

Modernizing healthcare in Germany by introducing the eHealthcard

The Action Programme Information Society Germany 2006 and the Healthcare Reform

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Germany has a healthcare system using sophisticated technologies. But the sector-oriented service structures and pillars of our healthcare system are also reflected in the area of ICT. In the German healthcare system every institution in itself is an isolated solution, partially in line with the latest scientific research, but singular. As a rule, the limits of information technology are reached where the economic and business capacities of one's own institution are exhausted.

Therefore the existing solutions regularly have to cope with the problem of incompatibility, only in exceptional cases there is a well functioning interoperability. Consequently, the essential advantage of telematics, which is in particular the use of synergistic benefits, is given away. Also the advantages offered by disease management programmes which do not focus on the structures of services but on persons, could still be consolidated by digital documentation covering and connecting a broad range of institutions.

Therefore both the infrastructural conditions for the use of telematics have to be improved and also important key applications such as the electronic prescription have to be boosted. By introducing the new electronic health card, the nationwide use of health telematics in Germany can be promoted. The activities of the Federal Government and the legislation initiated within the scope of the Act on the Modernization of the Statutory Health Insurance (Health Reform 2003) serve these improvements.

The Federal Government is striving for a nationwide and cross-institutional networked use of information technologies.

The resolution unanimously adopted at the 75th Conference of Health Ministers in 2002 showed that nowadays the stakeholders consider telematics to be generally indispensable. For the first time the provision of quality-assured health information e.g. by establishing health information portals for

the general public is formulated as a public function of the Federal Government and the Laender.

The Working Group of the Federal Government and the Laender on Telematics in Health Care has been commissioned to develop, in co-operation with the Federal Ministry of Health and Social Security, a national strategy for the nationwide and interoperable use of health telematics applications, connected with a binding plan describing the steps of implementation. This is a joint task of the Federal Government, the Federal Laender and the self-governing bodies in the healthcare system (Selbstverwaltung).

To this end, the basis of the Federal Government's work will be the agreement reached with the central organisations in the healthcare system on a joint action for the further development of telematics. In their declaration of 3rd May 2002 the Federal Ministry of Health (and Social Security) and the central associations of self-administration committed themselves "to develop a new infrastructure for telematics on the basis of a general framework architecture, to improve and/or introduce the electronic communication (electronic prescription, electronic discharge letter by the physician) and to introduce the former health insurance card as an electronic health card in the future". The stakeholders agreed that they wanted to find joint solutions to further details, functionalities, standardization, and financing because of the common benefit to be expected.

For this purpose a Steering Group on Telematics has been established where all stakeholders involved are represented, ranging from the Federal Government Commissioner for Matters related to Disabled Persons via the Data Protection Commissioner, the self-governing bodies, the patients' representatives up to scientists. Its tasks include the formation of political consensus and the

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development of a national strategy for the use of health telematics.

These measures are accompanied by activities of the Action Forum on Health Telematics and of the German industry, and furthermore by research and pilot projects of the Federal Ministries of Education and Research and of Health and Social Security which will develop and test approaches to solutions in specified problem areas. This includes the prerequisites for quality-assured health information portals for the general public on the Internet. A particular important measure is the funding of the fundamental project of IT architecture: "bIT4health – better IT for better health".

The German activities are connected with the European agreements to establish infrastructures for health telematics (eEurope 2002 and eEurope2005 Action Plans).

- The objective is the standardization of a communication infrastructure based on a harmonized framework of IT architecture promoting competition. The electronic health card has an important role as a flagship project in building up an infrastructure for telematics.
- In 2006, 80 millions of electronic health cards, giving also access to medical data, are to be distributed to persons insured under the statutory and private health insurance scheme.
- The use of the electronic health card is linked with an electronic health professional card (HPC). A corresponding initiative has been launched by the Laender for this purpose – parallel to the activities of the German Medical Association. By the year 2006 about 300,000 HPCs with a digital signature could be distributed.
- As of 2006 it will be feasible to electronically deal with about 750 million prescriptions every year. Since the electronic prescription offers the opportunity of connecting the drug documentation with drug information systems, the side effects and undesirable interactions

of pharmaceutical products can be considerably reduced. In conjunction with the drug documentation the electronic prescription will lead to an improved supply of pharmaceutical products and to annual savings amounting to more than 1 billion euro.

- The electronic prescription is also meant to support the electronic commerce with pharmaceutical products in Germany and other states of the European Economic Area, which will become possible as of 1st January 2004.
- The electronic health card is the lead-in to the electronic patient record.
- The distribution is connected with the introduction of the European health insurance card (carried on the reverse side substitute for the European health insurance certificate E-111. In a first step, the card will be issued in an "eye-readable format" but offering the possibility of integrating electronic data sets. By the year 2008 decisions are foreseen on the transition to an electronic health card. The decisions reached in Seville and the eEurope 2005 Action Plan envisage the extension to further functionalities, e.g. the storage of emergency medical data and the accessibility of electronic patient records.).

Infrastructure and framework architecture of telematics

The systems which are used also have to be capable of communicating electronically. A prerequisite for this is the concept of a general structural framework of telematics and an adequately integrated security infrastructure.

"bIT4health – better IT for better health" – this was the approach by the Federal Ministry of Health and Social Security when the task of providing support for the introduction of the electronic health card was launched. Its objective is the lasting standardization of an information structure,

based on a harmonized sustainable architecture of telematics. The results should be generally valid and should be neither affecting competition nor depend on the respective product. A migration concept is being developed for the procedures and components so far. In this way the ability to plan sustainable and to achieve added values is assured for all stakeholders.

The foundations have already been laid by European projects as e.g. TrustHealth and PICNIC as well as by recommendations on telematics by the German industry. Groundwork was also done by Teletrust e.V., the working groups of "BundOnline" and the Action Forum on Health Telematics. The existing activities have to be closely interlinked with one another. All decisions within this project should be made in transparency and be discussed with the authoritative partners of industry and the self-governing bodies. The final agreement on a framework architecture for telematics in the German healthcare system is to be reached within the Steering Group and according to § 291a SBG V.

Electronic health card

In his policy statement of 14th March 2003 – accompanying the "agenda 2010" – the Federal Chancellor Gerhard Schröder acknowledged "that we have not fully exhausted the potential inherent in a modernization of communication technology in the health service". In this connection he announced that in addition to the electronic patient record, an electronic health card is to be introduced by 1st January 2006. Now that the Act on the Modernization of the Statutory Health Insurance has been adopted by the Bundestag and the Bundesrat, the legal basis for realizing this project definitely exists.

Electronic health cards and HPCs will become the electronic keys for the cross-institutional co-operation of the stakeholders in healthcare, interlinking more than 80 million patients with about 270,000 physicians, 77,000 dentists, 2000 hospitals, 22,000 pharmacies and more than 300 health insurance funds.

In its function as a second generation patient chip card, the electronic health card

is going to replace the now available electronic health insurance card. Its technology and functions will be extended and it shall be offered to the insured persons for use as a health card.

For this purpose it is necessary to arrange the health card as a microprocessor card which is suitable for electronic identification, encryption and digital signature. In this way the best possible reliability and security of the data can be guaranteed.

As a rule, the use of the new card as a health card shall be voluntary. This means that every insured person will receive a new electronic health card with its administrative functions, but it will be left to his/her discretion whether he/she wants to make use of the additional functions, i.e. the medicinal part, or not. The use of the administrative part of the electronic prescription shall become obligatory.

The electronic health card has a particular significance for enhancing links between the patients' data which are distributed and documented at different places. In its function as a link between the electronic prescription and the electronic patient record it does not only improve the emergency medical treatment and/or the drug and therapy safety. New applications of telematics are being developed and/or may occur.

The electronic health card is a communications interface between the various bodies responsible within the German healthcare system – in the patients' hands. Holding their cards and on the basis of their authorization they are deciding themselves on whether and which additional information is stored and who may be given the right to access. The implementation of their already existing rights to have access to the documentation themselves and to receive hard-copy printouts and/or copies of it, will be facilitated. In connection with their personal signature card bearing a qualified signature, they may also handle their personal data or data made available to them by their physicians in a particular personal folder. For data protection controls every access is recorded and the last 50 ones are stored.

One of the essential preconditions for the acceptance of the card is a convincing data security concept. During the last legislative term the amendment of the Digital Signa-

ture Act provided an important prerequisite for a secure communication within the healthcare system. Apart from a few controlled exceptions, the use of the electronic health card shall, as a rule, only be possible in connection with a health professional card (HPC) bearing a qualified digital signature.

Electronic patient record

The electronic health card serves as the basis and thus also as a lead-in to other applications of telematics, as e.g. the electronic patient record.

Within an infrastructure of telematics and on a medium-term basis, the electronic patient record is an important patient-related information link for the various bodies responsible for healthcare in the outpatient, in-patient, rehabilitation and nursing care sector. It provides for the informational basis for integrated healthcare and disease management programmes. Thus far there are only isolated solutions and proprietary offers – both at national and also at European level. At European level, however, the concepts are currently being driven by the initiative “EUREC” (European Medical Record) with the participation of the German industry and by the work of the Action Forum on Health Telematics.

Yet, important aspects of data protection have to be settled. The rights of access to patients’ data being stored in various places but virtually integrated in the electronic patient record have to be defined. To this end, new IT solutions are being developed which have to be extended. In this connection the civil liberties of the patients to the protection of their data have to be balanced with their right of the best possible treatment. In this context the introduction of the voluntary concept of the electronic health card is a pragmatic intermediary step emphasizing the patients’ rights with regard to control over and release of their medical data.

Electronic prescription

In today’s processes the prescription undergoes several expensive discontinuities of media. The largest part of the about 750

million prescriptions per year is issued by PC, then, however, they are printed for the patients. Later on the pharmacies pass the paper prints to their data processing centres for scanning and for the purpose of reimbursement by digital processing and from there they are sent to the health insurance funds.

The electronic prescription improves both, the writing and issuing of the doctor’s prescription and also the subsequent processing and accounting procedures. To this extent the electronic prescription is an example of best practice of a telematics application which pays its way economically, even in the short term.

The interaction of drug documentation and drug information systems decisively improves the quality of treatment. Undesired side-effects can be avoided more easily and personal incompatibilities can be taken into consideration.

At the same time a more efficient and rapid communication between physicians, pharmacies and health insurance funds becomes possible – without discontinuities of media. By inclusion of all stakeholders of healthcare, the electronic prescription is therefore attributed a key role in the introduction of information and communication technologies in healthcare.

Evaluation, transparency

In view of the increasing relevance of IT applications in healthcare, adequate framework conditions for introducing further applications of telematics have to be developed and stipulated. Prior to the selection of concrete telematics applications and systems they have to be evaluated on a technical, economic and medical background (HTA). Surveys on procedures applied in practice or still being developed have to be elaborated and assessed systematically (determination and selection of best practices). As a basis on the way to this end, the “TELA” database is currently being established in co-operation with the Federal Laender and harmonized with the corresponding European activities of the eEurope 2002 Action Plan. It shall be made available to the general public and accompany the development of evaluation procedures for telematics applications.

Patient empowerment

With the increasing use of the Internet the patients can be given opportunities of information connected with a rapid, simple and low-cost access to medical knowledge, in the interest of an improved health promotion and preventive healthcare. At the same time, however, the risks of health information imparted via the Web are growing, since to a large degree its quality and reliability are beyond any regulatory influence. Top quality information as well as dubious publications, useful pieces of advice as well as dangerous recommendations can be found there. At the same time the Web technology serves as a basis for new forms of commercial offers (e-commerce) and new possibilities for the arrangement of product-related advertising (interactivity, linking, combination of advertising messages with reliable health information).

Well-established methods of quality controlled publication are working to an only very limited extent on the Internet. The more important are those procedures of quality assurance which develop efficient quality seals for the orientation of Web users. In the interest of the patients, the origin of recommendations has to be transparent on the one hand, and their medical reliability has to be ensured on the other hand.

The "eEurope 2002" Action Plan has created a European framework by elaborating a key set of common quality criteria.

At the same time the Federal Government initiated the Action Forum for Health Information Systems (AFGIS) where in the meantime more than 150 suppliers of health information services, bodies responsible for health education as well as institutions and organizations in the fields of consumer and patient protection as well as of quality assurance have joined to build up a quality network. In this way reliable health information on various topics is available to both, the health professions and also to the patients.

The standards and structures for quality assurance and quality control which have been developed in the AFGIS working groups receive considerable attention at an international level, too. When the EU quality criteria for health-related Web sites

were elaborated, AFGIS participated as a non-governmental organization on behalf of the Federal Republic of Germany. The transparency criteria adopted by AFGIS correspond to the European quality criteria recommended for health-related Web sites. Therefore the Federal Government continues to support the application of this model scheme in the appropriate EU committees.

Moreover, there are endeavours to develop and test the conditions and structures for a public health portal of the Federal Government operationalizing the criteria of AFGIS for a central public health portal.

In this way IT is now ready to serve as the major tool for the modernization of the German Healthcare System, improving quality and efficiency at the same time, within a new eHealth environment.