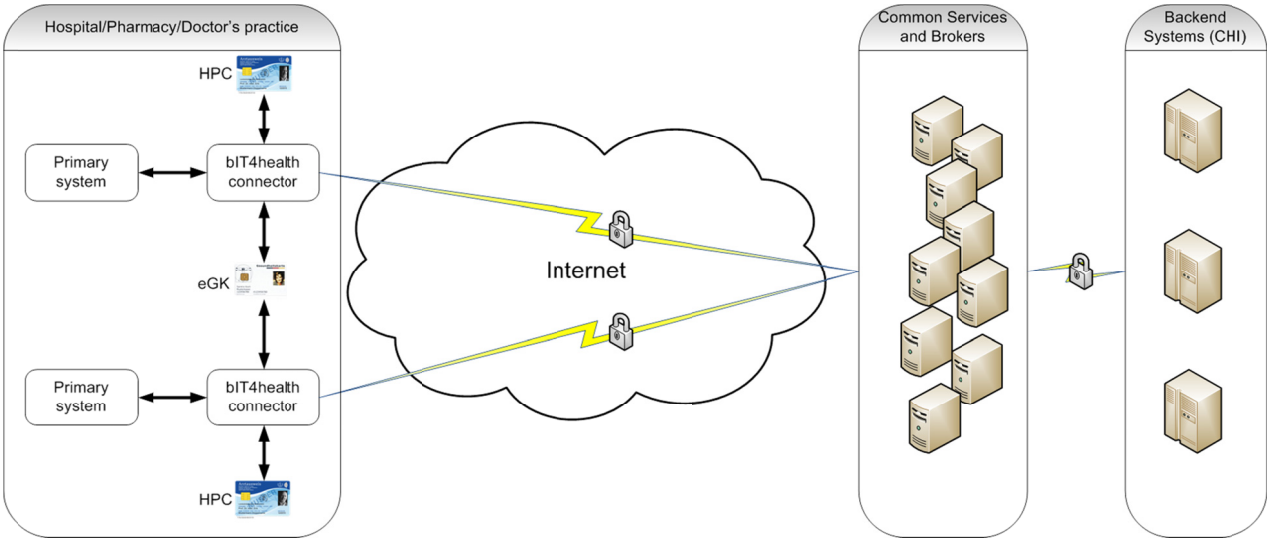

6) Patient's receipt

The last application defined by law is the patient's receipt. Usually, an insurant of a compulsory health fund does not have to pay for his treatment and thus neither sees a bill nor does he know what his treatment is costing the health insurance. The patient's receipt is a document telling the patient, how much his treatment actually costs. The reason behind this is twofold. Firstly, the patient shall be sensitized to the costs his treatment is causing. It is hoped, that with an improved cost -consciousness comes an improved health -consciousness. Secondly, in order to prevent invoicing fraud, the patient should check that the treatment the doctor bills to the health insurance is the treatment he received [10].

IV. Architecture

The architecture for the eGK project consists of several parts. In the doctor's practices, pharmacies and hospitals *primary systems* like hospital information systems (HIS) exist. These systems will be connected to the *telematics infrastructure* by means of the so-called *bIT4health connector* which is a certified black box product that provides a VPN-secured connection to the telematics infrastructure over the internet. The *telematics infrastructure* provides access to services needed for the various applications. Those services include common services such as a time service, a name service and a services directory service as well as the services needed for the applications themselves like a service to manage a patient's master data. The latter are provided by the individual health insurance funds and run on their *backend systems*.

The eGK is the patient's key to the telematics infrastructure. It is a smartcard and contains a certificate to authenticate him against the system [13]. Additionally it provides encryption features and can carry additional information such as the patient's emergency data and pointers to other data within the telematics infrastructure (eRezept, eArztbrief or ePatientenakte). With the eGK the patient has complete control over his data. He can view the data that is stored on his card or in the telematics infrastructure about him, restrict access to it or even delete parts of it like a prescription not filled. All of the patient's data is encrypted using a combination of symmetric and asymmetric encryption technologies [12]. Access to the eGK is secured with a PIN as known from mobile phones or cash cards.

The HPC (health professional card) is the doctor's equivalent of the eGK. With the HPC, a medical service provider authenticates himself against the telematics infrastructure. Together with the patient's eGK (and his PIN) the health professional can access the patient's data, add new entries – e.g. to an electronic health record – or store a prescription which he signs with his HPC. In addition to the HPC, a doctor's practice is authenticated using a secure module card (SMC). With a SMC, the practice personnel can access a patient's master data without the presence of a HPC thus simplifying processes. Beforehand, the SMC has to be initialized with a doctor's HPC though. Different types of SMCs are planned, for example to facilitate the signing of prescriptions by using RFID tokens or finger print sensors.

V. Security and Privacy

When the eGK was designed, special emphasis was put on security and privacy aspects. The *telematics infrastructure* was designed from the beginning, such that the patient is master over his own data [14]. Therefore, every patient's data can only be accessed with his consent. This is expressed by the patient's need to insert his eGK into a smart card reader and to enter his PIN in order for the health professional to access the patient's data. There is only one exception to this rule. In case of an emergency, a health professional can access a patient's emergency data with his HPC. This is to ensure that vital data can be accessed even when the patient can't give his consent, e.g. when he is unconscious. The patient's consent is implied though, because the emergency data application is an optional application and the patient had to agree on the usage beforehand.

The optionality of the advanced applications like the ePA

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also expresses the patient's right to determine the use of his personal data as demanded by the German Supreme Constitutional Court (Bundesverfassungsgericht, BVerfG). Additionally, the planned telematics infrastructure meets state-of-the-art security standards preventing unauthorized use of a patient's data [15].

VI. State of affairs

For developing the software and hardware specifications, to invite tenders and to test the components, the joint self government founded the Gematik (Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH). In accordance to the GMG and the by-law about the execution of tests for the introduction of the eGK [16], the Gematik defined several releases. All releases will go through three test stages. In the first stage, components like smartcards, card terminals, connectors and primary systems are tested in a laboratory environment. In the second stage prospective users of the telematics infrastructure, i.e. doctors, their assistants, pharmacists and patients, test the components in a controlled environment. The third stage is a field test, where the components are tested in the field. It was planned to do field tests with 10.000 and 100.000 users but in August 2008 the 100.000 users test was cancelled because the responsible politicians felt, that the results of the previous tests yielded enough positive results to proceed straight to the basic rollout.

Release 0 (currently 0.5.2), also called basic rollout, only contains the proof of eligibility to receive medical service. It defines the layout of the eGK, what part of the patient's master data has to be printed on the eGK and what data it has to hold. This release is an offline release, i.e. no connection to the telematics infrastructure exists.

Release 1 (currently 1.3.1) is an offline release too, but additionally contains specifications for the storage of electronic prescriptions (eRezept) and emergency data on the card itself. This release corresponds to the first test section as postulated in [16]. Release 1 is being tested since mid-2007 in seven test regions. The tests have shown that the new eGK poses a massive interference with current processes in doctor's practices and pharmacies. It takes for example longer to read a patient's master data from the new eGK then from the old patient's card [17] and even much longer (about 15 seconds) to store an electronic prescription on the card [18]. Preliminary results from the test region Schleswig-Holstein even led to the cancellation of the tests there in March 2008 [19]. All HPCs had to be replaced because of wrong certificate attributes and 30% of the 25 participating doctors locked their HPCs due to wrongly entered PINs. 10% of these even locked their HPCs irreversibly. 75% of the 7553 issued eGKs were locked due to wrongly entered PINs or attempts to store emergency data on the card without the presence of a HPC. The primary reason for these problems is the handling of the eGK with up to 3 different PINs which is problematic especially for elder people. Before the tests even started, the test region Bremen cancelled the contracts for the tests in November 2006. The Association of Statutory Health Insurance Physicians Bremen concluded that there is almost no benefit for the physicians with the current plans of the project. Medical or economic benefits would only come with the introduction of the eArztbrief and the ePatientenakte which were neither specified nor planned at that moment [20].

Release 2 (currently 2.2.3 and 2.3.4) correspond to test sections 2 and 3 as postulated in [16]. With theses releases, the online validity check of the patient's master data as well as the online storage and retrieval of prescriptions and the emergency data are to be tested. Release 2.2.3 is the release for the second stage test, i.e. a test with prospective users, whereas release 2.3.4 is the release for the field test with 10.000 users.

On December 12, 2008, the basic rollout started with the installation of the first card terminal compatible with the new eGK and the telematics infrastructure in the Nordrhein region [21]. In the next months, patients and doctors in this and neighboring regions will get their eGKs, HPCs and card terminals.

On December 15, 2008, the Gematik decided to begin with the online rollout of the telematics infrastructure, i.e. with the building of the concrete services. Focus will be on a service for the patient's master data that will provide online validation and actualization of a patient's master data and the eArztbrief [22]. Software and hardware vendors are displeased with this shift of focus because they concentrated on implementing the eRezept and the emergency data management applications [23].

VII. Criticisms

Criticism on the eGK and the telematics infrastructure comes mostly from doctors and civil rights groups. Doctors fear that the storage of sensible medical information on central server systems will negatively influence the doctor-patient relationship. They fear that the data can easily be accessed by third parties. They also criticize the cost distribution. They fear that they will have to raise most of the investment costs, whereas the health insurance funds are the actual beneficiaries of the new eGK and the telematics infrastructure. This led to an official rejection of the eGK in its planned form through the German Medical Association in May 2008 [24]. The decision of the Gematik to include only the patient master data management service and the eArztbrief in the online rollout can be seen as an answer to criticism in a position paper on the eGK of the German Medical Association [25].

Civil rights groups like the Chaos Computer Club (CCC) criticize the central storage of medical data and the data security of the planned eGK and the telematics infrastructure [26] as well as the costs for the project that will amortize in 10 years at the earliest [27].

VIII. Conclusion

The planned eGK and the telematics infrastructure is one of the biggest ongoing IT projects in Germany. With the new eGK and its mandatory applications, health insurance funds can reduce their costs and thus the insurance contributions. With the optional applications like the planned electronic health record, the quality of a patient's treatment can be improved and costs can be saved by

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avoiding multiple examinations on the same subject. Unfortunately the main focus was set on reducing costs for the health insurance funds, thus provoking resistance among doctors and pharmacists. Additionally some far-reaching questionable decisions have been made out of political reasons which might have a negative influence on the overall project [8, 28]. On the other hand, technical experts attest the project state-of-the art design principles [15].

The new eGK and the telematics infrastructure have a great potential. We hope though, that in the future, more emphasis will be put on a user-centric design and the communication of the security and privacy principles of the eGK so that fears among patients and physicians can be reduced.

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