Patient Data to Go: Germany's National Smart Card Project

Save to myBoK

by Bernd Blobel, PhD, and Peter Pharow

Smart cards help keep consumers and their health data in the same place. In Germany, a national project enters the test phase.

It's a major challenge getting patients and their data in the same room. As consumers increasingly receive their care from a variety of providers, their health data becomes increasingly dispersed over a variety of facilities. Because quality care depends on providers having complete, up-to-date information, effective communication among care providers is vital. Providers can keep in touch among departments through local area networks and across organizations via the Internet. Germany, like a number of countries around the world, is exploring an additional method of keeping data and patients together: smart cards that consumers carry with them.

Currently in the test phase, Germany's national plan calls for the eventual distribution of up to 85 million cards to consumers and another 400,000 cards to providers by 2006. The consumer cards will carry e-prescriptions, provide basic administrative and health data, and link to patient history. The cards will be protected with high security standards.

Smart Cards in Healthcare

Over the last 30 years, the simple health insurance card has become increasingly high-tech. The first innovation came with memory cards, magnetic strip cards, and optically read cards that acted as simple storage devices. Like paper cards, basic memory cards can be written once and read many times. The next innovation was the chip card, which can be written and read multiple times and is capable of basic security functions.

The latest chip cards introduced to healthcare are smart cards capable of processing information. Similar to small computers, these cards can store and process data and enact stringent security protocols. In the past decade, such cards have begun to make their way into health systems around the world.

Smart cards can be deployed in several ways. Cards can contain all relevant medical data, similar to a complete traditional paper record. Presumably, a consumer's entire medical record could reside in his or her wallet. Alternatively, the card can be used solely as a pointer, containing links to data stored in networked systems. A combination of the two methods arguably provides the most flexibility.

Processor cards offer advanced security features that expand their potential use in healthcare far beyond that of simple memory cards. In Europe and beyond, smart cards are frequently used as security tools to control access to protected health information.

The basic security principle consists in a certified binding of a principal (e.g., a human user, an organization, a device, system, or application) to a unique electronic identifier. This binding additionally establishes the associated properties and rights (also called attributes) of the principal. Communication security services provide identification and authentication of the communicating principal; availability, integrity, confidentiality, and accountability of the information exchanged; and notary services such as time stamps.

Application security services concern the authorization and access control to data and functions. They further deal with the accountability of principals; audit tracking; the availability, integrity, and confidentiality of data and functions; and notary services.

The German Consumer Card

The German health card—the focus of the bIT4health project—is part of a wider government initiative to implement a comprehensive e-health environment. This platform will link smart cards carried by consumers with interoperable networks where providers store health data and where supporting security services are based. The cards will act as keys to services, carrying a small amount of resident information and otherwise providing links to personal health data stored in networks.

Content of the Consumer eGK Cards	
Insurance information	Emergency health data
Medication history	Private information for patient use only
Electronic prescription	Provider's report
Links to health records	European Union health insurance information
Billing Receipts	

Two sets of cards will comprise the system—one issued to providers and one to consumers. Both cards will replace currently held paper documents. The consumer cards will replace approximately 80 million general health insurance cards now in use. The old insurance cards contain administrative data only; they do not provide identification, security, or medical data.

The new consumer card, called the electronic health card (eGK, elektronische Gesundheitskarte), will be much more sophisticated, capable of storing, updating, and securing a variety of data. It will serve as a health insurance card, a record of immunization and vaccination, an electronic prescription slip, a pointer to the patient's health records, and more. The eGK will accommodate the following data sets:

- Insurance information
- European health insurance information, which allows citizens of European Union (EU) member states to receive care in other member states
- Electronic prescriptions
- Medication history
- Health data for care in emergency situations
- Providers' report
- Links to health records
- Private information entered by the consumer that providers cannot access
- Receipts of patient bills

Use of the insurance information, the EU health insurance information, and the e-prescription function will be mandatory— consumers must make use of these components. Use of the other components will be optional. Consumers may choose to add their past health history to the card, for example, through links to health records. Information on current medications can be supplied either as data residing on the card or links pointing to an online record. How medication information will be added to the cards remains to be decided. Healthcare providers will be required to offer and support all components of the card.

To ensure security and confidentiality, data on the consumer eGK can only be accessed through a card held by healthcare providers, the Health Professional Card (HPC). (An exception is the patient's emergency data set, which may be read without the authentication of an HPC.) The consumer cards will also contain an audit function, which will log approximately 50 different access activities.

The initial functions offered on the card were chosen by their relative impact. The success of the program will be determined in large part by the public's response to the cards—strong adoption by consumers will be key to the system's ability to realize expected benefits. E-prescription was chosen as an initial and mandatory function because it offers significant, immediate improvements in patient safety. Like the US, a main goal of Germany's electronic health platform is a reduction in medication

errors—an estimated 25,000 patient deaths are attributed to medication errors in Germany each year. The business case for e-prescriptions is also compelling. Studies estimate a return on investment from these functions within one to two years.

There is reason to be hopeful that the public will also put the cards' optional functions to use. Consumers have responded positively to a similar though more limited patient health card in the past. More than 95 percent of patients who received the DIABCARD, a card supporting the care of diabetics, reported appreciating or highly appreciating the card.

In addition to improving patient safety and reducing cost, e-prescriptions also represent a core function of the electronic health record. Establishing medication files is a good initial step toward building electronic health record systems.

Standard Patient Health Card Data

The upcoming International Organization for Standardization (ISO) standard 21549 "Health Informatics—Patient Healthcard Data" provides data standards to guide the development of interoperable patient health cards.

The standard is a result of collaboration between ISO technical committee 215 on health informatics and CEN/TC 251, European Standardization of Health Informatics. It replaces the European Prestandard ENV 12018, adopted by CEN in 1995.

The new standard consists of the following eight parts:

1. General structure
2. Common objects
3. Limited clinical data
4. Extended clinical data
5. Identification data
6. Administrative data
7. Electronic prescription
8. Links

Data carried on the card can be categorized in three broad types: identification (of the device itself and the individual carrying the card), administrative, and clinical. Cards may support collaboration with network-based systems. For that purpose, any type of link information has been specified.

The following figure illustrates the overall structure for patient health card data according to ISO 21549.
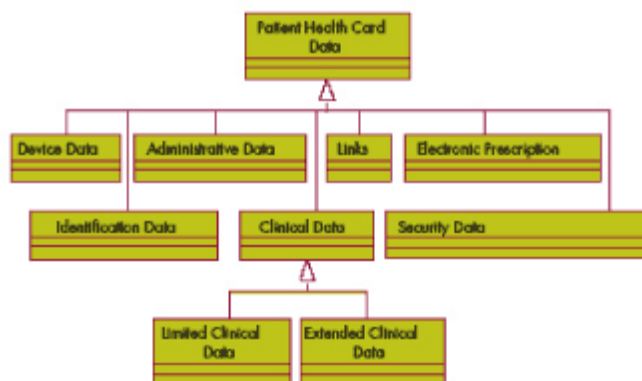
The Health Professional Card

The HPC will be issued to all physicians, pharmacists, and service providers. In addition to acting as a key to consumer cards, the HPC will serve as the provider's personal identification card and will replace the current professional license document.

The provider cards will be issued in advance of the eGKs. The new cards are expected to introduce immediate benefits even before the consumer cards are in use. The HPCs will enable legally valid electronic signatures and facilitate secure exchange of information between providers and networks.

Authentication

The HPC performs five basic functions. It is personalized with the care provider's name and picture, serving as a typical identification card that will identify the provider in settings such as home care and healthcare facilities. It will also serve as a basic electronic certificate, providing simple authentication to any digital device it is presented to. This level of authentication is an intentionally fast and simple method, to be used in secure settings, since there is no special security against theft of the card. This trade-off between security and simplicity is intended as a direct electronic analogue to the physical presentation of the paper identification card currently used.

The HPC also supports much more stringent authentication procedures. Each card will carry the private key of the provider's unique asymmetric ID key pair. For the advanced security services, a public key infrastructure will be put into place. Virtually any reader unit will be able to look up a provider's public key and use it to check the private key on the card being presented. This enables strong security in an otherwise unsecured environment.

Another key pair on the HPC will support the implementation of hybrid, symmetric-asymmetric transport encryption. In such systems, transportation protocols such as HCPP and S/MIME define how the messages interchanged are to be encrypted and decrypted. The final authentication element of the HPC is the private key of an asymmetric key pair for legally binding electronic signatures, according to the German signature law. The specifics of the health professional are contained in a number of attribute certificates appended to the provider's signature. A special institutional card to be plugged into a secure device will allow for team-based operations such as pharmacies.

The components of the HPC include:

- Elementary files at the master-file level for general data objects and the card verifiable certificate
- Applications providing the following services:

    - Electronic identification of the health professional
    - Electronic signature creation
    - Client-server authentication
    - Document decipherment
    - Card-to-card authentication (e.g., HPC-eGK and HPC-SMC)

- Cryptographic application providing information for the primary system (e.g., a doctor's office system) to support the communication between the system and the HPC

The HPC security mechanisms require different types of end-user certificates: e-signature certificates, authentication certificates, and key enciphering certificates. Additional certificates without a key (so-called attribute certificates) complete the card infrastructure. Attribute certificates in the context of the German HPC do rule certain aspects of permission and qualification.

Pilot Projects

Currently HPCs are being implemented in several regional pilot projects. The pilot regions provided application specifications based on the national standards but varied to meet regional conditions (e.g., vendor dependencies and specific diseases in specific regions).

The pilot regions have about 10 months to implement their regional architecture and infrastructure, distribute cards, and test applications, infrastructure, and interfaces. The regions will then have two more months to show interoperability between

different vendors (e.g., desktop computers, cards, and readers) as well as show interoperability between trusted third-party service providers.

The experiences of the test regions will then be reviewed and evaluated, and conclusions and best practices will be shared with nonpilot regions. This phase will encompass an estimated six-month period as improvements are made in order to start the real deployment process. The initial plan called for all cards—both to providers and consumers—to be distributed by January 2006, but given the complexity of the project and the very heterogeneous structure of state-run health systems in Germany, a later date is expected.

The German project is ambitious, and it promises major returns in greater patient safety and more cost-effective care. It also lays the foundation for innovative electronic health record systems. HIM professionals in the US and elsewhere will have learned much by the time the first eGKs reach the hands of German healthcare consumers.

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Acknowledgment

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