



Your medical history all on a smart card

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You are suddenly taken ill in the middle of a country where you do not speak the language and you cannot explain in detail your medical history. What do you do? You use sign language as intelligently as you can, and hope for the best.

In a few years, assuming the standardization process proceeds smoothly, this will soon be a problem of

the past: you will carry your health card with you, where your medical history is instantly clear to the practitioner wherever he or she is, who can ascertain what he or she has to do with a minimum of dialogue.

Being able to carry a secure card that holds, or gives access to, your medical records is a powerful tool in improving patient care.

By using smart cards, medical professionals are able to access the patient data they need much more quickly and reliably than conventional paper file and document methods, saving invaluable time and expense – and time may be at a premium. Even though there are some tricky problems to be resolved – ethical as well as technical – such cards in healthcare are almost certain eventually to become an everyday part of our lives – and improve them greatly.

Working group 5 on Health Cards of ISO/TC 215, Health Informatics, came into being in April 1999, and at its initial meeting in October drew up a plan of potential work. Four work items have now been officially approved and are already well advanced – others are in different stages of development. Below the author surveys the health card scene and studies one standard specifically – ISO/DIS 21549, Health informatics – Patient health card data, that could have rapid and important repercussions and an influential future.

What is a health card?

A health card is a card containing computer-readable data that is issued to a patient or healthcare professional to facilitate the provision of healthcare. Since the late 1980's, there have been a number of projects involving health card trials. More recently, some countries in the European Union have planned or instigated major national or regional implementations of the health card.

Several different technologies can be used to allow computer-readable data to be stored on a health card. These include bar codes, magnetic stripes, integrated circuit memory cards, integrated circuit smart cards and optical memory cards. There is a range of uses for health cards in healthcare information systems. These include administrative functions, emergency health cards, records of speciality-specific care, and general patient-held medical records.

The field is already vast, and growing in complexity, size and potentialities for health cards as new horizons open up. But it is crucial for their use to develop optimally that overall, globalized, interoperable systems exist; unless such systems come into being, the applications can only be partial and fragmented. Recognized International Standards, developed by international consensus and accepted worldwide, have an important role to play to ensure their emergence.

What is health card interoperability?

Interoperability between health card systems is the ability of one health card system to read, use and/or update the data, on health cards issued by another health card system.

A "health card system" is the sum of the health cards issued and all the hardware and software used in a particular implementation. The considerations about interoperability apply, at one extreme, to two identical systems and, at the other extreme, to two completely different systems, one or both of which have been extended in some way to allow access to health cards issued by the other.

Many of the suggested benefits of health cards derive from the portability of health cards across geographical and organizational boundaries. However, even where two or more projects use the same technologies for the same range of functions there are variations and incompatibilities between implementations. There is, therefore, a strong case for concerted efforts to develop interoperable health card systems.

Interoperability is considered to be one of the most important prerequisites for widespread use of health cards. Many of the potential clinical and administrative benefits depend on widespread use, so that interoperability is a key to unlocking these benefits to the realization of a global market for, and use of, health cards.

Enter ISO/TC 215/WG 5, Health cards

Currently within ISO/TC 215, *Health informatics*, WG 5, *Health cards*, 49 experts from 18 different nations have been nominated by their national standards bodies, and are hard at work bringing harmonization of systems and interoperability into this fast-moving sector.



The working group's "kick-off" meeting was held in October 1999 during the "Health Cards 99" international conference. ISO/TC 215/WG 5's brief was to produce standards in the field of healthcare usage of machine-readable cards compliant with the physical characteristics, including dimensions, defined in ISO/IEC 7810, *Identification cards – Physical characteristics*. The WG was to place special emphasis on technology-independent data structures leading to interoperability and compatibility, including the communication of data.

WG 5's mission was to focus on cards used to identify both patients and healthcare providers both as individuals to information systems and in terms of record linkage. It had also to focus on patient data cards intended to convey a healthcare data set of medical importance that was not necessarily immediately available or useable by other means. From this scope, it is obvious that the emphasis lay on developing standards for *the content* of cards and not on the *techniques*. The latter is covered by other groups, such as the ISO/IEC JTC1/SC 17, *Information technology – Identification cards and related devices*, that has developed, among other standards, the important series ISO 7816, *Identification cards – Integrated circuit(s) cards with contacts*.

Though the standards have to be "technique independent", the group only considers cards produced according to ISO/IEC 7810, *Identification cards – Physical characteristics*, i.e. only cards which are the size of a credit card.

Standardization – regional experience

WG 5 had some groundwork and experience of studies and trials carried out in different countries, regions and arenas to help them. The most recent European document is the eEurope Smart Card Initiative's white paper "Smart Cards as Enabling Technology for Future-Proof Healthcare: A Requirements Survey" (<http://www.europe-smartcards.org>)

The results of this study are expected to form the central element in the European Union input into this wider international initiative. The main theme of the strategy is to re-use rather than re-invent. The published standards from ISO and CEN (the European Committee for Standardization), existing work of European Union-funded projects, nationally endorsed initiatives, and relevant industrial contributions will be adopted wherever possible. The task is to assemble this existing work, if necessary identifying pragmatic profiles and subsets, to deliver results that meet the perceived needs for functional interoperability.

Work ahead for ISO

In the course of its first meetings, the WG 5 group discussed five possible new work items, which in the meantime have been further refined and revised a number of times :

- Extension of European registration standards to cards
- Technical report for the use of cards in healthcare
- Electronic prescription on cards
- References and record linkage (Links)
- Patient health card data

We look below at these each in turn, and before studying in detail the latter key item, ISO/DIS 21549, *Health informatics – Patient health card data*.

Extension of European registration standards to cards

This item of work specifies identification cards and the extension of the two European standards, EN 1387, *Machine-readable cards – Healthcare applications – Cards: general characteristics*, and EN 1867, *Machine readable cards – Healthcare applications – Numbering system and registration procedure for issuer identifiers*. The problem is the absence of a registration authority. However on the ISO

Putting fears to rest

overcoming reticence to the use of health cards



The use of personal health data is a very delicate subject : users need to be convinced that the risks of public revelation of health data (patient transparency) are not founded. Such fears are real and need to be analysed in order to be allayed, even though the risks involved in health cards are hard to assess. Those that are in favour of the cards underline their manifest and manifold benefits : lower administrative costs and better attention given to the patient that come from having fuller and more precise information. But even this latter point can, however, also come under fire, as mere information in the form of bald facts can give rise to new problems – although not disputed by the doctors – such as to how to define areas of responsibility, which parts of the card they should be able to “ read ” in order to prescribe the correct medications, etc. Other doubts have to do with emergencies and the use of biometric functions, as, for example, the possible difficulties to decide whether a patient who is unconscious has his or her own card or that of someone else in his or her wallet or purse.

A study carried out by the European Commission (EUROCARDS action) has shown that in many European countries thinking of introducing the smart card in its health systems, the card was not considered as an isolated object in itself but as a technology linked to within a more global system of communication. EUROCARDS recommends the following order of priority for cards : **1. administrative cards that have administrative purposes ; 2. cards for medical professionals ; 3. cards for emergencies ; 4. cards for patients.**

Smart cards are a key element in the application of telematics to medicine. Interoperability between systems of health cards aims to allow the administrative information and emergency clinical information, stocked in various separate health cards, to be read by healthcare professionals using different computers and different software. This is one of the preoccupations of the G7 project on global health services.

The existing health cards show the administrative benefits to be derived from using the information to identify the patient, social security, health insurance, etc., in Europe, in particular, in Germany, France and Slovenia. The smart card is considered the key to getting into the present-day telematic infrastructure, weighed up against the necessary identification of the user and the needs of security ; also a means to supplement and integrate the existing physical infrastructure to transfer data where the bearer of the information is the cardholder moving from one point of service to another.

level, there exists ISO 7826, *Information technology – General structure for the interchange of code values – Part 1: Identification of coding schemes*, and Part 2: *Registration of coding schemes*. These two International Standards had been accepted as working drafts in March 2001, and experts were nominated to examine them under the chairmanship of Japan; this group has set out to adapt the “old” European standards and hopefully to have them adopted as International Standards in a near future.

Technical report for the use of cards in healthcare

This proposal was made by the USA at the first meeting, recommending a technical report on the use of cards in healthcare, and was supported by all countries. Subsequently, the group decided that this was not a topic suited to an “International Standard”, but it will be worked on voluntarily within the group.

Electronic prescriptions on cards

From the outset, one of the major topics of WG 5 has been electronic medication prescriptions. During discussions it soon became obvious, however, that many national definitions already existed, e.g. in Australia. It was thus agreed to start with an investigation of already-existing standards, and to decide after that whether a specific format for “electronic prescriptions” on cards is needed. It was also agreed that, particularly in this case, a closer link to the working group ISO/TC 215 WG 1, *Health records and modelling coordination*, needed to be established.

The group finally decided to go for an International Standard, but to integrate the electronic prescription into the Patient health card data standard (ISO/DIS 21549). At the last meeting in April 2002, discussions centred round whether to have a comprehensive electronic prescription including full medical history or merely “medication data”. This is part 7 of the overall ISO/DIS 21549, *Patient health card data*, and has re-

cently been adopted as a CD (Committee Draft).

References and record linkage

Much debated was the need for a standard on the storage of references and links to specific data items. Some were of the opinion that this should be covered by a standard for a patient data set, while others wanted to aim for an additional standard and to consider each possible link to networks.

The group was aware that this was not a topic specific only to cards, but they were not aware of any other ongoing work on standards in that area. Finally, it was decided to have this topic also integrated into the overall standard on Patient health card data.

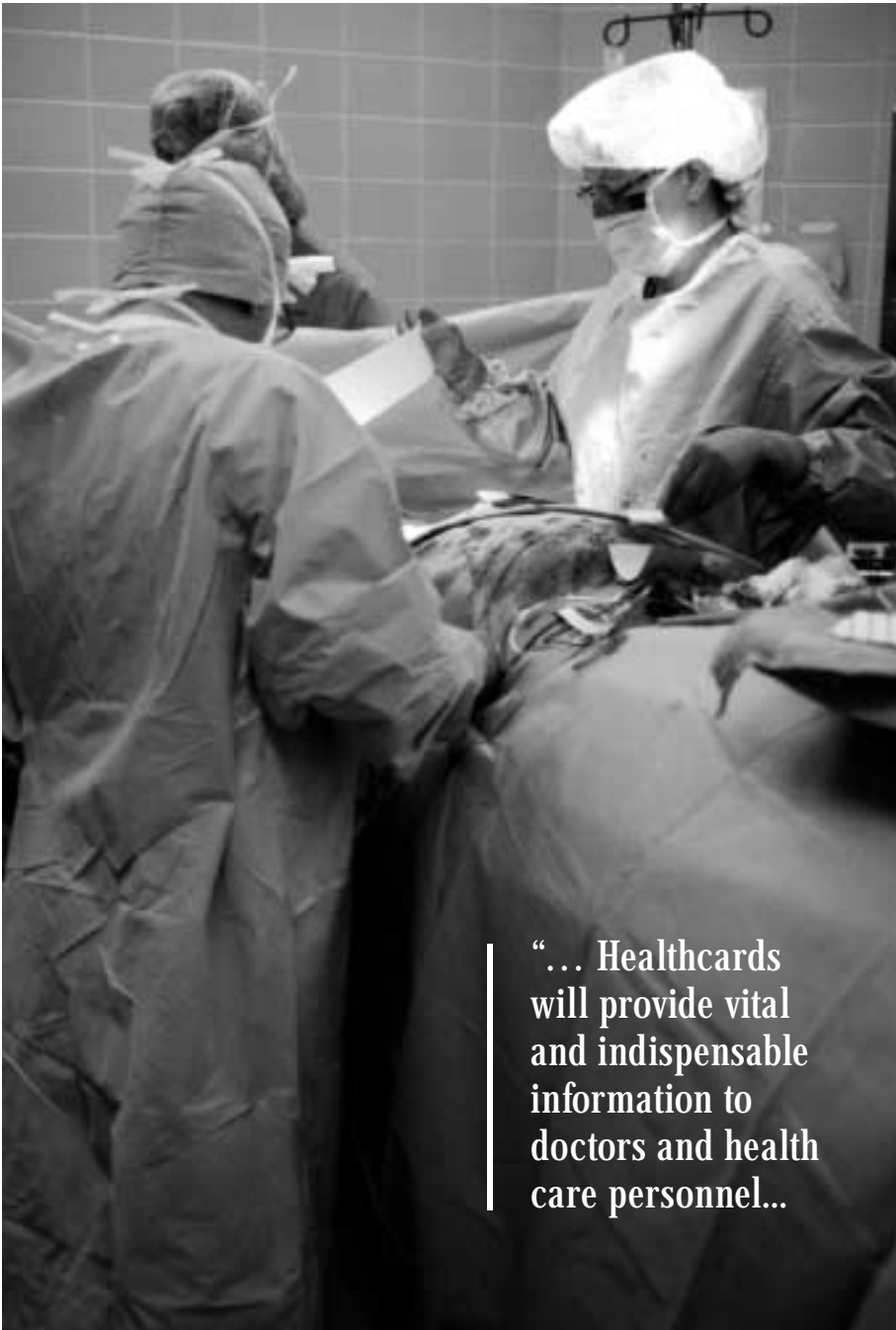
Patient health card data

A natural work item – and a key, “generic” one – was the definition of a patient data set for cards. There is existing work in this area, e.g. the European Pre-standard ENV 12018, *Identification, administrative and common clinical data structures for intermittently connected devices used in health care (including machine readable cards)*, which is currently under revision, and



Where health cards have been introduced, the approach has to be delicate, as trust in their confidentiality and effectiveness needs first to be won and uptake may take a little time. In Taiwan, for instance – a recent example of acceptance of a national card, that includes health data – the IC health card rollout marked a major milestone in the technology advancement of health services, and there are to be multiple stages in this project, such as ongoing infrastructure upgrades, public education and acceptance of the new card system. “We will employ the latest technology to ensure a smooth transition and operation for both health professionals and card users,” said Louis Liu, General Manager of Department of Planning and Evaluation of BNHI. “To this end we are working closely with the public and healthcare providers to anticipate the future needs of card users and to respond quickly to different user scenarios,” added Mr. Liu.

In Europe, Austria is currently introducing a national Health card system and Germany is planning to replace its nationwide insurance card (memory card) by a processor card with medical data included on it also by 2006. Both countries are certain to apply the standard-to-be, ISO/DIS 21549.



“... Healthcards will provide vital and indispensable information to doctors and health care personnel...”

there is also the internationally-agreed G7, *Interoperability-data-set*, which had been enhanced by coupling with the NETLINK-project in 1999 and 2000.

The new standard, ISO/DIS 21549, *Health informatics – Patient health card data*, is to be based mainly on “stable data”, which can be stored on a voluntary basis with the patient’s informed consent. But at the same time, it is intended to exceed what is commonly considered the “emergency data set”.

Because of the decision to have the electronic prescription and the linkage information integrated into this standard, it now has become an eight-part work item ¹⁾.

Let’s look first at the overall rationale behind it and the scope of what it wants to cover.

With a more mobile population, greater healthcare delivery in the community and at patients’ homes, together with a greater demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and

About the author



Born in 1954, Jürgen Sembritzki studied Informatics with priority on medical applications at the University of Braunschweig and the Medical University (MHH) of Hanover.

In 1991, he took over the management of the Informatics Department of the Central Research Institute (ZI). From 1992 to 1995 he was responsible for the introduction of the health insurance card in Germany, especially for equipping practices.

In September 2000, he joined the Centre for Telematics in Health Care Ltd. (ZTG GmbH) as Head of Department on Telematics projects. Since 1 July 2001, he has been Managing Director of the ZTG GmbH.

Convener of ISO 215, *Health Informatics*, Working Group WG 5, *Health cards*, Jürgen Sembritzki is Managing Director of the Centre for Telematics in Health Care Ltd. He is also a member of ISO/TC 215, *Health Informatics*, WG 4, *Security*, Vice-Chairman of CEN/TC 251, *Health Informatics*, member of CEN/TC 251 WG III, *Security, safety and quality*, and Convener of eEurope Smartcard Trailblazer 11, *Health Cards*. He is Chair of national mirror group to CEN/TC 251 and ISO/TC 215, DIN Fachbereich G Medizinische Informatik.

¹⁾ ISO/DIS 21549, *Health informatics – Patient health card data*. Part 1: *General structure*; Part 2: *Common objects*; Part 3: *Limited clinical data*; Part 4: *Extended clinical data*; Part 5: *Identification data*; Part 6: *Administrative data*; Part 7: *Electronic prescription*; Part 8: *Links*.

other systems; therefore, during their operational lifetime, they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

What is in a patient's health card data ?

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types : identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given health card *de facto* has to contain device data and identification data, and may, in addition, contain administrative, clinical, prescription and linkage data.

Device data is defined to include :

- Identification of the device itself
- Identification of the functions and functioning capabilities of the device.

Identification data may include:

- Unique identification of the device holder or of all other persons to whom the data carried by the device are related.

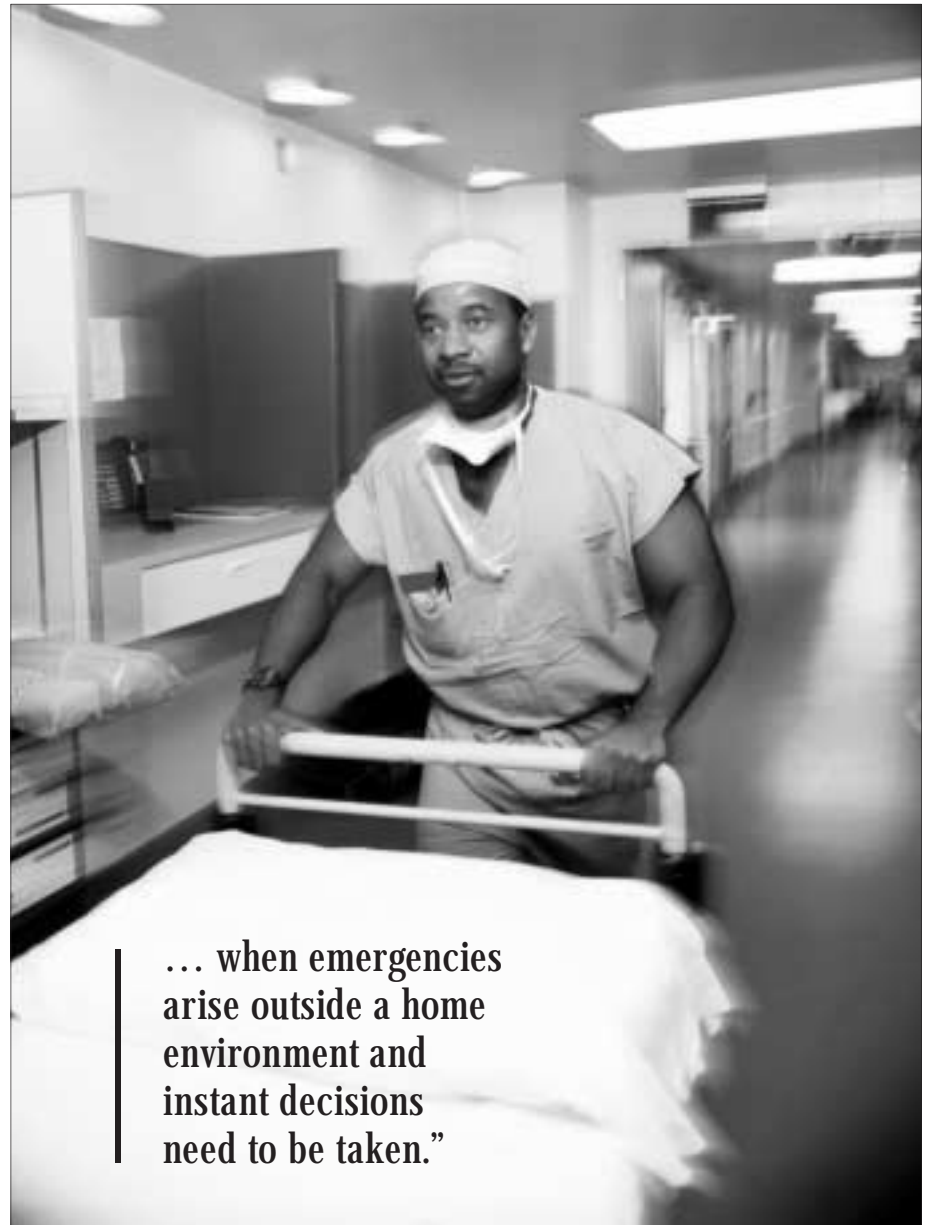
Administrative data may include:

- Complementary persons related data
- Identification of the funding of the health care, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefit;
- Other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include :

- Items that provide information about health and health events;
- Their appraisal and labelling by a healthcare professional (HCP);
- Related actions planned, requested or performed.

Data in the four categories share many features. For instance, each may need to include ID numbers, names and dates. Some information may have clinical as well as administrative uses. It has therefore been considered inadequate to carry a simple list of items carried by healthcare data cards without applying a generic organization, based on the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes. □



... when emergencies arise outside a home environment and instant decisions need to be taken."