Open Smart Card Infrastructure for Europe

v2

Volume 1: **Application white papers and market oriented background documents**

Part 4: **Smart Cards as Enabling Technology for Future-Proof Healthcare: a requirements survey**

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1 Management Summary

The eEurope Smart Card (eESC) initiative "is designed to encourage the deployment of smart cards across Europe and respond to the wants and needs of the citizens and the business community". This White Paper extends this mission to the field of health and healthcare; thereby highlighting patients and citizens wants and needs in the emerging era of eHealth services.

The use of telecommunication and informatics within healthcare, i.e. health telematics or eHealth, has received increasing attention by policy makers, patients and health professionals in recent years. There is wide consensus that applications like networked electronic health records, broadband communication and secure networks have a high potential to improve the quality and availability of health care. By integrating mobile interactive devices healthcare services can become "ubiquitously available" and thus enhance the quality of life for citizens and patients throughout Europe and the world.

In many respects these potentials still have to be developed in most European nations: a fully functional health telematics infrastructure as intended by the eEurope 2002 action plan has nowhere been established nationwide. The eEurope action plan 2005 further focuses on resolving infrastructure issues for eHealth deployment. As well as plans for Europe-wide replacement of paper forms for health insurance reimbursement by electronic means, elements of a health telematics infrastructure are targeted: *"The Commission intends to support a common approach to patient identifiers and electronic health record architecture through standardisation and will support the exchange of good practices on possible additional functionalities, such as medical emergency data and secure access to personal health information."*

This White Paper dovetails with the framework of the action plan 2005 and current EU policies. It provides a synthesis of challenges in the healthcare sector, the health policy framework, key elements for interoperable health telematics infrastructures and experiences of known projects (lessons learned). On the policy level, there is a need for Europe-wide health telematics strategies to establish the synergies of smart cards and health networks. This White Paper recommends starting points and building blocks for such strategies. It outlines the synergies of 'state of the art' smart cards (i.e. with microprocessors) and of standard-based, interoperable, networked health telematics applications.

European policy on Health Cards should emphasise the function of cards to support security infrastructures in healthcare, rather than to store medical data directly on the cards, which was an earlier focus of attention. Health networks and smart cards should be seen as a combined resource, and additional unique functionality can be built on the combined availability of health professional cards and patient cards. Health data on patient cards will – in addition to ID and network security features – be limited to a selection of medical and administrative information, e.g. electronic prescriptions, emergency information and disease management related data. Additional data (electronic health record information) will be referenced via links and accessed across networks using the smart cards security features like asymmetric cryptography and qualified electronic signatures.

2 Introduction

This White Paper has been written by authors within the eESC TB 11 and has been approved in the 'Trailblazer's' meetings. It has been available on the eESC website since August 2002 and has thus been open for external comments.

2.1 Background: The eEurope Smart Card Initiative[2] and the "Health" Trailblazer

"Within the overall eEurope 2002 initiative a smart card action plan was specified, the first step of which was the creation of a Smart Card Charter setting down the issues that have to be resolved before smart cards can fully act to support the aspirations of citizens with respect to ICT. The action plan addresses both the citizens needs and those of the business community in terms of business cases, multi-functionality and interoperability of systems and infrastructure, and the provision of trust in all aspects of service delivery."[3]

"The trailblazer on health [one of the 12 projects of the Smart Card Charter] should give recommendations for a European wide interoperability of health cards. This applies to patient data cards as well as to health professional cards and to their usage in networks. It covers administrative data as well as health/health related data […]." [4]

This document is the "White Paper" which constitutes a principal output of 'Trailblazer' 11. It presents views expressed by members who have specific experience in the use of Smart Cards in the health care sector.

2.2 Scope of the document

This document is a "White Paper" on smart cards as enabling technology for future-proof healthcare[5]. It provides policy guidelines and recommendations for achieving the Smart Card Charter objectives in this area.

Chapter 3 identifies the challenges currently faced - or to be faced in the near future - by the health care sector as well as by social security and by welfare.

Chapter 4 identifies the core functions required for successfully meeting these challenges, which should take advantage of synergies between smart cards and networks.

To meet successfully the challenges stated in *Chapter 3* three visions have so far been identified. These should be implemented in the short (2 year) or medium (5 year) term:

⇨ Secure access to health, and health insurance related, information for all in the short term, via synergies between smart cards and the Internet (see Chapter 0),

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[2] For more details, see www.eeurope-smartcards.org

[3] Extract from the Smart Card Charter Work Plan "Common Requirement, Part 1 (version 7)"

[4] Extract from the Smart Card Charter Work Plan "Common Requirement, Part 2 (version 7)"

[5] "healthcare" in this document is used as a placeholder for 'direct' healthcare, health related administration issues and some aspects of social and other health coverage.

- ⇨ Pan-European use of smart cards (see Chapter 6),
- ⇨ Secure access to health and health insurance related information for everybody concerned in the medium term, via smart cards, wireless networks and various "interacting devices" (see Chapter 7).

As Chapter 5 highlights, the Internet, being already a universal, largely standardised everyday technology can be transformed into a secure, trustworthy network for healthcare by applying highly secure ("strong") cryptographic procedures using suitable smart card technology. This technology also provides Europe-wide interoperability (Chapter 6) in the context mainly of reimbursement processes. Chapter 7 highlights mobile healthcare and interacting devices. Chapter 8 describes card projects and national roll-outs in Europe.

Each of these visions is treated with the same approach and structure:

- ⇨ sub-section n.1: detailed description of the current situation in the area,
- ⇨ sub-section n.2: statement of a vision for meeting the needs,
- ⇨ sub-section n.3: identification and description of the social and economic benefits to be derived from the vision,
- ⇨ sub-section n.4: identification of internal and external requirements and conditions for implementing the vision step by step.

A glossary, based as far as possible on the "Telemedicine Glossary 4th Edition, 2002 Working Document, ed. L. Beolchi, DG INFSO-B1, Brussels, 2002" has been included as an annex to this document.

2.3 Intended readers

In line with the SCC objectives "bringing down the barriers for mass deployment of smart cards", the intended readers of this White Paper are the following:

- ⇨ European, National, regional and sectoral bodies, whose objective is to improve health care services availability, quality and integration,
- ⇨ Potential investors in smart card information systems, including social and health insurance[6] bodies as well as health care providers and professionals,
- ⇨ Architects of telematic infrastructures to support health care systems

The expectations of healthcare professionals and of patients are not fully covered: these were not part of the primary scope of the working group's (eESC Trailblazer 11) investigations in preparation of this document.

[6] Note: In this document, the words "health insurance" are intended to cover public and private health insurers and non-insured third-party health finance arrangements.

3 Smart cards as tools for Europe-wide eHealth strategies

3.1 The challenges in the health care sector

Healthcare systems are facing new and growing challenges from demographic and socio-cultural changes, progress in medical research and medical technology and, last but not least, globalisation and the European integration process. Within this context, health telematics (e-Health) has the potential to become a central structuring factor for healthcare in the information society of the future by improving rapidly the quality and the availability of health care.

Telecommunications and informatics have already been used in medicine for many years. But only since the Internet has developed into a universal, largely standardised everyday technology (“Evernet”), could many ideas be realised in affordable applications that are suited to practical use. The highly secure cryptographic procedures necessary to ensure confidential data transmission are available to help apply these technologies in medicine and in overall healthcare.

The Healthcare sector is experiencing radical transformation as a result of the increasingly widespread deployment of information technology. Such technology, as a core component throughout broadband communication infrastructures and networks, makes possible the delivery of “ubiquitously available” and enhanced healthcare services to patients.

Nowhere is this more apparent than in European member states, where telemedicine and more recently eHealth projects have been deployed in numerous countries, driven by enthusiasts and by 'early adopters' of this technology.

Beyond the particular needs of the different country-specific healthcare systems there seems to be a consensus on the priority for integrated, cross-sector and patient-oriented healthcare activities. This integration best meets health needs taking into account quality of care and economic feasibility. The necessary information, communication and security infrastructure plays a key role in meeting these needs.

However there are also some barriers and obstacles that need to be addressed:

- ⇨ Lack of a political mandate to introduce health cards on a national scale. Currently, only France, Germany, Belgium and Slovenia have completed a national smart card roll-out and benefit from the advantages of having a health-related national smart card infrastructure;
- ⇨ Lack of a political mandate and of support to achieve Europe-wide interoperability of smart card systems;
- ⇨ Wide differences in European health care systems and insurance systems which lead to different legal and regulatory systems (or vice versa);
- ⇨ Lack of security and confidentiality regulations. Smart cards and PKI are essential options for addressing these issues.

3.2 Health Telematics infrastructure and smart cards in European healthcare systems

There is a long history in the policy-development of the European Parliament, and of certain European Member States, of plans and projects related to the use of chip cards and smart cards within the healthcare sector. The study “A European Health Card”, which was commissioned by the STOA (Scientific and Technological Options Assessment Group) Programme of the European Parliament from MEDEA (Italy)' provides documentation on related activities started as early as 1981[7]: The commissioning of this study illustrates the longstanding 'policy' commitment to the issue. While it must be valuable that the European Parliament in this study has again reviewed smart cards in healthcare, the report issued in Spring 2001 has nevertheless been criticised as possibly not reflecting in its conclusions the balance of recent health card developments in Europe. Chapter 7 therefore provides a

[7] Documents issued by the European Parliament (and related) on the European health card:

13/10/1981 The European Parliament expressed its opinion that a voluntary, unique European health card could be successfully issued only if individuals were likely to request it.

21/12/1983 The European Commission submitted to the Council’s consideration a recommendation for adopting an emergency health card (multilingual, folded paper, uniform with the driving license).

23/05/1984 and 16/11/1984 The Social and Economic Committee expressed its opinion about the Commission recommendation.

29/05/1986 The Council adopted a resolution about the adoption of the (paper) European emergency card. This resolution did not take account of all the problems regarding data update and liability.

16/10/1989 The European Commission wrote a report about the implementation of the Council’s resolution. The report’s conclusions were that some countries did not have the right implementation measures for the card while other countries, such as Germany, Luxembourg and Portugal in particular, had developed them. The report concluded that technological improvements needed to be made. The Advanced Informatics in Medicine ('AIM') Project was expected to cover these.

24/10/1995 The European Parliament and the EU Council issued a Directive about protection of personal data and handling and exchange of that data.

1996 Report (Giacomo Leopardi) to the Committee on the Environment, Public Health and Consumer Protection.

30/06/1997 The European Parliament and the Council issued a decision about the adoption of a European programme on healthcare monitoring.

more up-to-date review of ongoing activities and their role in the visions and functionalities described throughout this paper.

It is worth noting that the wording “European Health Card” might properly be interpreted as either "A (one uniform) European Health Card" or "potentially-many (interoperable and standards-based) European Health Cards". This White Paper and the policy of the Trail-blazer 11 Health within the eEurope Smart Card Initiative (i.e. the authors) subscribe to the second (‘potentially-many’) meaning of the words.

3.3 *e*Europe Action Plan 2005 as a framework of reference for health card use

The desirable objective at European level has already been illustrated in the “***e***Europe 2002 Action Plan“, which proposes extensive infrastructures for health telematics in all European nations by the end of 2002. In these nations, determined implementation steps will be necessary to achieve this objective. The recently adopted ***e***Europe 2005 action plan explicitly mentions the crucial role of an **Electronic health card and the synergies in the use of cards to access networked electronic patient records:**

“**Electronic health cards.** Building on the agreement at the Barcelona European Council that a European health insurance card will replace paper based forms needed for health treatment in another Member State, the Commission will make a proposal before the Spring Council in 2003. The Commission intends to support a common approach to patient identifiers and electronic health record architecture through standardisation and will support the exchange of good practices on possible additional functionalities, such as medical emergency data and secure access to personal health information.”

The final sentence particularly of this paragraph describes the synergies of smart cards as security tokens and secure medical network infrastructures. Such synergies have guided the proceedings of the health group within the smart card charter.

3.4 Europe wide e-Health strategy for the use of smart cards

The extensive and interoperable use of health telematics applications requires supporting general conditions and infrastructure measures. For these reasons, it is advisable to promote and coordinate the use of health telematics in Europe - both by health policy makers (including self-governing organizations of the healthcare sector) and in science, research and in relevant funding. The new EU research project “Roadmaps for European research on Smartcard Technologies” (RESET) linked to the eESC might be a way to follow up these plans.

Increasing personal and business mobility across Europe, together with the spread of relative prosperity, have increased awareness and expectations of available health systems, whether public or private. Citizens and businesses in many countries increasingly demand public and private systems to work together in delivering the same quality of care with equal effectiveness all over Europe.

There is a need to plan and implement eHealth applications based on Europe-wide interoperability of eHealth infrastructures. This calls for Pan-European eHealth strategies sup-

plemented by step-by-step planning of individual implementation phases. A start can be made by establishing an infrastructure for health telematics. Approaches for making available the necessary investment and operating resources have to be found as soon as possible, on a basis acceptable to all parties.

Europe as a whole needs thorough work on the development of strategies for the introduction of e-Health applications. These strategies should provide clear guidance both for health policy makers at European and national levels and for the healthcare actors and their organisations – mostly through voluntary adoption of the strategies. Strategies have to ensure long-term success by covering visionary perspectives as well as functional steps towards full implementation, agreed with all parties involved. Successful implementation – at European and national levels – is also dependent on the appropriate policy, legal and financial regulations required for integrating eHealth smoothly into the organisational structures and workflows of the relevant healthcare systems, institutions, social and health insurers, providers, etc.

3.5 Core functionalities to support patient-oriented, networked healthcare

To support patient-oriented, networked healthcare, the synergies of smart cards and networks can be exploited to enable the following core functionalities:

(a) Enabling patients and health professionals to collaborate and share patient and other health-related data for continuity of care.

(b) Enabling healthcare providers, healthcare insurers and welfare institutions to establish reliable and efficient communication processes; hence enabling patient-focused delivery of high quality care and at the same time saving resources by efficient support for administrative procedures.

(c) Providing a secure and individualised system that allows patients to monitor their personal health.

(d) Offering user-friendly and personalised interactive secure systems to provide citizens and patients with general health information as well as personal guidance.

(e) Supporting citizens and patients in adopting appropriate lifestyle changes or improvements to ensure better health, illness prevention and rehabilitation.

(f) Supporting safe mobility by enforcing the provision of emergency care and specifically enabling support for those who may need regular and more intensive healthcare services.

(g) Supporting increased mobility for business, training, expatriates, skills dissemination and leisure.

(h) Supporting continuity of coverage and quality of care for people regardless of their type of (public and/or private) health coverage.

(i) Improving the availability and effectiveness of intervention by providing mobile communication between carers.

➔ ➔ ➔ thus contributing to improving the citizen's and patient's quality of life.

In the past many projects tried to build their communication infrastructure either on patient cards or on networks, but it is now widely accepted that some needs, e.g. the need of security, privacy and universal access to patient data, may only be met by combining the functions of smart cards and networks. Thus the synergies of these two technologies can be used and internationally convergent paths for infrastructures may be built and operated.

Any smart card system should be seen as an intrinsic component of an information network. Uniting the strength of the two technologies - smart cards and net - optimal utilisation of technological hardware can be achieved and effective functions provided. Such an approach is safest in keeping systems open to future technological developments. The cards and their support infrastructure can be seen as a "portable virtual network" facilitating, securing and supplementing the stationary information networks. Hence smart cards are an intrinsic component of trustworthy information networks in healthcare.

3.6 Current role of smart cards in the health care sector

In the health domain, more recent smart card applications have reached the market as dual-card systems including:

Insured patient's card which could include the following data (or remote data access pointers)

- ⇨ Administrative data (i.e. insured ID, name and address, health coverage 'coordinates', period of entitlement, availability period, relevant regulation, etc.).
- ⇨ Medical data (emergency clinical data, protected private file).
- ⇨ Security components, possibly including biometrics, e.g. for reliable identification of the person covered and secure access to personal health data of the patient.

Health practitioner card for secure access to patient data stored either in a patient card or on a remote server, possibly with security components (i.e. PKI, crypto-processor, data encryption keys, encryption algorithms, digital signature, authentication certificates, biometrics features, etc.).

During the 1990's, many European and North American countries issued health cards (i.e. micro-processor cards, memory card or magnetic stripe cards) combined with on- or off-line software applications. These countries included France, Italy, Germany, Slovenia, Canada, USA, etc.[8]

[8] For further details see "Result of the evaluation and socio-economic assessment of the integrated solution", NETLINK deliverable D5. URL: http://www.sesam-vitale.fr/Netlink

4 Key elements to establish for a Health Telematics Infrastructure

4.1 Infrastructure

One of the central tasks in coming years will be the establishment of a “health telematics infrastructure” as mentioned in the action plan eEurope 2002. This implies not only establishing Internet connections between outpatient and in-patient healthcare institutions, but also the systematic establishment of information, communication and security infrastructures suited for the trusted transmission of patient-related health data in compliance with European and national laws and data protection regulations.

4.2 Smart cards as key elements of security infrastructures for healthcare

Unprotected electronic transmission of personal patient data via open networks like the Internet is, as previously noted, rejected internationally. Hard cryptography (highly secure encryption procedures) is considered a necessary element of an adequate security infrastructure for the healthcare sector. Accordingly, the use of qualified electronic signatures[9] and asymmetric encryption is needed. These procedures rely on a Public Key Infrastructure (PKI), which also comprises 'certification services' providers and directory services, which could be set up on a state level or by industry players or be built specially for the healthcare sector. For any alternative, the infrastructure must be able to handle the demands for the high levels of security, which are essential in the healthcare sector where transmission of patient data is included.

[9] As defined by the EU directive.

Many European Member States are already planning, or have started to build up, security infrastructures for their healthcare systems: In Spring 2001, the British Department of Health published plans for the use of cryptography within the context of the National Health Service ('NHS'); France offers chip cards with cryptographic functions, Finland issues electronic identity cards, which might be used in healthcare as well; Slovenia has issued modern smart cards to everyone with social health insurance. Nevertheless at the time of writing no country in Europe had completely established a healthcare-specific Public Key Infrastructure (PKI) that would allow for the use of digital signatures and asymmetric encryption using smart cards with up-to-date encryption technology.

European Member States should define common rules for Public Key Infrastructures suitable for healthcare systems. Ideally these common rules would involve the smart cards and the Public Key Infrastructures being interoperable, at least to the extent that this can be possible for different healthcare systems. This interoperability is needed at the latest by the time the Member States move to substitute electronic nationwide documents for paper-based ones. Otherwise any form of cross-border treatment and medical care for patients travelling through Europe would be hampered by unreadable electronic documents and inaccessible personal medical information for many European citizens/patients.

To get this consistency, the **Global Interoperability Framework** [10] is a Smart Card Charter initiative which has developed the concept summarised in figure 1, illustrating how smart cards with interoperable IAS [11] can be used across domains and Front Office Applications as a secure nucleus application.

In this model, generic IAS data would be common to different domains, without preventing the loading of domain-specific data on the same card.

[10] The full title of this document of the eEurope Smart Card Charter is “Global Interoperability Framework for Identification, Authentication and electronic Signature with Smart Cards”. Some details on its content are provided in the glossary of annex 8 below.

[11] IAS stands for “Identification, Authentication and electronic Signature”

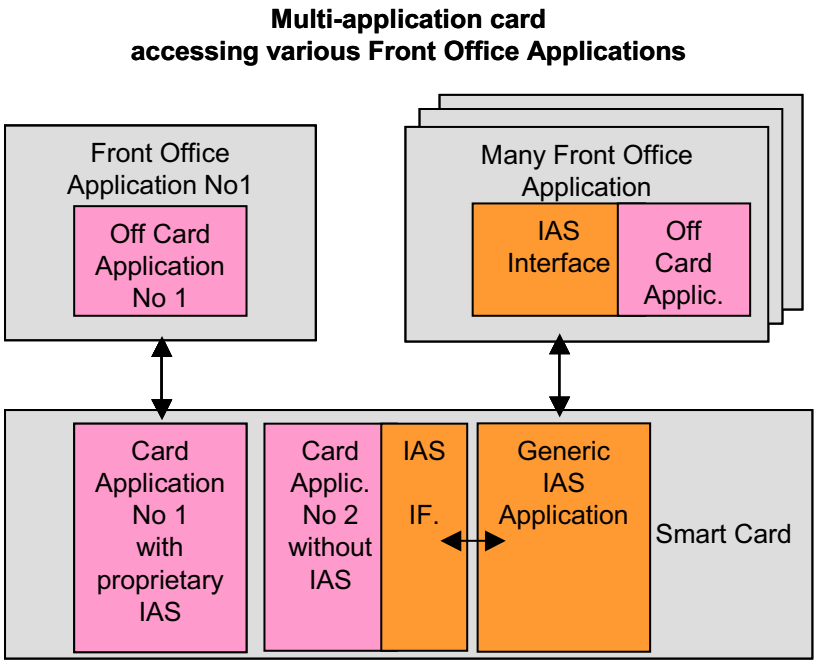

Figure 1: Multi-application card accessing various Front Office Applications

Vice versa, the interoperable IAS concept also enables a service provider from a particular domain to offer its services to citizens holding different smart cards.

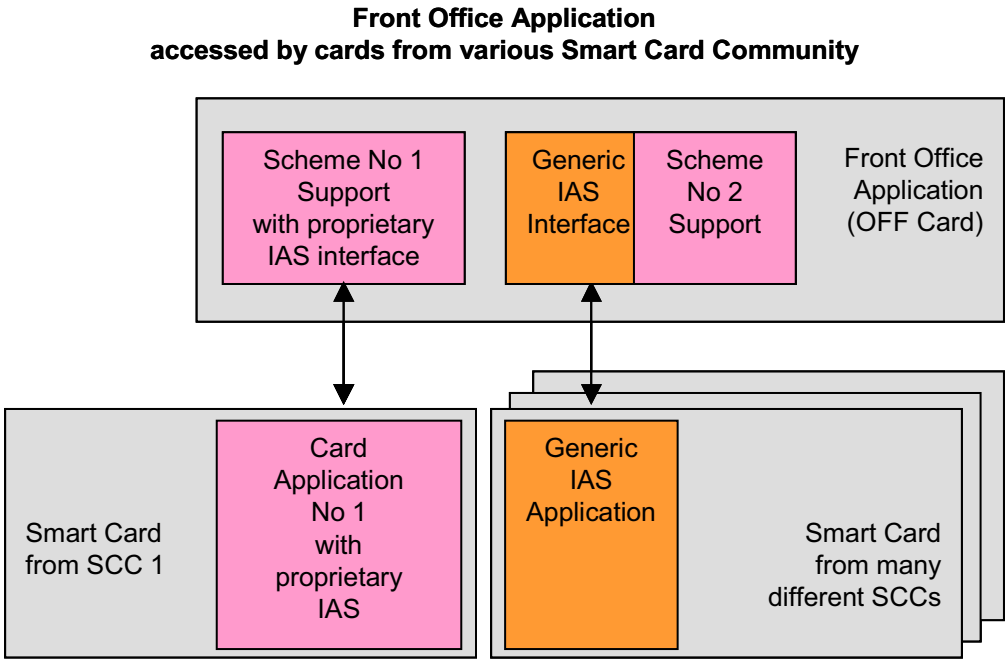

Figure 2: Front Office Applications accessed by cards from various smart card communities

The strategy of the *e*Europe SCC has been to promote regionally implemented and independent systems interacting with each other. This General Interoperability Framework (GIF) is based on only a few internationally accepted standards like ISO 7816 for basic smart card definition, PKI based on the eSign Directive and the CEN/ISSS Workshop E-sign CWA's, evaluated by Common Criteria and used in inter-governmental agreements for mutual client authorisation. The selected standard for terminal unification is FINREAD.

By contrast, a different strategy comes from the Japanese NICSS project, requiring system integrators to apply the standards for card/terminal/application software level to regional applications running in the same NICSS frame. This approach cannot be suitable for Europe, where a variety of systems are running already. Only the interaction between NICSS and independent regional systems remains feasible in Europe.

4.3 Electronic IDs for patients and health professionals

The introduction of electronic IDs, e.g. “Health Professional Cards”, with cryptographic functions (digital signature, encryption, authentication) into European healthcare systems requires Public Key Infrastructures and other measures involving use of smart cards. In addition, the appropriate legislative bodies need to clarify the admissibility and reliability of substituting electronic documents for paper-based ones. So the conditions for validity of electronic signatures in healthcare must be determined in the context of the European Directive on Electronic Signatures (called eSign Directive later in this document)[12].

4.4 Legally binding data transmissions, privacy and security

In Europe and worldwide, methodologies are being developed for the electronic transmission of findings and other patient data. ‘Qualified’ electronic signatures in accordance with the EU Directive are an important element in giving such transmissions a legally binding effect. Secure encryption procedures are suitable means for ensuring data protection and data security during data transfer and storage.

4.5 Promotion of eHealth Standards by implementation

European (CEN etc.) and worldwide (ISO etc.) standardisation activities are often experienced as unnecessarily complex and insufficiently implemented. Advanced EHR-standards such as the four-part European draft standard on Electronic Healthcare Record Communication (prENV13606-1-4) offer a conceptual basis for software systems without pre-specifying extensive detail. The potential benefit of these standards can only be tested by actual use. Based on such actual use, valuable experience and qualified support will feed back to the improvement of European standards.

Minimum standards for medical documentation are needed to ensure meaningful electronic collection, transmission and storage of patient-related health information. In addition, standardised data formats are necessary to ensure that patient-related health data can be integrated consistently in the relevant electronic patient records.

[12] Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures, Official Journal L 013, 19/01/2000 p. 0012 – 0020.

4.6 Collaboration between the Healthcare actors and the eHealth industry

Another key issue is the need for collaboration between Healthcare and the eHealth industry in order to ensure that solutions and implementation plans are available and in line with the requirements, budgets, skills and transformation of the industry. Note that this task could be supported through the European Health Telematics Association (EHTEL).

4.7 Establishment of an interoperability platform

The new technologies have obvious potential but their implementation in Europe is still not well established. Although world-leading technical components and system solutions for electronic data interchange are available here, isolated solutions, both as regards location and content, still dominate the landscape. Future-proof solutions have to be designed consistently if European and international interoperability is to be assured.

This White Paper specifies requirements and key elements for an interoperability platform for health smart cards and thus aims at providing a convergence path for the use of smart cards in networked healthcare. This should establish a common platform for health services of the new generation.

The paper illustrates the usefulness of open platform architectures, applying the same infrastructure to different medical application areas and to different application services (administrative, authorisation and identification, patient record). It summarises the ways in which health smart cards across Europe help ensure security, privacy and data integrity. This is intended to help with the broader acceptance of smart cards.

4.8 Selected experiences/projects to build health telematics infrastructures

Recent activities at European policy-making level within the ***e***Europe 2002 and the ***e***Europe 2005 Action Plan have already been mentioned. These exist within a framework prepared by the European Parliament, whose recently commissioned study on this issue has been noted, and other European and global developments. The experiences and projects described are already progressing in practice towards the usage of synergies of smart cards and networks. A further – much more detailed – survey of existing and already finished projects and activities is provided in chapter 8.

Standardisation activities on health cards within the International Standardisation Organisation ISO are described in annex 9.1.

4.8.1 NETLINK project

During the period 1998-2000, NETLINK was funded by the European Commission, then ‘DG XIII’ (now DG INFSO), as a project of the 'Fourth Framework Programme' on Research and Development, Health Telematics Applications (code name HC 4016). It brought together participants from France, Germany, Italy and the Province of Quebec in Canada.

The project's main objective was to make new nation-wide health information systems (providing continuity of care, enhancement of quality of care and simplification of administrative procedures) interoperable for the benefit of patients, health practitioners and social health insurance funds. This was to be seen as a first step towards the establishment of standards or recommendations for the healthcare sector in the E.U. and even worldwide[13].

NETLINK's approach was to define data structures and to make recommendations on how to implement and to ensure interoperability. There are 'mandatory' and 'optional' datasets. Each participating country may select the relevant dataset to be included in the card, whereas the API of the card reader will only read what is 'mandatory' in accordance with local regulation. Each application uses locally-appropriate data as authorised at a national level. However all data on the card should be capable of display and no display software should generate an error. Any missing 'mandatory' fields should have a special indicator noting that 'mandatory' data are missing.

The NETLINK Consortium was compliant with the G8 SP6 Health Card initiative which addressed interoperability of Health Cards at G8 level - any software which claims to be G-8 compatible must be able to read and process the entire G-8 data set. Interoperability with the DIABCARD project (cf. 4.8.3) could also be established.

The NETLINK project pilot sites are still in operation at the time of writing.

4.8.2 G8 SP6 Health Cards[14]

The G8 SP6 health card group included the G8 countries developing or interested in Health Card projects, including participants from Canada, France, Germany, Italy, Japan and USA, with official representatives of governments. Several manufacturers and universities also supported the group activity. The objective was to prepare for a "European Health Passport" by adopting standardised methodology for implementation of smart card projects.

On the interoperability technical aspects, the G8 SP6 HC group developed technical specifications for a patient data set and an emergency data set. The workgroup has also adopted part of the NETLINK specification for interoperability as a G8 recommendation.

The same specifications were adopted by ISO TC 215 WG 5 (health cards).

4.8.3 DIABCARD project

DIABCARD, a chip card project sponsored by the EU, started in 1994. It is still ongoing. Within this project a chip card based medical information system for patients with diabetes was designed. An electronic patient record was implemented on a smart card. The smart card was actually regarded as a portable electronic record. The emphasis was on chronic

[13] Annex D of the NETLINK Requirements for Interoperability document version 2.1 (see www.sesam-vitale.fr/netlink) contains NETLINK proposals for modification to the G8 SP6 HC recommendations. Chapter IV deals with Patient Data Card (PDC) access free requirements.

[14] In the meantime, the G8 SP6 HC label was changed to Global Healthcare Applications.

diseases and exemplified by diabetes. The card also held data for the treatment of diabetes, emergency and administrative data. Standardisation and interoperability were considered main issues right from the beginning. Therefore, the G7 interoperability data set and also standardised medical data sets on diabetes were implemented. A minimum data set was defined.

Besides the data level interoperability and standardisation were to be achieved on the chip card level, the card reader level, and application level, too. On card and card reader level these standards are PC/SC – Personal Computer/Smart Card (PC/SC) and OpenCard Framework (OCF). In order to support interoperability to other health cards the DIABCARD architecture was based on the EU/G7 interoperability specification.

The DIABCARD Server was developed as a high level application interface to handle interoperability issues like the use of different card readers and cards and, moreover, the ability to handle chip cards from other projects are addressed within these modules. Interoperability was demonstrated by reading emergency data from a Cardlink card by the DIABCARD system, though both projects used different types of microprocessor cards (Cardlink used a Setec SetCos card and DIABCARD an IBM MFC card); and also by integrating the DIABCARD card into an existing medical information system (doctor's office computer system by Millenium/Dedalus). This interface makes possible both access to the EU/G7 interoperable data and to DIABCARD patient data. It supplies functions to access both the structure of the DIABCARD Data Set (e.g. data item types, allowed values) and the medical data itself (single item values, item value groups). Data are checked for compliance with the DIABCARD Data Set. It uses chip card functionality provided by the DIABCARD Data Interface.

In order to identify most of the underlying problems and to overcome the barriers against the inadequate use of the DIABCARD the system was evaluated at various stages in various healthcare settings across Europe, in Barcelona, Spain, Athens and Thessaloniki, Greece, Munich and Koblenz, Germany, Vienna, Austria and in the region of Umbria, Italy.

The results demonstrated that medical smart cards are a good tool for carrying computer-based patient records. Both the capacity and the functionality of the existing cards were sufficient for a speciality patient record.

4.8.4 Former Project Proposal 'HealthCards.Net' from TB11

The objective of TB11 is to contribute to the Europe-wide interoperability of health cards. This applies to patient data cards as well as to health professional cards and to their use in networks. Interoperability covers administrative data as well as healthcare/health related data. The proposal "Healthcards.Net" (submitted for the IST-program in 2001) focused on the demonstration of synergies of smart cards and networks where smart cards function as keys to private data. The proposal was, however rejected for European funding.

4.8.5 Netc@rds project

Following the trails initiated during the former R&D phase by NETLINK, TRANSCARDS [15] and many other Pan-European initiatives, as well as those currently being 'blazed' in the programmes supported by the European Commission (e.g. the *e*-Europe SCC initiative), the NETC@RDS project consortium, as a kernel on behalf of national authorities of the participating countries, will set up a pilot. This will aim for full deployment of a wide trans-European network of *e*-services for mobile citizens, improving cross-border health care access procedures. The target population includes every E.U. citizen travelling to another E.U. country as student, posted worker, tourist or on business purposes.

These services will be implemented on the basis of existing or planned national information systems including smart cards and/or networking software applications within the participating countries. The NETC@RDS project will support wide scale demonstrators prior to full deployment inside the whole E.U. Partners from France, Germany, Austria and Greece, on behalf of their national Ministries of Health and Health Insurance funds, will develop appropriate card and network solutions for building-up interoperable Health care information systems for cross-border health care services. All European Member-States could be associated with the NETC@RDS initiative as observers, periodically informed of project progress, results and achievements.

In practical terms, the NETC@RDS project could show how to replace the administrative data on the E.U. paper forms E-111 & E-128, either by storing data on existing health smart cards or by permitting access through a secure Trans-European Extranet.

The project being co-ordinated by GIE SESAM-Vitale brings together associates from Germany, Austria, Greece and France supported by their supervising

Ministers and / or Health Insurance Funds. Quebec Health Insurance is also taking part in the project in the capacity of an assisting member. Netc@rds is 50% financed by the European Commission in the framework of DG INFSO Pan-European E-TEN programme. Support has been received from Public Health authorities in the participating Member-states (the Ministers of Health, Health Expenditure Financing Organisations and Public Hospitals), the Banque Carrefour of Belgian Social Security and the eEurope Smart Card Charter Steering Committee.

[15] TRANSCARDS is a project that was funded by the DG EMPLOYMENT and SOCIAL AFFAIRS in the period 1998-2001 (see www.sesam-vitale.fr/html/projets/Transcards).

5 Synergy between smart cards and the Internet

5.1 The facts

⇨ Internet and smart cards technologies are well spread and mature.

⇨ *e*-Commerce applications and debit/credit cards have proved the efficiency and cost effectiveness of the concept of combining these technologies for providing services in business-to-consumer (‘ B2C’) mode.

⇨ However, problems are growing in matching technological achievement with old habits and rules for its use.

5.2 The Vision

In a very few years, smart cards combined with Internet access points could be widely spread over Europe.

⇨ Each citizen would hold a smart card

⇨ Each citizen could access the Internet (at home or in public kiosks)

⇨ Internet access points would be equipped with card readers

⇨ Legal and administrative rules would have been defined and introduced, to organise the electronic exchange of information in all necessary detail

⇨ Electronic services acceptance and trust would have been widely achieved

These elements could significantly contribute to improving health-related processes and functions and in particular:

⇨ The processes of personal identification, privacy protection and electronic processing;

⇨ The functions of healthcare administration, healthcare delivery and healthcare policy management.

The scenario described below, a 'proof of concept' for the vision outlined above, could apply not only to basic health care but also to mental health care such as stress related and early-addictive disorders, as well as to various aspects of social welfare (e.g. protection against domestic violence). Secure data exchange, together with easy access for all to specifically designed applications over the Internet, could encourage citizens to volunteer details of their condition to suitable confidential processes - to which the card is a trusted key (cards are often referred to as tokens of trust).

Under strict privacy protection mechanisms, the scenario involves three stages:

(j) Pre-Diagnosis: Card-Accessed Application (home computing or public kiosk) for "first aid consultation"

(k) Diagnosis: Thorough examination by a health Practitioner/ancillary who holds a "professional" card authorising access at a suitable security level

(l) Post-Diagnosis: Condition monitoring and validation through card-accessed applications.

5.3 Social and economic benefits to be derived from the Vision

Smart cards can add mechanisms to the Internet to implement security (data protection and anonymity-confidentiality) which are easy to use. The Internet has given data on smart cards the possibility to "go wide", escaping the confines of card readers attached to off-line terminals. In Health Care, any IT system combining Internet and smart cards could claim to be more "human-centric" than the old typical models for two main reasons:

⇨ Citizen's and patient's own awareness of their health related data and information, because smart cards offer ubiquitous access to information.

⇨ Citizen's and patient's empowerment, because secured information can be circulated without prohibition.

5.3.1 Improving reliability of personal identification/authentication

⇓ Smart cards ensure reliable identification/authentication over the Internet and can even simplify it. By doing so they support the function of "providing a secure and individualised system that will allow patients to monitor their health"(see section 3.5 (c))

Digital Certificates corresponding to each and every citizen can not only identify/authenticate a person but also carry efficiently his/her special attributes, privileges and access rights concerning public and personal data in a PKI/Internet world.

Loaded in a smart card, such features could lead to a significant simplification to the benefit of citizens in a very large number of processes: no need to remember numerous PINs or to carry multiple papers with different identification tokens for a variety of applications.

A unique token of identification can open a whole new world of information and services - simply by insertion in a card reader's slot wherever this is attached either to a PC or any other type of terminal (e.g. info kiosks - see chapter 7) and activating the card with a single PIN or using biometrics when security and ease of use so demands.

The reliability of this kind of identification/authentication should build citizen's trust in the technical means for privacy protection when his/her health data are made available to him/her and to authorised health professional(s) through the Internet.

Because of this simplification, traditional 'face to face' health examination or assessment could be assisted or even replaced (where appropriate) by applications relying on secure data validation, storage and exchange. Health care practitioners will benefit from such processes both in time and acquisition of information, thus improving the efficiency of the health care system.

5.3.2 Securing access to personal data over the Internet

⇓ Smart cards secure access to personal data over the Internet, offer better accessibility to personal data, better sharing of clinical knowledge and reports. Smart cards thus promote the functions of:

- ⇨ "Enabling patients and health professionals to collaborate and share patient and other health-related data for continuity of care"(see section 3.5, (a))
- ⇨ "Supporting citizens and patients in adopting appropriate lifestyle changes or improvements to ensure better health, illness prevention and rehabilitation" (see section 3.4, (e))
- ⇨ "Supporting safe mobility by enforcing the provision of emergency care and specifically enabling support for those who may need regular and intensified healthcare services" (see section 3.5, (f))
- ⇨ "Improving the availability and effectiveness of the intervention by providing mobile communication between carers"(see section 3.4, (i))

The growth of digital trust will allow for collaboration not only between health professionals of various disciplines and locations but also between individuals and patients' groups seeking information, guidance and comfort.

The Internet can appear to be a 'tangled web', but all groups of users may be reassured by card technology that their personal data will stay out of reach from non-authorised actions. If patients feel that some 'stigma' attaches to a condition they suspect they have, the neutral dialogue offered with secure systems can give them the confidence to seek help, and can build trust in medical advice and access to support groups. Health care will not be delivered unless it is known who needs it and for what reason.

Physical location is not an issue for the Internet. The inhabitants of isolated islands or villages, of mountain tops or city centres, all share the same privileges if they have the necessary connectivity.

Health practitioners need never feel remote from the centre of evolution, as information is equally circulated to all. Clinical reports could cease to depend on a practitioner's writing style, because all necessary data can be simply entered in a uniform format, with free text reserved only for unstructured data. The Internet – having been transformed through the employment of 'hard' encryption into a trustworthy communication network for personal health data – can, with suitable bandwidth, also readily carry medical images (e.g. scans, ultra sounds) to help doctors to discuss a patient's treatment with each other. In all these functions a virtual server-network could be considered and evaluated, and the availability of smart card technology is an essential enabler for security and customisation (see also first paragraph 5.3.1 and 6.2.1).

In addition to the "Virtual Portable Network" established by card & network synergies, a patient data card can improve the quality of care and the security of the patient by storing limited amounts of data directly within the smart card. As well as patient ID, coverage information and emergency records, the patient data card (PDC) can carry selected important, current and accurate patient health information, e.g. central elements from the patient's disease history. The transfer of electronic prescriptions and other medical and administrative documents between two points of care can also be enabled by using smart cards as a mean of secure, temporary data storage. PDCs can support emergency treatment, where data can be accessed through a stand-alone unit employing a card reader, and can also strengthen patient empowerment. They can be particularly useful in a shared care environment. Where systems permit mobility between doctors, they can be an essential support for a patient's choice of healthcare provider.

Today's life style aims at healthy old age, but chronic disease incidence rises also with growing life-expectation. Elderly people are often less mobile and not able or willing to use the Internet. The health card can be linked to devices for measurement (e.g. of blood glucose, blood pressure, intra-ocular pressure) and the values can be stored on the card as 'time series'. This uses the card as a temporary transport system. When the physician sees the patient he can be sure that he is receiving accurate, up-to-date patient data and can recommend the most appropriate treatment. Duplications of medical tests can often be avoided.

A health card with data on the patient's allergies and medication history can also help to avoid the risk of prescribing potentially dangerous combinations of drugs, even when network access is not available.

5.3.3 Enabling new privacy-related applications to be developed

⇓ Smart cards simplify data encryption over the Internet and by doing so support the function of "Offering user-friendly and personalised interactive secure systems to provide citizens and patients with general health information as well as personal guidance" (see section 3.5, (d))

Smart cards can supplement a citizen's identification with a set of attributes, qualities and abilities, not only an administrative serial number. This can help individualise health care treatment and offer a gateway to information concerning medical conditions according to a set of predefined rules - a 'patient's personal profile'. New applications can be developed including search engines and data mining tools (data warehouse solutions identifying data correlations over a large amount of data). These applications could rely on having presented all relevant information in the most appropriate way for the individual case, with no concessions in terms of security and data protection. The simplification of data encryption using smart cards allows the patient to be fully informed, without imposing extra time and effort on health practitioners.

With a smart card and the relevant applications, citizens/patients could get personal access to medical concepts and to guidance on the reasonable limits of certainty in diagnosis and prognosis. This would also help to broaden the understanding of medical concepts by patients and the public generally.

A potentially-attractive model for e-health applications could be "open", i.e. allowing for on-line downloading (via IP) both to cards and terminals of new applications or upgrades of the existing ones, without compromising any of the security objectives (authentication, non-repudiation etc). This model is explored in Chapter 6.

From a 'consumer' perspective, an "open" model empowers the citizen, with a "real time" choice of applications.

Three categories of applications relying on the new ease-of-use of encryption and strong authentication, can be distinguished:

- ⇨ On-card applications targeting health and social welfare should give the citizen real choice when dealing with services.
- ⇨ Applications running on smart card terminals to make technology accessible to all citizens and to offer new opportunities for terminal manufacturers in a new sector.
- ⇨ Server Applications (Distributed applications supporting the services described above) e.g.: Medical software ergonomics, Visualisation of clinical images, clinical image management and IT Management for Hospitals and Institutions.

5.3.4 Improving health care administration

⇓ Smart cards can improve health care administration by allowing better, cheaper and faster data entry and data management (e.g. health care reimbursement processing). Smart cards thus support the function of "supporting continuity of coverage and quality of care for people with public and/or private health coverage"(see section 3.5, (h)).

Manual data entry is liable to typing errors. Reduced data entry, using electronic identification, can improve the error-rate for the whole process. Applications can be activated by the simultaneous insertion of smart cards for both patients and health practitioners. Some patient medical data (e.g. emergency data) can be stored on the card and can easily be retrieved at any time in the card's life cycle. Data entry for administrative and mostly stable medical Information needs only to be performed once at the 'personalisation' stage of

eHealth applications: after that, the data will be routinely accessible after successful authentication.

Information technologies have from the start offered the prospect of reducing paperwork costs and procedural problems. They do so in many ways, but today in the era of 'ubiquitous Internet', administrators can share resources and process information in a still more efficient way, based on the uniform electronic forms notionally present in all distributed health systems. For citizens, reimbursement, say, could be a one step "transparent" process (e.g. from insurance organisations directly to bank accounts) combining smart cards for securing the system and networks for making the system ubiquitous.

More automated, faster processing can also be cheaper. Citizens themselves should benefit from the savings, in enhanced services or reduced or contained costs, optimising the price/service trade-off.

Data management can be cheaper too using electronic forms, especially because institutions introducing them have the opportunity for a thorough reengineering not only of their data management processes but also of every process and functionality related to patient information. Much can be learned from past experience, in terms of functionality and usability - there is a record of rich experience in European public and private health sectors, which the new technology can help to converge on better service for citizens.

5.3.5 New tools for enhanced policy management capabilities

⇓ Smart cards improve health care policy management by making cheaper and more powerful the collection of anonymous statistical information to be used for assessing effectiveness and efficiency of health policies. In this way, smart cards support the function of "supporting continuity of coverage and quality of care for people with public and/or private health coverage"(see section 3.5, (h)

Statistics in recent years have shown that North Americans and Europeans typically consume large amounts of prescribed drugs and over-the-counter ('OTC') medicines. Some of these are needed, some not, and some may even be prescribed in hazardous combination. Consumption habits for OTC drugs can be the result of national cultures, but prescribed drugs would normally be subject to specific policies. Smart cards can make it easier to avoid adverse interactions between prescribed drugs and even between prescriptions and OTC drugs.

Pharmaceutical companies, who are influential worldwide, can already monitor drug circulation by asking health professionals about their preferences and "habits". They do so in order to plan production and re-focus their research activities if necessary. Social and other health insurance organisations aim to reduce costs of over-prescribed medicines. To do so, they need statistical data on the actual amount of over-prescriptions circulating. Monitoring the chain of supply (from the doctor to the chemist) could prove beneficial for both the Insurance Organisations and the Pharmaceutical Companies. Smart cards may thus support monitoring (drug surveillance) applications, where the pure 'logistic' system would be transformed into a 'human-centric' one, thereby allowing for the analysis of actual medication usage in relation to diagnostic categories etc. Since such IT systems have to

be designed with regard to data protection and privacy, smart cards can be used as a reliable mean to assure the anonymity of the patients in such analysis.

5.4 Requirements and conditions for implementing the Vision

5.4.1 Requirements for further investigation by other 'trailblazers' ('TB's) or similar organisations carrying on the eEurope Smart Card Initiative 2002 activities

The following issues should be further investigated by specialised groups of experts such as the other trailblazers of the eEurope Smart Card Initiative or their successors:

- ⇨ Public identification and interoperability with insurance identification ➔ TB01,
  A health/insurance/benefits token could be part of national digital I.D.-systems. In any case, National Digital IDs should be interoperable, allowing for a citizen's mobility throughout Europe, and enabling easily interoperable solutions for Health Care Institutions.
- ⇨ Electronic signature, confidentiality, authentication ➔ TB02, TB12,
  Health-specific revocation processes (i.e. regular updates on certificates which are no longer valid) should be considered. The smart card could be seen as a 'professional licence token' for health practitioners. Digital Certificate Revocation processes should support cases where a doctor is disqualified, or the license is suspended for a period of time, due to malpractice etc.
- ⇨ Dual slot card readers ➔ TB04,
  The FINREAD specification developed within the eESC closely follows an "open model" architecture.
  When supporting a dual slot, FINREAD (either as it now stands, or the future embedded and trusted versions) will allow for multiple card signing. Signing of the patient's card by the practitioner's card allows "trustworthy" communication between physician and patient (in technical terms).
- ⇨ Multi-Application platform ➔ TB07,
  A smart card could be a multi-application card, thus allowing for interoperability between different services and service providers (e.g. Social and other health insurance institutions – Public or Private) in the same country or abroad, as well as allowing tokens for e-Government on the same platform.
  Legal issues need to be addressed to create trusted relationships between card users, application owners and infrastructure operators. Dispute settlement mechanisms need also to be established, to avoid recourse to formal judicial proceedings.
- ⇨ User interface, user requirements ➔ TB08,
  Following the TB8 User interface guidelines, smart cards can be used by all citizens, taking proper account of:
  - Age and cultural differences (some holders routinely use technology, others may not, etc)

- The interests of special groups such as people with 'special needs', chronic illnesses etc
- Human interfaces so that the contents of the card can be read in the most appropriate and efficient way.
- The interests of the medical/health professional world: while citizens will see an immediate benefit from the integration of technology into the system, medical professionals will probably need to adapt their traditional style of practice.

5.4.2 Policy and economical requirements

A key element of any e-Government policy for the use of the Internet is to ensure that systems can be used by citizens with no geopolitical limitations, when appropriate. This also applies to projects in the health care sector and encourages the use of interoperable systems.

Another issue will be to manage the 'inertia' of past systems: specific age groups are not well acquainted with either Internet or smart cards. Efforts may be necessary to inform and train (when necessary) citizens about the advantages that the new 'models' could offer. So-called digital trust is vital for systems in health care. If citizens can be persuaded that trust can be guaranteed by technology, the need for training is lessened (the ideas in 4.3.1 and 4.3.5 could help grow confidence). Ideally, the use of smart cards should be so easy that no training is needed. Help lines would, of course, be necessary.

5.4.3 Functional requirements

The vision as outlined above could be implemented by reference to the following ideals:

⇨ Ubiquity: All potential users can readily take advantage of the infrastructure and the services it can provide.

⇨ Ease of use: There are logical and consistent (preferably intuitive) rules and procedures for use of the infrastructure.

⇨ Compliance with the minimum data set required for interoperability (GIF-like requirement following the Global Interoperability Framework)

⇨ Good functionality should allow easy access via standard PCs, handsets or PDAs, and also where appropriate via public telephones, Internet kiosks, set top boxes or enhanced TV sets.

⇨ Usability: Health cards and their inter-acting devices should be easy to use

⇨ Cost effectiveness: The net 'value' provided needs to be consistent with investment and running costs - otherwise the infrastructure will not be built or operated.

⇨ Standards: The basic elements of the infrastructure and the ways in which they interrelate should be clearly defined, with an expectation of stability over time.

⇨ Openness: The infrastructures should be available to everyone on a non-discriminatory and unrestricted basis.

5.4.4 Implementation Strategy Requirements

Successful Implementation in a number of countries (mainly France, Austria, Germany, Netherlands, Slovenia, United Kingdom) has demonstrated the value of the set up of 'national' committees and organisations, that are in a position to concentrate on the task of the co-ordination of activities between various sectors in order to "redesign" the existing infrastructures supported by state of the art technology. This is of particular importance in the healthcare sector, where social and health insurers insurance organisations often link to separate Ministries of Health and/or Social Affairs and not to some overall coordinating influence in national government. Also, some actors such as health professionals may have significant autonomy in some Member States.

It would be the main task of such a Committee to launch nationwide projects preferably in distinct stages in order to produce concrete stage by stage results. This large-scale operation relies for success on public consensus too, so a focal point of the Implementation Strategy should be to build this consensus based on demonstration and education, in order to achieve confidence in the new infrastructure.

5.4.5 Technical Requirements

Smart cards have microprocessors and can thus include all facilities for processing and cryptography. Today there are 32 bit, 64K EEPROM memory and crypto libraries, microprocessors allowing for either DSA or ECDSA, and AES encryption and signing. Technology advances rapidly so efforts should be made also in any planned re-engineering within the health sector to prepare for the additional facilities and services which will certainly be available within 2 - 3 years of implementation.

If it is decided to use FINREAD as the terminal for all e-Europe's sectors and relevant applications (as represented by SCC TBs), specifications could be updated to dual-slot using embedded and trusted FINREAD techniques already in the development stage. As mentioned in paragraph 5.4.1 (requirements relevant to other TBs), a note to TB4 ('generic card reader') was prepared presenting the case for a dual slot reader for accommodating the special requirements of the health care domain.

JEFF ('Java' code from ROM) and STIP ('Small terminal interoperability') platforms could be considered for unified upgrade of terminals. The relevant TB 7 has produced significant documentation describing the platforms mentioned here.

As before, it is critical for internetworking (IP) that reliability percentages are achieved that go beyond typical application levels elsewhere. Where it is a matter of 'life and death' for patients, evidently IP nodes and paths should be 'always on'. The new 'Internet Protocol version 6' offers an excellent mechanism for this.

5.4.6 Requirements for new regulation or legal measures

Paper documents such as IDs and Health Insurance 'booklets' used as evidence of cover in some countries have formal legal status. In systems where paper is replaced by electronic media such as smart cards, legal measures may be needed to establish the same level of formal acceptability. Depending on the system-migration pattern, joint running may need to be legal for a specific period of time.

Legal measures also have to cover:

- ⇨ 'Ownership' of the electronic health care record
- ⇨ Unified data protection laws
- ⇨ Certification and Registration authorities
- ⇨ Validity of electronic forms and transactions

6 Europe-Wide usage of smart cards

“Europe-Wide usage of smart cards” refers not only to inter-nation data exchange (e.g. while reading cards issued by different States) but also involves exchanges at the inter-regional or even intra-sector level as well (e.g. cards issued by different providers nationally to be read with different equipment).

This chapter focuses on cross-border interoperability between health care information systems, contributing to citizens' mobility for learning, professional training, posted work, or any other activity that requires citizens to move inside the E.U. common space, whether at home or across E.U. internal borders.

From an application viewpoint, both administrative and medical functions are covered here.

While interoperability could perhaps be found in the 'lowest common denominator' of technology available between countries, this White Paper considers the prospect of common technology at a higher level. It assumes that the services provided will combine smart card equipment (i.e. cards and terminals including card readers) with, where necessary, telecom applications based on IT networks or even GSM technology.

6.1 Facts on mobility and cross-border healthcare reimbursement

6.1.1 Citizens' mobility inside the E.U

Over the last decade, geographic mobility between the EU Member States has remained relatively low, with 225,000 people – or 0.1% of the total EU population – changing official residence between two countries in 2000. But geographic mobility between regions is becoming increasingly important, with about 1.2% of the total EU population changing official residence to another region in 1999 (typically within the same Member State). Some 2 million workers aged 15-64 have changed residence between regions, representing about 1.4% of the EU employed population. By comparison, in the US, 5,9% of the total population changed residence between States in 1999[16]. The European Commission considers therefore that citizens' mobility is an area to be promoted.

Tourism too has particular economic importance for future growth and employment in the European Union. It is estimated that tourism directly employs about 8 million people in the European Union, representing roughly 5% of total employment and of GDP, and 30% of total external trade in services. Including related employment, and GDP indicated in other sectors such as transport or distributive trade, the figure rises to 20 million jobs and to roughly 12% of GDP[17].

6.1.2 Health care expense reimbursement procedures

Within the European Union there are at least as many health care systems as there are Member-States. This is the result of differing legislation resulting in varying procedures, different types of coverage (social and health insurers), and various kinds of interactions between institutions at top level. Complex procedures are therefore needed to cover mobility situations:

- ⇨ The insured patient could be receiving health care benefits-in-kind in her/his home country (i.e. the country where she/he is insured). In some countries, the insured person will be charged by the health practitioner for medical fees, in some others no fees will be charged and in still others, only the payment of a small part of the total fees will be requested from the insured patient. In the first situation, after the patient has paid for the medical expenditures, she/he will typically receive a 'settlement sheet' as proof of payment and will then send it to the health/sickness fund for reimbursement.
- ⇨ The insured patient may also receive health care abroad. When provided under his/her health coverage, cross-border administrative procedures for health care payment need to be applied.

At the European scale, health care reimbursement money flow during the last decade has remained relatively stable between E.U. Member-States. For example, the average yearly total amount of money claimed for health care delivered between France and the other

[16] Source: Commission's Action Plan for skills and mobility, 13th February 2002 COM 2002(72) Final.

[17] http://europa.eu.int/comm/enterprise/services/tourism/tourismeu.htm

countries is about 411 MEURO. About 74% of that money (304 MEURO) is claimed by France from other countries. Over 90 % of the claims are relevant to E.U. Member–States. In 1999, 488 000 E125 forms (i.e. cross-border health care cost invoices) were claimed for. About 384 000 patients were involved.

These figures underestimate the likely requirements. Many people do not even know they can benefit from health care access facilities across the E.U while they need medical assistance outside their home country. Also, those who are aware of such facilities may be deterred by the multiple administrative obstacles they encounter when receiving health care assistance in certain of the E.U. countries.

The tables below show cross-border refund of health expenditures within the European Union in 1998:

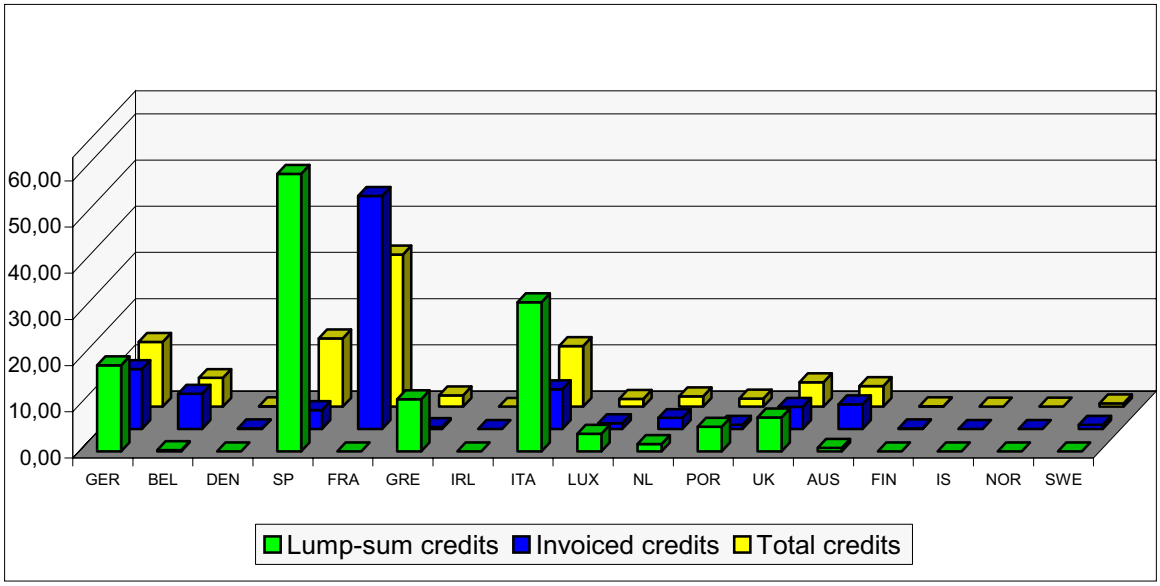

Figure 1: Claims from countries as a proportion of the total cost of the health care coordination policy (as at 31 December 1998)[18]

[18] Table extracted from the AIM report “Implications of recent jurisprudence on the coordination of health care protection systems - General report produced for the Directorate-General for Employment and Social Affairs of the European Commission - May 2000” using as source: the CASSTM report (CA.SS.TM 230/99)

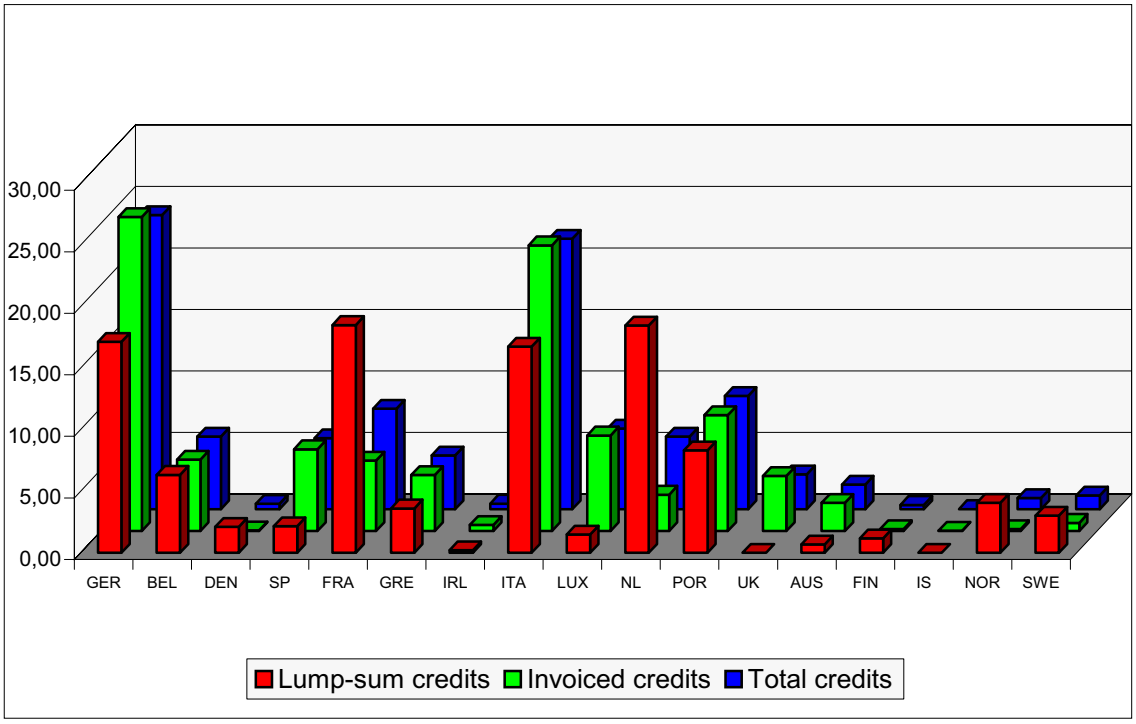

Figure 2: Debts from countries as a proportion of the total cost of the health care co-ordination policy (as at 31 December 1998)[19]

6.1.3 Lack of interoperable solutions

Most of the smart card and IT network software applications deployed in the schemes of local or national health information systems are however available only in the context of national regulation - they were designed for the national or local health care information system. Most of the services provided by such systems are not available abroad and many may not even be interoperable between different regions within the same country.

Administrative procedures for international cases therefore still rely on paper in the Member States even where smart cards are used and administrative procedures computerised. In the Member States where patient clinical data are, or will be, electronically available (i.e. on smart cards or through networks), Health Professionals still cannot in international cases have access to the patient clinical data, even in an emergency situation. Interoperable solutions at trans-European level could dramatically improve the quality of services provided to citizens in social security and health applications.

Simplified implementation of cross-border processes could thus apply, at the same time providing reliable cost and claim control by health institutions, which are largely funded by taxpayers. Significant cost savings could then be obtained.

[19] Ditto as footnote 18.

Clinical data could be carried by secure health networks and/or patient smart cards subject to uniform regulation. Health practitioners could thus have access to patient medical files anywhere and at any time.

European industry has a business opportunity to offer interoperable technical solutions for health care services inside the E.U. and even worldwide. Large-scale rollout of these solutions could also boost the influence of E.U. industry and promote worldwide standardisation.

6.1.4 Convergent policy and procedure simplification to remove legal barriers in the E.U

A number of studies such as the one issued by the STOA Panel[20] stated that there is a need for a European health card but many problems have to be resolved prior to issuing such a card, notably the issues dealing with regulation, security and confidentiality. The multiple obstacles described above have reduced citizens' mobility inside the E.U. According to E.U. common policy, geographic mobility could be promoted by removing administrative and legal barriers.

The complexity of the cross-border refund procedure represents a significant cost burden for the Member States. Cross-border administrative procedure simplification could therefore, be a first step towards convergence of legal issues. It would obviously provide significant benefits for people with medical care needs whilst they are outside their home country.

6.2 The Vision: Smart Card Interoperability

6.2.1 Rationale

Smart cards would be interoperable (i.e. usable) irrespective of the Member State or the sector in which and for the purpose of which they have been issued (smart card interoperability). They would technically mirror the Internet “ubiquity”, to the possible benefit of all people moving within the European Union.

This would support the mobility of European citizens and remove a barrier within the European labour market:

- ⇨ When applied to health-insurance related processes, this could significantly support the modernisation of cross-border/cross-sector administrative procedures;
- ⇨ When applied to health related activities, this could significantly support the collaboration and share of information for ensuring the continuity of care.

Interoperable smart cards in the health care field should permit:

[20] A European Health Card, Final Study, European Parliament, DGR PE 296.701/Fin.St.

- ⇨ Citizens to use a smart card as proof of entitlement or accreditation when receiving 'benefits in kind' for immediate medical care (i.e. emergencies), or in the context of cross-border care pathways.
- ⇨ Citizens to use a smart card for emergency data.
- ⇨ Health Fund institutions to use secure IT networks for administrative data transmission including clearing data flows inside EU Member-States and associated nations.
- ⇨ Health Professionals to have secure exchanges of clinical data and/or access to medical information, by using a smart card with IT networks.
- ⇨ Citizens with chronic diseases to use smart cards to ensure continuity of care.
- ⇨ Citizens to have confidential access to their personal clinical electronic records, using a smart card in combination with IT networks in accordance with regulations and legal restrictions applicable by the Member-State (e.g. utilisation of electronic archiving via secure internet access; demonstrated by various pilot projects across Europe).
- ⇨ Development of a patient data card which could hold the following data or refer to them:
  - Patient's personal data
  - Insurance Data
  - Emergency data
  - Clinical data
  - Prescription data
  - Patient PIN and secure keys for mutual authentication between card and read/write device

For that purpose, the synergies between smart cards and the Internet would be of great help for building-up interoperable systems. Smart cards from different Member States do not necessarily need to have the same content, as long as they provide on-line access to supplementary or even complementary data.

Therefore, practical solutions would focus on a common minimum dataset and on common services. The emphasis should be on the following items, which are already part of the NETLINK "Requirements for Interoperability" document:

- ⇨ Procedure simplification by using a health card as a proof of entitlement, or to access proof of entitlement, for patients and/or for refunding hospitals' medical fees.
- ⇨ Patient medical emergency dataset codification for emergency situations.
- ⇨ Secure on-line access to a remote medical database to help health practitioners while they are treating patients from other countries, and/or patients who have been treated by a hospital abroad.

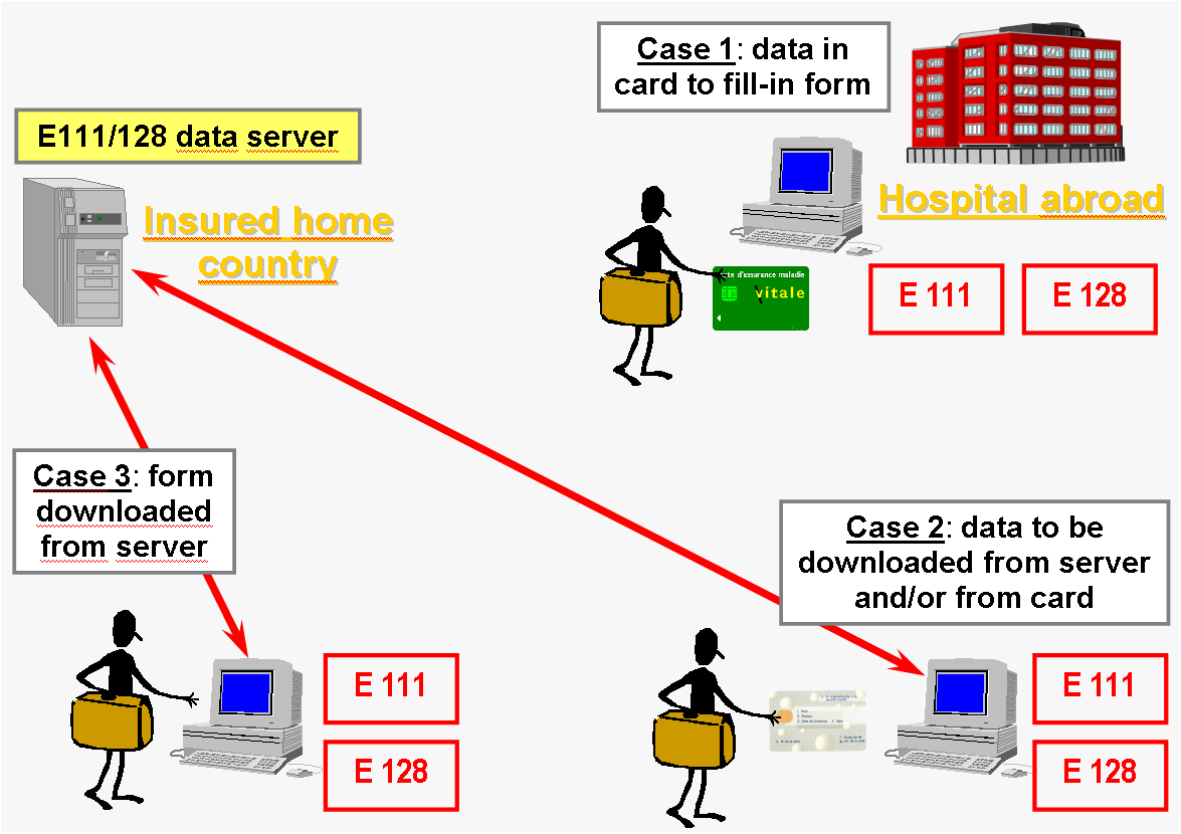

Figure 3: Simplified cross-border procedure for immediate care (E111) and/or necessary health care (E128)[21]

Due to a rising number of European citizens being additionally covered by supplementary or full private health insurance, card related processes (e.g. reimbursement and access to/proof of healthcare) will have to be coordinated between public and private insurers in order so serve all citizens accordingly.

6.3 Social and economic benefits to be derived from the Vision

⇓ Smart card Interoperability with regard to medical data ensures:

⇨ Complementarities in cross-border health care, providing the best quality of service; in addition to card interoperability, this requires official commitments between the health institutional actors concerned (social and health insurers, providers, etc.),

⇨ Continuity of clinical treatment with on/off-line secure access to information for Health Professionals and patients, in accordance with regulations,

⇨ Better quality of care by avoiding double/non-matching medication and secondary disease,

and by doing so supports the functions of:

[21] This drawing has been extracted from the Netc@rds project running under the e-Ten programme since September 2002.

⇨ "Enabling patients and health professionals to collaborate and share patient and other health-related data for continuity of care"(see section 3.5, (a)),

⇨ "Supporting continuity of coverage and quality of care for people with public and/or private health cover"(see section 3.5, (h)).

⇓ Smart card Interoperability with regard to administrative data ensures:

⇨ Simplification of administrative procedures by using smart cards combined with IT network technologies,

⇨ Cost reduction by reducing the paper form processing costs while increasing the speed of cross-border refunds,

⇨ Encouraging the mobility and autonomy of elderly people and those with chronic diseases,

and by doing so supports the functions of:

⇨ "Supporting safe mobility by enforcing the provision of emergency care and specifically enabling support for those who may need regular and intensified healthcare service" (see section 3.5, (f))

⇨ "Supporting increased mobility for business travel, expatriates, and leisure travel"(see section 3.5, (g).

6.4 Requirements and conditions for implementing the Vision

6.4.1 Requirements for further investigation by other 'trailblazers' ('TB's) or similar organisations carrying on the eEurope Smart Card Initiative 2002 activities

The following issues are to be further investigated by specialised groups of experts such as the other trailblazers of the eEurope Smart Card Initiative or their successors:

⇨ Public identification and interoperability with insurance identification ➔ TB01,
A health/insurance/benefits token could be part of the national digital I.D.-systems. In any case, the National Digital IDs should be interoperable allowing for citizen's mobility throughout Europe, easily enabling interoperable solutions for Health Care Institutions. For example, the Belgian government is issuing a national ID smart card which could technically also be used as a key for secure download of additional data from a remote health insurance front office, i.e. a portal or a server.

⇨ Card readers ➔ TB04
In order to let the industry - i.e. manufacturers, software editors, access providers and services providers - have free choice of interoperable reader implementation, TB04 should enhance the choice of programming languages for building up virtual machines.

6.4.2 Policy and economical requirements

The vision of an “interoperability solution” is scarcely new. Much has already been established, as mentioned above. Where full implementation was not previously achieved, a principal reason might have been the lack of a strong willingness from some of the key institutions.

A vital requirement is therefore to obtain a strong political mandate for implementing the above vision, e.g. for contributing to converging policies in the field of:

- ⇨ E.U. citizenship,
- ⇨ Promoting skills and mobility in the European Union,
- ⇨ Improving balanced healthcare quality of service inside the E.U.,
- ⇨ Information Society (i.e. e-Government and Administrative procedure simplification).

Such a mandate should then enable building a consensus between all actors concerned (i.e. the ministries in charge of health and social affairs, social and health insurers, health professionals, patient representatives, etc.) on the same clear and well-defined objective.

The mandate should also ensure that this objective is supported by suitable priority in allocation of budgets and expertise.

For supporting the implementation of such a mandate, a thorough business plan is required which should:

- ⇨ Review and adapt economic models for demonstrating potential savings in health expenditure,
- ⇨ Estimate the financial requirements and identify the necessary budget lines.

6.4.3 Functional requirements

Smart card interoperability requires that for administrative and/or medical data, solutions are found, standards established and consistently implemented and codification arranged as required. Such work has already been described in Section 5.1, dealing with the activities of ISO TC 251 WG5.

Proposed interoperability also relies on the availability of the necessary on-line data, in the event that they are not loaded on the card. This requires for instance that health coverage data, E1xx -series related data or private coverage data, emergency data and patient data record are made available through a secure network, or the Internet, with the appropriate security measures.

The databases in which the above-mentioned data are held should have XML interfaces to allow exchange of data between applications.

Overcoming the language barrier is a necessity. In a domain potentially as critical as health, language constraints can actually be dangerous. With appropriate “translation” applications, all medical data stored in the card (or on a foreign server) could automatically

be displayed in the appropriate language for the local health care practitioner easily to establish a diagnosis and to help to decide on treatment.

6.4.4 Implementation Strategy Requirements

Implementation Strategy needs to involve completed or on-going nation-wide projects. It works best if introduced in distinct stages, offering tangible benefits at each stage. This is because deployment of *Smart Card Interoperability* is always a very large-scale project involving many actors and resources.

Such a project should therefore start with a minimal set of standardised data and extend it step by step, building on the success of each previous step and on stable international standards. It always concerns individuals (i.e. insured persons, health practitioners, etc.), so particular measures need to be taken to ensure the adequacy of the benefits offered to them and to build their understanding of current and future benefits offered by each stage.

6.4.5 Technical Requirements

Interoperability between the different technical components (i.e. cards, readers, software and databases) is required to achieve these objectives.

Interoperability specifications should be derived from former European project requirements supported by the CEC (NETLINK, TRUSTHEALTH, DIABCARD etc.) and from on-going initiatives (E-EUROPE TB11, TB4, TB2, TB12) as well as from the output of Standards bodies' (e.g. CEN/ISSS Workshop, ISO TC 215 WG5 recommendations).

Cross-border interoperability should build on:

- ⇨ Smart cards, security features (authentication certificate, digital signature, data encryption, biometric measures, …).
- ⇨ Intelligent readers (i.e. including both programmable/transparent modes) and interacting devices[22]).
- ⇨ Open software APIs
- ⇨ IT networking of secure applications (i.e. including messaging systems, remote database access, etc.).

In the Global Interoperability Framework described, multi-application and/or multi-card FINREAD readers could be appropriate solutions for interoperable 'architecture' in terms of design and implementation.

According to the FINREAD requirements and specifications,[23] the reader could work either in raw-mode (transparent mode), or in programming mode (secure mode) which is the de-

[22] See chapter 6.

[23] FINREAD Technical Specifications were issued July 2001 and are in the Public Domain and freely downloadable (see http://www.finread.com/).

fault set-up of the FCR[24]. Both modes could be available not only for financial applications but also for other application domains (e.g. Health or e-government):

⇨ In the transparent mode the card reader should be PC/SC compliant.

⇨ In the secure mode, plug-in software[25] should be either hard-wire-implemented or downloaded tothe card reader memory.

6.4.6 Requirements for new regulation or legal provisions

Regulation will need to be updated in some particular cases so that health institutions and organisations providing services by the use of smart cards can combine information with IT network applications.

Multilateral agreement would also be required to give patients the right, under suitable conditions, to access foreign health care systems, upon presentation of their national health 'insurance' card or their national ID card.

6.4.7 Requirements for organisational changes and re-engineering of procedures

Cross-border electronic exchange of data using smart card interoperability and the combination of IT networks will require some organisational changes:

⇨ The recognition of cards issued in other countries when such recognition is not explicitly provided for by law,

⇨ Possible changes in the card life cycle, e.g. when loading the data for use abroad,

⇨ Establishment of security level agreements between the institutions offering access to their databases through the Internet or a secure network, and for the organisations in charge of card reader security.

[24] FINREAD Card Readers

[25] A Java TM application signed by the appropriate entity may be downloaded by the FCR. When a FCRA is activated, the FCR operates in secure mode.

7 Mobile Healthcare: Smart cards and "interacting devices"

"Interacting, mobile devices" are broadly defined to include any device interfacing locally or remotely with a card. Smart cards contain fully functional programming devices and can additionally store selected information. Hence, they can be programmed to perform multiple applications on various devices, including personal computer and mobile computing devices. To this extent, the smart cards can act as the "key" enabling the operation of an interacting device. These include any devices enabling a cardholder to display the content of the card for verification purposes or for initiating an updating process (thus including also for example public kiosks and mobile phones). The vital element is the provision of ubiquitous and easy access to content (whether on card or server) by cardholders. Of equal importance is the attainment of better user acceptance and trust in the technology, which should be strengthened by the use of the smart card. Since the user has the power to initiate the operation of the interacting device with his/her card and can control the nature and number of individuals who can also access the protected information, he or she should develop a positive attitude towards technology advancements and become more comfortable with technology in everyday activities.

The smart cards which enable the operation of a device effectively set up the interacting devices as core instruments for the sharing of information between authenticated users and for the seamless updating of relevant information content.

7.1 Facts on the need for and the options for mobile healthcare

"Interacting devices" can be considered in two ways: they bridge smart cards to the rest of the information system, independently of the technical base, and they provide the human interface between the card / card holder and the application.

The actual infrastructure of installed devices naturally influences the feasibility of specific e-health / e-social and e-government applications. The systems must be easily available for citizens if they are to provide accessible, cheap and secure services.

Citizens' 'biometrics' can be an alternative to PIN entry into smart cards that enable the operation of a device and sharing of information.. Biometric methods could also be considered for the initiation of a process, or for providing access to the information held on the system. As smart cards enable distributed PKI usage, the opportunity arises to integrate biometrics as the preferred way of ensuring secure access to networks.

7.1.1 Real life extracts

1.5 Million EU citizens a year die from cardiovascular disease, the No 1 cause of deaths in EU countries, accounting for 42% of all deaths in Europe.

A patient with a cardiac problem, at risk of a heart attack, can be treated in hospital over an average of 12 days, and may need close monitoring for the rest of his/her life This is costly and time-consuming in terms of tests and doctor visits.

Smart cards together with interacting devices can bring advanced technology to patient care. Interacting devices enable the patient to monitor his/her health status, transfer important medical information to healthcare professionals in real time, safeguarding also the patient's personal data through authorised access to information. This can be facilitated by the deployment of smart cards, as referred also in section 3.4 on the core functionalities to support patient-oriented, networked health care.

In this way, remote diagnosis, consultations with healthcare experts, and continuous monitoring of a patient's health status can be feasible, impacting the prevention of critical events, while dramatically reducing the expenses previously associated with hospital treatment and doctor visits.

7.1.2 Encouraging highlights

Connected computation everywhere will rapidly change the interaction of people and objects with the digital world:

Wireless connectivity is becoming common practice for industries today. Networks are increasingly widely used for resource-sharing by businesses and consumers alike. In the healthcare environment, networks are used for the provision (or exchange) of patient medi-

cal records, information on drugs, and the transmission of claims. The expansion of handheld and mobile devices (*interacting devices*) has encouraged the availability and use of wireless networks, facilitating connectivity for mobile users. 'Ubiquitous' patient-doctor communication has thus become feasible and need no longer be limited in time and place.

Interoperable devices (i.e. wireless phones integrated with PDAs) are gaining in popularity. Universal 'WAP' facilitates delivery and presentation of the web content to handheld devices combining computing elements and networking features - such devices support mobility and – at the same time – fit seamlessly with everyday activities. There are evident applications in healthcare for medical data exchange and processing.

Connectivity of mobile devices will be cost-effective, when technologies like GPRS (General Packet Radio Service) become more affordable for large scale use. GPRS allows mobile devices to be connected via IP addresses and allows digital transmissions at theoretical speeds of up to 115kb/s per channel. GPRS is expected to provide a cost-effective and efficient use of network resources for packet mode data applications. It makes on-line and real time connection to the Internet possible from suitable mobile phones. Given that GPRS is already a reality in Europe, with few problems yet to solve, there are relevant applications in the health care sector which are promising and viable in terms of economic and social benefits. These applications will benefit from wide Internet accessibility and popularity, as well as the availability of the mobile phones described above in the European market and the further diffusion of 3G technologies in mobile telecommunications.

7.1.3 Stagnation effect

"Techno-phobia" can still constrain the effective exploitation of market opportunities and full customer satisfaction.

At worst, poor familiarity with the emerging technologies, and the advanced services and features which can accompany them, can block understanding of their advantages and limit the beneficiaries to the technology initiators themselves.

There has also been something of a 'technology recession' as well, deriving from the public and private sector reluctance to invest heavily in the appropriate infrastructure so as to encourage the widespread uptake of the mobile technologies.

7.1.4 Financing

Total investment costs of nation-wide smart card based systems are a function of the price of the cards, of the interacting devices infrastructure and of the cost of hardware and software on the server side. Less-evident but significant costs come from activities like public relations, convergence of human interfaces and dialogue scripts between citizen / cardholder and the interacting device.

The banking sector (Europay-MasterCard) assumes that the number of mobile hand sets connected to the Internet will exceed the number of PC's already connected, by the end of 2002. Even if this is an overestimate, the availability and use of mobile devices will certainly influence the integration of large system architecture, and will surely encourage sharing of cards and interacting devices – a true multi-application concept.

For the moment, investors are faced with a lack of potential scale and of technical certainty. Manufacturers and implementers of chips, smart cards and interacting devices (terminals) still need reliable standards. To justify investment, they need some certainty about likely roll-out of e-health, e-social and e-government applications.

7.2 The Vision: Smart cards used in mobile interactive devices

Wider application of smart handheld devices would encourage healthcare's use of intensive remote diagnosis, prevention and monitoring. Priming interacting devices with smart card data identifying the holder would be the next step in utility and convenience for healthcare, serving the provider and the service recipient, while also safeguarding valuable medical data (cf. 4.2 Smart cards as key elements of security infrastructures for healthcare). Interacting handheld devices and mobile phones are nowadays merging to produce new kinds of solution in device integration with communications technology.

Recent technological developments thus seem to open the way to web server databases accessed by cardholders in a secure and context-sensitive way.

Effective incorporation of interacting devices into health care service provision envisages the following:

- ⇨ The citizen is empowered with a smart card as well as micro (handheld) -devices and mobile phones utilizing WAP and GPRS. Indeed, a mobile phone may already be seen as a combination of a card, a hand held device and telephone
- ⇨ Wireless web access is available and adequate
- ⇨ Wireless technologies, hardware, protocols and standards are firmly established
- ⇨ Wireless communications and applications are widely disseminated

These points, arising from mobility and the broader availability of connectivity, and speeding-up access to information on demand, will allow:

- ⇨ The provision of healthcare services with close patient-doctor communication and patient monitoring
- ⇨ Healthcare administration which can automate previously time-consuming processes and thus minimise costs

7.3 Social and economic benefits of "ubiquitously available" health services

7.3.1 Real time patient-doctor interactive communication

Introducing interacting devices in healthcare can relieve traditional nursing areas from routine patient monitoring tasks and can reinforce patient responsibility. Patient-doctor real time communication can thus be enabled. This can have two results: patients have better control of their existing health situation, while enjoying a normal life, and healthcare professionals can allocate their time more effectively and efficiently, monitor their patients' condition on a daily basis, and follow their progress closely, without unreasonably long or frequent patient visits.

The real-time patient-doctor communication allows patients on continuing medical surveillance to stay at home with minimal disruption to their daily lives. Patients can thus become more self-administered and self-reliant. Close monitoring of their health status can also minimise the need for extra medical intervention.

As well as these benefits from health care improvement, cost savings due to proper service provision are equally important. A large e-health system, just like an e-government or e-business system, can operate via just one central server easily accessible by customers. So maintenance, upgrade, and new services can be implemented in one secure location without any inconvenience to cardholders everywhere. Administration can be a significant component of the costs of health systems; so all cost savings in this area must be welcomed.

7.3.2 Healthcare services quality optimisation

Wireless devices can enable care-givers to review patient records and test results, to enter diagnosis information during patient visits and to consult drug lists and log costs, without the need for a wired network connection. Mobile and wireless solutions for the healthcare industry include:

- ⇨ Mobile care delivery which records patient information at the point-of-care, gathers patient history, monitors vital signs and offers ambulatory care;
- ⇨ Intelligent devices which include diagnostic devices, kidney dialysis, patient monitoring, blood glucose monitoring, medication dispensing devices and home disease management;
- ⇨ Physicians' orders and result systems, including prescription writing, laboratory specimen collection, tracking of samples and reviewing of test results;
- ⇨ Sales force automation solutions which support pharmaceutical and medical sales.

Automation can have significant effects on quality and costs. It can help reduce medical error; prevent duplicate entries, increase data accuracy, improve patient care and decrease operating costs.

Integration of mobile point-of-care solutions with existing systems means patient data can be captured and made available across all hospital departments, providing easy tracking of patient care. The overall result can be an improvement in patient care, backed by em-

powered, patient-focused healthcare workers who have access to the information they need to do their jobs accurately and efficiently. A mobile healthcare worker, for example, can receive doctors' referrals, or changes in the treatment of current patients. The mobile user can then update the patient's caregivers and provide additional details on the patient's medication. Orders and billing information can also be sent. Synchronisation takes place as required, and because only changed information is synchronised, connection costs are kept to a minimum.

7.3.3 Evolution of new services

Communication via interacting devices can create a new, effective and efficient channel for instantly delivering information in the form of electronic messages. These new services may include:

- ⇨ *e*-Prescribing – enabling physicians electronically to write, order and renew prescriptions and to renew information related to the selected drug on a real-time basis;
- ⇨ *e*-Lab ordering and viewing – enabling physicians to write, modify and order laboratory tests, view laboratory test results, and review information related to the selection of a laboratory test;
- ⇨ Patient medication histories – enabling hosting of patient medication histories and presentation to the physician, offering services specific to the patient and "selected care pathways";
- ⇨ Automated customised messages – providing physicians with therapy protocol-specific and 'care-pathway'-specific messages, such as drugs renewals, interchanges, and formulary compliance, and general messages intended for many users, such as drug recalls or 'new indication' approvals;
- ⇨ Disease Management - enabling the Citizen to access the service provider on the Internet via card authentication, and to get advice on care;
- ⇨ Imaging – provision of access to large data files like radiographs and other graphical outputs of recent diagnostic scans;
- ⇨ Rapid communication between different social and health insurers in case of mixed coverage.

7.4 Requirements and conditions for implementing the Vision

7.4.1 Requirements for further investigation by other 'trailblazers' ('TB's) or similar organisations carrying on the eEurope Smart Card Initiative activities

The following issues are to be further investigated by specialised groups of experts such as the other trailblazers of the eEurope Smart Card Initiative or their successors:

- ⇨ Public identification and interoperability with coverage identification ➔ TB01
  - Public ID definition
- ⇨ Electronic signature, confidentiality, authentication and non-repudiation ➔ TB02

- Patient & doctor authentication;
- Medical records management and security in transactions;
- Protocols, services and standards supporting PKI;
- Protection at all points of entry;
- Protection of data integrity.

⇨ Profiles, card security ➔ TB03

- Public ID;
- Control access to resources based on identity.

⇨ Card readers ➔ TB04,

- Dual-slot card readers, for parallel authentication of patient and doctor, as a basis for enhanced security and reliable authentication process.

⇨ User interface, user requirements ➔ TB08,

- "User friendly" design of handheld devices for the disabled and elderly;
- "Design For All" principle applied to the handheld devices.

⇨ Interfacing with other e-Gov. applications ➔ TB10

- A common European eGovernment policy, allowing for citizen and patient mobility by securing cross-border administrative procedures with reference to public/private coverage through Europe-wide interoperability;
- Convergence of health care infrastructures for implementing interactive services in the medical sector;
- Further e-Gov. applications in the healthcare sector.

⇨ Multi-application Cards ➔ TB 12

- Smart cards able to provide multi-application facilities, and to support different types of interacting device;
- Studies to assess what 'strong' security provisions are acceptable to and desirable by the user;
- Studies to assess card-system acceptance and legal status.

7.4.2 Policy and economic requirements

However challenging the introduction and use of enhanced technology may be for system-integrators, it is the 'cardholders' themselves who are the final natural decision makers. Acceptance and achievement of any business plan depends crucially on the trust the public will have in the technology. So it is vital to have the support of a 'transparent' and trustworthy plan, backed by respected legal provisions and an appropriate PR campaign.

It is important to provide equal access to the technology for all citizens including disabled or other handicapped people. Age, cultural and socio-economic constraints to diffusion of technology should be addressed, to ensure that all citizens are free, and willing, to take full advantage of what can be offered.

Indeed, if the vision is to be attained, technology must be made appealing to the general public. So effort should not be limited to technology infrastructures and their customisation, but extended to development of broader public awareness of emerging technologies, how to use them and how they can help with daily tasks. Training on the use of smart cards and smart devices should be provided - especially to the medical and nursing communities.

Now that much more is known, from previous projects, about the technology and system requirements and how they can be applied, it is easier for system-providers and user-institutions to plan for optimal 'consumer' acceptance. Consumers cannot be expected to accept inconvenient or insecure systems.

7.4.3 Functional requirements

Shareability: Common resources offer economies of scale, minimise duplication of effort, and – if appropriately organised – encourage the introduction of competing innovative solutions.

Ubiquity: All potential users can readily take advantage of the infrastructure and the services it can provide.

Integrity: The infrastructure operates at such a high level of manageability and reliability that it gets noticed only when it stops working properly.

Ease of use: There are logical and consistent (preferably intuitive) rules and procedures for use of the infrastructure.

Functionality: The range of functions provided by each system may vary, but two general rules should be observed:

- ⇨ Compliance with the minimum data set required for interoperability (GIF[26]-like requirement);
- ⇨ Ensuring common, simple usage of the whole set of interacting devices;
- ⇨ Ensuring safety by providing backup and fallback mechanisms.

Good functionality should allow easy access via standard PCs, handsets or PDAs, and also where appropriate via public telephones, Internet kiosks, set-top boxes or enhanced TV sets.

Usability: Health cards and inter-acting devices should be easy-to-use

Cost effectiveness: The net 'value' provided needs to be consistent with investment and running costs or the infrastructure may never be built or operated.

Standards: The basic elements of the infrastructure and the ways in which they interrelate should be clearly defined, with an expectation of stability over time.

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[26] GIF stands for "Global Interoperability Framework for Identification, Authentication and electronic Signature with Smart cards".

Openness: The infrastructure should be available to everyone on a non-discriminatory and unrestricted basis.

Voluntary-based: The citizen should be able to decide to whom he/she will grant access rights, when using such a health card.

7.4.4 Implementation Strategy Requirements

Implementation strategy will involve wide adoption of smart devices and issue of smart cards, thus permitting enhanced care and cure protocols. Several issues regarding utilisation models for smart cards and the penetration of interacting devices in health monitoring, prevention, and recovery should therefore be considered:

7.4.4.1 Cards

Investment in smart cards involves significant costs, spread over many features. For newly integrated systems, it is unlikely to be possible to use already- issued cards which might be technically incompatible or omit data which cannot easily be sourced in an upgrade. There are also questions of public credibility if existing cards are used for extended applications (e.g. for example if a telephone card were to migrate to a medical card). By contrast, interacting devices have the advantage of being upgradeable on-line even when widely dispersed over the application area.

As the typical life cycle of any card is around 2 years, phased introduction of new cards can be attractive. If new applications cannot for presentation reasons be hosted on the legacy card, new cards become inevitable. Widespread health systems do not need to be based on exactly the same type of smart card anyway. Some cards could even have dual interfaces to offer 'contactless' read/write, or to offer enhanced cryptography for a subset of cardholders (e.g. medical professionals).

Three principal arrangements are usually recognised:

- ⇨ Cardholder oriented model – where the cardholder downloads ('pulls') applications publicly offered by providers using an interacting device infrastructure. A problem here is the credibility of the core I-A-S [27] - is the cardholder authorised?
- ⇨ Card issuer oriented model – where the issuer 'pushes' pre-selected applications to the cardholder for acceptance
- ⇨ Service provider centred model – where the service provider ensures a 'bridge' to the cardholder so that the bridge can be used for cardholder access to third party applications.

7.4.4.2 Interacting devices

The possibilities include:

- ⇨ Upgrade of old devices, plus installation of new devices (e.g. STIP, Java consortium, FINREAD)

[27] 'IAS' - Identification, Authentication and electronic Signature.

- ⇨ Variable upgrade requirements across different types of devices influenced by the roll-out, depending on evolutions in other sectors (e.g. GSM-SMS-W@P, Internet, PDA operating systems upgrades, Bluetooth / Wi-Fi and other contactless interfaces...) There could be a great variety of interacting devices: simple or dual slot peripherals (optionally equipped with displays, keypads, fingerprint scanners ...), desktop or mobile "point-of-sale like" terminals, enhanced public phones, public internet access kiosks, ATM machines, PDAs (hand held terminals), portable PCs and of course mobile phones, which will probably become the most important handsets of all.
- ⇨ Recent system design approaches have been able to take better advantage of the variety of devices when implementing user requirements. In practice, this means finding ways to reuse already distributed equipment and to host new applications without jeopardising the existing ones. For this purpose "interdependence" as between card, interacting device and server/application levels is recommended.
- ⇨ The user may migrate to the newly designed application in three ways:
  - Upgrading existing smart card solutions (perhaps by upgrading a GSM SIM card to host a new application). There may be obstacles to such a solution for legal reasons or because existing security may not be adequate
  - Upgrading of existing interacting devices to accept the technology envisaged by the STIP (Small Terminal Interoperability Platform) concept. The way forward might be a software upgrade of a POS terminal, or a hardware upgrade of a handset to a 'dual card' device. The central issue is that hardware implementation should embody application-independent facilities, allowing use of existing and unspecified future interacting devices, with easy plug-compatibility and supervision of the terminal and applications hosted.
  - The third way is by enabling on-line access to the application by focusing on the server/application side. The smart card can thus be understood as a security access module (SAM) and the interacting device will 'bridge' to the 'client side' and/or act as a human interface.

7.4.5 Technical Requirements

These requirements can be met by currently available technology. Availability of the following features makes introduction still more accessible:

- ⇨ Bluetooth – Based on short-range radio-frequency transmission, Bluetooth is a Wireless Personal Area Network (WPAN) which allows devices to establish short range point-to-point connections, forming ad hoc networks. The technology allows mobile products to achieve connectivity quickly, as part of a highly mobile network that can change as devices move in and out of range.
- ⇨ WLAN – Wireless Local Area Networks also use radio frequencies, particularly spread-spectrum technology, to transfer information between devices in a less-limited local area. WLANs are easy to deploy and configure, scaleable and cost-effective. They facilitate network portability and make real-time data available with wider coverage than Bluetooth.
- ⇨ Interacting devices may themselves be equipped with non-invasive lightweight sensors for continuous data acquisition, e.g. of trend data

⇨ Better battery technology

Further opportunities arising from recent technical development are listed in Annex 9.2.

7.4.6 Requirements for new regulation or legal measures

Healthcare issues are highly confidential to the patient and the accuracy of the data relayed to the patient-database determines the treatment process, so it is essential that privacy and security questions are fully resolved, guaranteeing a high level of security for the data and transactions.

Multi-application systems require, in addition, the formal allocation of responsibilities between providers of independent applications co-hosted on the card.

Data also need to be protected against misuse for unauthorised commercial or competitive reasons, by establishing suitable rules and interoperability agreements.

7.4.7 Requirements for organisational changes

When patients themselves carry interacting devices, new methods for organising health care delivery may become possible. Health care providers can take advantage of this by connecting to their own new technologies. They can also help to develop the necessary 'human capital' in terms of training for the medical community and promotion of new care possibilities.

7.4.8 Requirements for procedure re-engineering

The delivery of healthcare services could be re-planned to take advantage of the new possibilities for personnel flexibility, system reliability and interoperability, and for patient satisfaction.

7.5 Summary

The previous sections have shown how the adoption of smartcards in healthcare can produce major advantages for European mobility, quality of care and health cost-effectiveness, while at the same time making best use of European industrial advantage.

Across Europe there is already wide experience of the technologies described – some health applications are already into the third generation of development. The results of all this experience continue to be used to initiate new projects aimed at further improvement and convergence.

The next section gives examples of established applications, and of new research and pilots in a number of countries.

8 TB 11 Survey: European Health Card Projects

8.1 Introduction

This survey appears as an Annex to the White paper "Smart Cards as Enabling Technology for Future-Proof Healthcare: A Requirements Survey" of Trailblazer 11 "Health" of the eEurope Smart Card Initiative, but it can also be read as a stand-alone document.

The history of large scale deployment of health cards in the health care sector goes back to the late eighties / early nineties, when France and Germany each started national programmes on the nationwide introduction of health insurance cards. Since then other nations, e.g. Slovenia and Belgium, have also introduced health cards and various projects have been started all over Europe.

The European Commission funded several projects to gain experience in the use of such cards and to stimulate their introduction in Europe. The best known in this series are DIABCARD, CARDLINK and NETLINK, all dealing with different aspects of health cards. These projects are now finished. The only health card project funded currently in the European programme DG INFSO E-TEN is NETC@RDS. The objectives of this project are mainly of an administrative nature, using cards and/or IT Networks technology in a European-wide network for health care entitlement when travelling. NETC@RDS main objective is to replace paper-forms E111 (entitlement for immediate care) for tourists and E128 (entitlement for any care) for posted workers and students by electronic forms by reading national Health Insurance Card and/or by downloading the e-form from secure servers through an Internet portal of European Health services.

This activity also has to be seen in the context of the European Council's decision in March 2002 in Barcelona to introduce a European health insurance card, which is intended to replace the current paper forms needed for health treatment in another member state. The Commission will present a proposal before the European council in March 2003. This initiative is led by the Directorate General (DG) Employment, partnered by DG Information Society, DG Enterprise and DG Health and Protection of Consumers (SANCO – 'SANté et protection des COnsommateurs). A working group has been set up to discuss legal and technical questions as well as possible solutions to simplify the existing administrative procedures in Europe. At minimum, this means the replacement of the paper form E111 "Certificate of Entitlement to Benefits in Kind During A Stay in a Member State ".

It seems probable that no nation will be obliged to introduce a smart card just for this purpose, nor will those who already have a card be required to replace it, so a solution has to be found to meet all preferences. New cards will somehow "contain" the information needed and existing cards will be enhanced to prove entitlement all over Europe.

However, which health insurance cards, and respectively which projects, already exist in Europe? This survey will answer that question. In accordance with the scope of ISO TC 215 WG 5[28] and the description of the STOA-report[29] this survey interprets a 'health card' as a machine readable card compliant with the physical characteristics, including dimen-

[28] International Standardisation Organisation Technical Committee "Health Informatics" Working Group 5 "Cards"

[29] A European Health Card , March 2001

sions, defined in ISO/IEC 7810, which means a credit-card sized plastic card with a magnetic stripe or an embedded chip that can either be memory-only or include also a microprocessor. Only current European health card projects and those under development are described in full detail: former projects will be briefly mentioned with a link to more information. Both patient data cards (PDC) and health professional cards (HPC) are considered. The focus is on those countries active in the eEurope Smart Card Charter, listed in alphabetical order.

Information is being provided on each project's nature, its objectives, the benefits expected, its status, the type of card used, the number of cards issued and a picture of the card if available. The information is based on the author's knowledge, interviews, research and the contributions of the TB 11 experts. It was not possible to gather comprehensive information from all countries and projects in the short time available for the task. Nevertheless this survey is as complete and up-to-date as possible. Additional information or corrections are very welcome and should be addressed to the author (j.sembritzki@ztg-nrw.de).

8.2 Austria

8.2.1 Social Insurance Chipcard – "e-card" (PDC)

Up to now, 43 million treatment and health insurance certificates have been issued every year in Austria. This system is now being replaced by an integrated network solution based on the social insurance microprocessor card, "e-card". The wide-ranging scope of this project includes 8 million digital signature compliant smart cards, 18,000 card reading devices, the introduction of an extensive computer network, the opening of a call centre as well as consultancy work and services covering all aspects of the smart card.

Initially only administrative data will be stored on the card, e.g. name of the insured person, date of birth, gender, insurance number, card number, entitlement, date and first specialist visited in a quarter (encrypted). But currently there is a debate about storing also the patient's medical data (emergency data) on a voluntary basis.

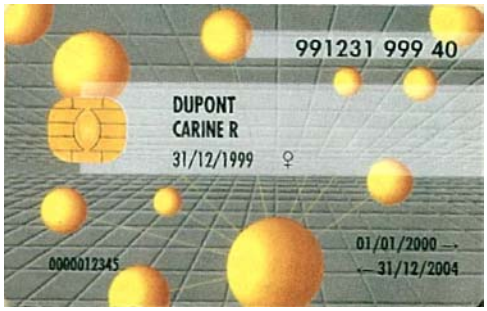
During the next two years, starting 2003, 8 million insured and their relatives will be equipped with e-cards and 12,000 physicians and hospitals with terminals. This is the largest organisational and technical project of Austrian Social Security.

More information/contact: http://www.sozvers.at/chipkarte/index.htm

8.3 Belgium

8.3.1 SIS - Card (PDC/HPC)

The Belgian Health Coverage's (Mutualités Belges) Social Identity System (SIS) requires smart cards for patients and doctors, pharmacists, hospitals (where the third party paying system applies).



The SIS health insurance card became mandatory for all social insured citizens (about 10.5 million) at the beginning of the year 2000 and contains a microchip with information about the person's health insurance.

It should enable more rational management of the health sector and also help to simplify reimbursement.

The SIS card is personal and stores two types of data in its memory chip.

- ⇨ Unprotected data, visibly indicated on the card and also keyed in electronically using a reader. These data are: surname, first forename and first letter of the second forename, date of birth, sex, social security number, card number, a unique 10-figure combination which is the identification number of the social identity card, card validity start date and end date. These data are freely accessible and write protected.
- ⇨ Protected data, which only key holders can access with a professional health service card called SAM and PIN verification. These data are: version number (indicating last change to the entitlements to reimbursement of healthcare), period of insurability (this period is bounded by a start date and an end date, including insurance organisation identification).

8.3.2 TRANSCARDS (PDC)

The aim of the Transcards project is to test, on a Franco-Belgian pilot site, the use of telematic networks and card technology (Belgian SIS card and French Vitale card) in the administrative procedure generated by the cross-border flow of patients, and to identify the general rules that could be applied and are re-usable elsewhere.

The main objective of TRANSCARDS, therefore, is to do away with the administrative forms for emergency treatment and scheduled treatment corresponding to the forms E111 and E112, by using the technologies (cards and readers) existing in both countries.

Advantages for all: the patients will see a simplification of the procedures for reimbursement of treatment; the Health Care Professionals (in a hospital complex) will be able to improve service to their patients, complementing the treatment due to the co-operation of both countries; the health insurance organisations will reduce their administrative costs; and the Governments will be better equipped to control the flow of finances.

8 hospitals in the "Thiérache" region have taken part in the experiment. The population concerned by Transcards corresponds to wage earners (i.e. Belgian and French salaried workers as well as non-salaried Belgian insured) benefiting from the general benefit scheme in this Franco-Belgian border region. Potentially, this represents 100 000 French people and 50 000 Belgians. In the experimental area hospitals, there is unrestricted cross-border circulation of patients and the most frequent entitlement forms (E111-E112) are replaced by forms printed out of data stored in the VITALE as well as SIS cards. The E125 form will still be used for reimbursements between the two countries.

The SIS and Vitale cards will replace the forms as far as cross-border patient identification is concerned. They will also provide a check on the insurability of patients. The information contained in the cards currently enables printing out of forms to be used by the parties involved (hospitals and insurers) in order to issue invoices for healthcare and obtain reimbursement of expenditure.

More information/contact: http://www.sesam-vitale.fr/html/projets/transcards.

8.4 Czech Republic

8.4.1 Macha (PDC/HPC)

In December 1995 a pilot project for the use of smart cards in the health sector of the Czech Republic started in the town of Litomerice. The project was initiated by the Ministry of Health of the Czech Republic and the VZP (General Health Insurance Organisation) to study the functionality of a card system for identification of patients/insured persons. The project was embedded in the framework of general reforms in the Czech Republic and specifically of the health sector.

With the successful termination of the first phase of this experiment a lot of information and expertise was gained. Nevertheless, the clear need was identified to continue and extend the project into a second phase, the **Macha II** phase of the project.

Macha II was set up in 1998 specifically to evaluate different technical possibilities for patient-insured identification in both the health and social insurance systems, including automatic processing on all information levels. It had been a target to extend the experiment to all inhabitants of Litomerice and to include additional service providers in the health system. Furthermore it was requested that phase II would yield a decision basis for the Czech Government to progress a nation-wide implementation of the most suitable technology.

The trial is continuing after the pilot finished and the whole system remains in use and operates correctly as at end 2002.

Based on **Macha** achievements, smart card technology has been recognised as suitable for this type of application, however the obstacle seems to be the cost of smart cards.

An office for personal data protection is in place in CZ and can provide a legal framework for implementation of electronic signatures.

Currently VZP has issued a public invitation-to-tender for analysis of nation wide roll out.

The objectives of the Macha project are as follows:

1. Analysis of the technical possibilities for secure and reliable identification of patient/insured
2. Analysis of the potential use of chip cards in other application areas
3. Analysis of the use of the cards for communication and transmission of data between health establishments
4. Definition of necessary data structures
5. Provision of a security analysis
6. To ensure harmonisation with similar activities in the EU and G7
7. Overview of activities concerning patient/insured identification in the EU and CEE countries
8. Examination of use of health professional cards

9. Defining steps and framework for nation wide implementation
10. Provision of technologies needed for testing and type approval
11. Establishing contacts and exchange of information with operators of other key health applications in the EU or Phare countries
12. Production of specialised documentation for legislative purposes
13. Testing possible applications to the social security sector
14. Testing of data and infrastructure sharing with other application areas, specifically the banking sector
15. Extension of the Macha experiment and introduction of new functionality to cardholders and acceptors
16. Ensuring smooth operation of the pilot project and regular evaluation of the pilot performance
17. Establishing international workshops and national seminars
18. Ensuring international co-operation to extend the scope of the pilot.

Main results of the pilots are that smart card technology suits patient/insured identification and authentication, that systems must be robust and must enable the simultaneous use of different types of cards to allow technology upgrade and that a priority should be identification of the card holder rather than use of cards as a (medical) data carrier.

Technically the smart cards used in the project comply with ISO international standards.

A microprocessor module MOTOROLA SC21 is used with the processor MC68HCO5SC1 (3 KB EEPROM, 6 KB ROM, 128 B RAM, 16 B security read only EEPROM. The operating

system is ORGA ICC series 4.1. For Macha II phase Orga Micardo cryptocard has been specified as a natural upgrade. Both types are currently operated simultaneously in one system without any obstacles.

About 29,000 cards were issued in this pilot , 15 000 in the **Macha II.**

An application hosted on the card has been designed, developed and implemented for social benefit distribution. This application was loaded into 15.000 **Macha II** cards.

This pilot extension is considered successful by representatives of the Ministry of Labour and Social Affairs and separate statements have been issued by this ministry. The **Macha** system is controlled by VZP and concurrently supported and maintained by its technical provider IMA (Institute of Microelectronic Applications).

A memorandum on collaboration between the Ministry of Health of the Czech Republic and the French system SESAM-Vitale has been signed.

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Jiri Ochozka, aproks@anet.cz

8.5 France

8.5.1 Vitale Card (PDC)

In 1993, the three major mandatory medical insurance schemes (for wage earners, for farmers, and for the self-employed) created the Sesam-Vitale EIG (Economic Interest Grouping). Since then, several other health-insurance organizations have joined the EIG, among them all the public complementary health-insurance bodies. Their common purpose is to develop a programme meeting the data exchange expectations and needs of all those involved in healthcare (i.e, insured patients, health professionals, health insurance funds).

France was one of the first countries in the world to introduce the large-scale use of smart cards in the health insurance system. The pioneering SESAM-VITALE system was the first fully automatic system in which microprocessor cards were used in the health sector. The system was initiated by the French Ministry of Health.

Today's Vitale card is a microprocessor card containing roughly 4 pages of text and replacing the standard 'soft copy', individual health insurance card. The first family version (Vitale 1) of the card contains administrative data, available to health professionals (i.e. physicians, pharmacists, dentists, physiotherapists, nurses, etc.) for immediate reading and storage of secure electronic health care cost claim sheet during the visit. According to the

software application and the terminal smart card reader equipment the e-sheet can be stored either in programmable secure reader memory or on the health professional computer hard disk. The sheets will be daily bound into secure electronic batches (e.g. every night) and sent out through the secure national health Intranet named RSS (Réseau Santé Social) to the Health Insurance front end servers for further cost clearing automatic process in the back office system). SESAM-Vitale is a highly secure dual-card system. The CPS (French health professional card), a highly secure microprocessor card, is compulsorally required when reading the patient Vitale card dataset for further electronic cost claim sheet set-up. Visibly printed on the card are surname, forename and social security number (NIR) on the front and the card serial number on the reverse side of the card. The data stored in the chip are separated in two zones and comprise NIR (Social Security number), health insurance system code, branch, entitlement start date, proof of entitlement, presence of permanent entitlement, Surname, Forename, date of birth, status of beneficiary, information specific to health insurance system, entitlement end date etc.

The SESAM-Vitale system simplifies the health care costs clearing procedure and also dramatically reduces insured patient refunding risks of delay by replacing 1 billion of yearly health care paper sheets with electronic transactions (average reimbursement time is now some days compared with up to 6 weeks before card roll-out). Furthermore, the SESAM-Vitale system provides health costs payment directly to health professionals by insurers. It is a tool to track healthcare spending and could in the future enable the transfer of electronic prescriptions to healthcare funds, responsible for reimbursement. It will also optimize health care costs with the best quality of service and provide the same health care service quality and access for all citizens. The Sesame-Vitale card is the heart of the health network (Reseau Sante-Social - RSS) that should link through a secured computer network each individual patient with all kinds of healthcare providers: public hospitals, private clinics, general practitioners, specialized doctors, nurses, etc. Already more than 57 million of these cards are currently used (64 million cards issued).

By early year 2004, the Vitale Card version 1.3 will be distributed to the population. It will include additional information like complementary health insurance administrative data (public and private as well), personal data (administrative only) and an European dataset including administrative information required either for E111 form issuance for immediate care, E112 form for programmed care or E128 form for any care (concerned insured are salaried workers and students). Thus, the above listed European forms could be potentially issued from any insured Vitale card in any other Member State health professional office equipped to read the card.

The second generation card (Vitale 2) - an individual health card - will include an emergency data set and possibly other medical parameters, that will only be available to health professionals using a professional health card for identification. 65 million of these cards have to be rolled out. Other medical information (e.g. patient medical history) could be stored on highly secure servers. Name code of this SESAM-Vitale enhancement is known as “Vitale ON-LINE”.

More information/contact: www.sesam-vitale.fr/netlink/ ;
International.Project@sesam-vitale.fr

8.5.2 CPS Card (HPC)

Parallel to the Vitale 1 card, France introduced a Health Professional Card (CPS – **C**arte de **P**rofessionnel de **S**anté. It identifies the Health professional and also provides authentication, digital signature and data encryption. Pharmacists and medical staff also receive a card, which can easily be recognised by its colour.

More than 425,000 cards have already been issued to Health Care Professionals, more than 90,000 of these to physicians.

More information/contact: http://www.gip-cps.fr/intro/PRE_cadres.htm
http://www.gip-cps.fr/

8.5.3 Netlink (PDC/HPC)

NETLINK was a Telematics project, partially funded by the European Commission, running from 01.07.98 - 30.11.2000. The project developed concepts and technology to pave the way for implementation of interoperable data card systems and Internet/Intranet solutions, before nationwide use in the healthcare sector.

In order to support healthcare services to the fullest extent, a secure health passport based on card technology was designed.

In the field of health care systems interoperability, NETLINK developed specifications for common solutions, particularly in security architecture, networks, health professional cards, and patient data cards.

The feasibility and economic viability of these integrated solutions was demonstrated in several implemented pilot sites.

Countries involved in the NETLINK consortium (France, Germany, Italy and the Canadian Province of Quebec) had set up new nation-wide Information systems in the healthcare sector. These implementations were based on the use of modern technologies: smart cards (used by health professionals and patients), computers (used by health professionals, hospitals and health insurance funds), large networks and trusted third parties (for security purposes). Their objective was to make these new nation-wide information systems interoperable for the benefit of patients (continuity of care, enhancement of quality of care, simplification of administrative procedures), health practitioners (facilitation of communication, continuity of care, simplification of administrative procedures), health insurance funds (facilitation of communication, simplification of administrative procedures).

The NETLINK project produced and maintained the NETLINK 'Requirements for Interoperability' specification and promoted it to the G8 countries and other nations involved in implementing health card solutions. Proactive relations with the Standardisation organisations were maintained. Several pilot sites were implemented to assure the feasibility and the economical viability of the solution.

A guideline for the development of future projects compliant with the NETLINK specifications was produced and an evaluation methodology was developed, assuring the certification of reliability and interoperability of future card projects following the NETLINK requirements.

NETLINK results and achievements can be categorised as:

1. Technical specifications,
2. Pilot site implementations and validation
3. Dissemination of, and pro-active support for, Standards

NETLINK developed the NETLINK 'requirements for interoperability' specification, which was adopted at the G8 level as the basis for the interoperability of Health Smart Cards. The objective was to specify the complete infrastructure: procedures, card terminals, HPC, PDC, security architecture and network protocols.

Based on these requirements, pilot sites were developed in France, Italy, Germany and Quebec-Canada. The pilot sites demonstrated several aspects:

- ⇨ Interoperability of health smart cards between the involved countries
- ⇨ Access to a distant medical database.
- ⇨ Administrative procedure simplification for reimbursement of medical fees.

The project partners included Information Technology (IT) providers **(**i.e**.** health-card based system designers and integrators**)** (GIE SESAM VITALE, GIP CPS, ZI, FINSIEL, MOTUS (Co-operating Partner Québec, Canada)), Health-care Service Provider organizations (CNAMTS, RAMQ, INPS) and Medical Institutions representing Health Professionals (CNOM, CNPS). The sponsoring and supporting partners included governmental institutions at national level (French Ministry of Employment and Solidarity Health Affairs, Italian Ministry of Health) or at federal level (German Associations of Office based Physicians (Regions of Bavaria, Hesse and South-Baden), Ministry of Health and Social Services of Québec).

More information/contact: http://www.sesam-vitale.fr/netlink

8.5.4 French-German NETLINK Pilot

French patients from Alsace (France) can now receive dialysis treatment in Germany, merely on production of their Vitale card previously updated with information held on European form E112. They are then admitted into one of the five pilot Dialysis Centres in the state of Baden-Württemberg in Germany. Prior to going abroad the card must be updated at any of the five CPAM (health insurance local office) at any public SESAM-Vitale terminal in the area of Alsace.

The scheme being used on French and German locations is interoperable. Pilot Dialysis Centres are able to read the E112 data on the Vitale card using their own IT facilities (reader, software package, terminal) without the need for any additional SESAM-Vitale facility.

More information/contact: www.sesam-vitale.fr/netlink/
International.Project@sesam-vitale.fr

8.6 Germany

Early on, a consensus was reached, among statutory health insurance partners and government in Germany, that a current digitised proof of insurance status would be a great asset. A very first model using a magnetic stripe had already been tested in the early 70's in Rendsburg-Eckernförde, but never proved successful, basically because the technical infrastructure was too expensive for field use and the data content too small. In 1987 a second model sponsored by one of the statutory insurances, the AOK, using embossing techniques was tested in Wiesbaden with a much more positive result.

8.6.1 Statutory Health Insurance Card (PDC)

In 1992 a law was enacted which ordered the introduction of smart cards for all statutory health insurances. The actual introduction of these Health Insurance Cards (HIC's) was then postponed until after another field test in 1993 where 256 Byte RAM-cards were issued in Wiesbaden, Böblingen and Weimar. In the following year, 1994, over 80 Million cards were issued throughout all 16 German states in 5 steps. In addition, over 147.000 card readers and dot matrix printers were issued to all licensed statutory physicians as well as ambulatory centres and old people´s homes.

The focus of these cards was naturally the administrative data of the statutory health insurance system, comprising name, address, date of birth, name and number of the insurer, insurance status and date of end of validity. All of these data were placed in a simple random access memory module in ASN-1 notation and printer interfaces were developed so that the card readers were able to print the data directly on insurance forms, in addition to serially transmitting this data to attached computer systems. At the time this was deemed sufficient in terms of a return on investment.

Two years later in 1996 the private health insurance companies in Germany were finally able to reach an agreement with the statutory health insurances for use of the reader and printer infrastructure and then issued their own analogous and interoperable insurance cards. These basically contained the same data as statutory health insurance cards. Some data fields were however modified for the purposes of private health insurance. The handling of these private cards by health care providers, and related organisational implications, remained unchanged.

So to this day, almost all German citizens have and use one of these cards.

During 2002 a debate began about introduction of a new health insurance card. The Ministry of Health announced an intention to introduce a smart card with additional medical data on a voluntary basis. The data under discussion are: emergency data, electronic prescription, referrals, physicians´ reports etc.

The new government, elected in September 2002, also expressed their wish to introduce such a new card, in the coalition agreement signed in October the same year.

With this background it is most likely that in 2003 a pre-project will be initiated and from 2004 onwards a new generation of cards will be introduced on a nationwide scale in Germany.

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8.6.2 German Health Professional Card (HPC)

In December 1997 a large meeting of all of the major players and potential communication parties in German health care met in Cologne by invitation of the German Medical Association and the German Administration of Office Based Physicians to discuss how an interoperable system of health professional cards could be achieved. The major result was that those groups have since then been actively working on this matter. Not only to focus on their own interests but take a larger view, so that potentially all groups concerned could use the same basic specification. From this beginning, by December 1999 the Electronic Physicians' ID became the first health professional card in Germany with an application-neutral design adaptable to most other professions in the German health community. In other words, the basic functions of this identification chip card are generic and not specific to any particular application or profession.

The official German Physicians' ID implements five different functions, which are specific to the user as a person:

First, this card is a classic visual identification card with a personalisation, including a picture, so that it can be used for general proof of ID in various medical settings, e.g. in a pharmacy, should the holder wish to purchase a prescription drug.

A second, similar function is in the electronic chip where a base certificate electronically signed by the issuing Medical Association identifies the holder by name and digitised picture and specifies his role as a physician. This function is intentionally not PIN-protected and is intended for easy and simple use in an already secure environment. As such, it is a direct counterpart of the visual ID function.

All other functions, specifically three private keys from asymmetric key pairs, are protected by a PIN and have to be explicitly activated. Each of these keys is dedicated to a specific purpose.

The first key is for secure client/server authentication within a medical application system using strong encryption.

The second key is used for transport encryption using a hybrid symmetric / asymmetric encoding scheme.

The third key is used for the generation of a personal electronic signature, which according to current German law has to have legally binding characteristics. A set of specific attribute certificates issued by the state Medical Association or the state Administration of Office Based Physicians can be appended to this signature by the signer if he so wishes.

In 1999 this specification version 1.0 had been finalised, officially approved and made available for pilot projects.

While it is already a large first step to have a physicians' ID, the original intention was to develop this specification as a model so that all other health professional roles could build their own specific ID. Therefore, naturally, in 2002 the pharmacists joined in and both associations, the pharmacists´ and the physicians´, financed the further development of specification version 2.0, which then can be used in common. The final draft is expected to be available end of 2002.

Lately also the dentists have expressed their interest in participating in the development.

More information/contact: http://www.hcp-protocol.de

8.6.3 QuaSi–Niere (PDC/HPC)

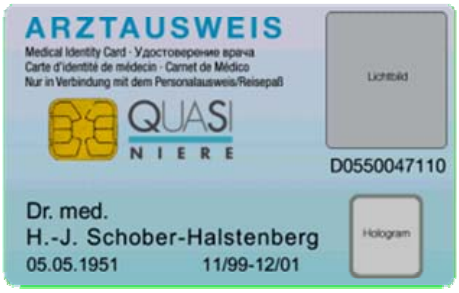
Modern lifelong medical treatment with dialysis and renal transplantation helps survival for nearly 1,100,000 people all over the world who are treated because of terminal renal failure. Renal disease registries which have been set up in all developed countries collect individual medical outcome records in epidemiological databases. The data is used on at an international level for benchmarking and provide national health care facilities with statistical information for the optimal control of health care resources. Renal replacement therapy is one of the most expensive therapies, due to the repetitive lifelong treatments several times a week with high-end technology. Reimbursement scenarios all over the world show that access to renal replacement therapy could have to be restricted in developed coun-

tries because it seems unaffordable to supply all patients. Different strategies exist e.g. to reduce or avoid terminal renal failure.

Germany offers to all of the more than 70,000 patients with renal failure lifelong medical therapy like dialysis or renal transplantation, without any restriction. In order to optimise therapy strategies and outcome on a longitudinal approach, the German registry for renal affairs and interests –QuaSi-Niere- had to solve difficult data protection demands. The implementations selected for external quality assurance procedures, concerning the outcome of the lifelong therapies, are prescribed in different laws of the German social system. There is much cooperation on an international level within the renal community.

In cooperation with several German IT-Industry partners, a working and sophisticated security infrastructure was built up in 1996. It is accepted by patients, physicians, therapy providers, insurance companies and governmental partners. Medical records are prepared for analysis within the electronic documentation and billing infrastructure of the more than 1300 renal therapy providers.

To run a central lifelong registration of medical records it is necessary in Germany to have an accepted and sophisticated data protection scheme. In consensus with the data protection registrars in Germany an adequate scheme was set up that is well accepted. Organisational and technical provisions ensure the highest possible security of individual medical records. In general, medical records can be divided into three entities: identification of the patient, identification of the provider and the medical information. For registry work it is not important who is the patient or the provider. For outcome research only a 'pseudonymised' medical record is necessary. Outcome research deals with treatment, co-morbidity and mortality. In principle the data protection scheme involves separation of all the three facts by a 'trusted third party': identification of patient, identification of the physician and medical treatment data. Special smart cards ensure the pseudonymisation algorithms and determine and guarantee security. From a data management point of view tables with patient names and names of treatment facilities need be no more secure than, say, uncritical like telephone directories.



A unique patient index is created at the Trusted Third Party and this unique patient number is transformed to a 3-DES-key. The treatment information is sent for analysis with the generated triple DES-key as an anonymous identifier. The calculation of the triple DES-key for replacing the patient's identifier and the provider's identifier is carried out using a crypto-smart card.

Data communication between the provider and the registry is only possible if the encryption smart card is placed in the reader.

The medical records are structured in XML syntax and before the transmission to the registry, the responsible physician has to sign electronically with his smart card. The files are then encrypted using smart card technologies.

For longitudinal analysis, unique patient identifiers are optional. In Germany there is no unique identifier for each citizen. For more than 60,000 patients in renal replacement therapy smart cards (patient data cards – PDC) were handed out to solve the individual unique registration and the access of a patient to his registered data within the data protection scheme. Data queries from a patient are initiated by the patient`s PDC and the access to medical records must have an authentication by a health professional's crypto-processor smart card (HPC). The authentication process is based on a symmetrical encryption. In order to transmit the patient's and doctor's request to the trusted third party an asymmetrical authentication between the trusted third party and the health professional is achieved and the patient's queries are assured by digital signatures and transmitted using standard cryptography. The health professional card authenticates also storage on the patient data card of about 4 Kbyte of relevant medical records, according to the G7/G8 interoperability data set. A special crypto-processor-smart card at the trusted third party proves the authentication process and is used to calculate the pseudonyms via triple DES.

In the QuaSi-Niere project more than 60,000 Patient Data Cards (PDC) were produced in co-operation with the national chip card industry. Since 1999 all PDCs and HPCs have been produced at the trusted third party (lawyer/notary) and posted to the providers.

More information/contact: www.quasi-niere.de

8.6.4 GesundheitsCard international (PDC)

The model project, which translates as "International health card", is an extension of the German health insurance card.

Within the framework of their cooperation, the partners CZ Groep (NL) and AOK Rhineland (D) have initiated the project as one further small step towards improving cross-border health care provision. The project started in June 2000.

The range of services provided includes:

- ⇨ specialist medical treatment
- ⇨ provision of medicines
- ⇨ any necessary hospital treatment involved

Also if additional approvals have been granted, medicines and aids as well as state-of-the-art treatment may be provided.

In practice, the procedures are as follows:

If the insured person needs specialist medical treatment in a neighbouring country, he applies to his Branch or to one of the cooperation partners. He gets help and detailed information from the staff there. Within 3 or 4 days he is sent the 'International health card'. Relevant information will be enclosed, detailing e.g. the service provider and the patient

report, which ensures an exchange of information between the person providing the treatment and the person referring the patient.

With the International health card, the insured person then contacts the registered doctor in Germany, or - in the Netherlands - the outpatients' department of a hospital. Domestic procedures afterwards apply to the customer from the neighbouring country.

Agreements with doctors, pharmacists and hospitals ensure the provision of the service, prescriptions and billing.

The advantages are obvious:

- ⇨ needs-oriented cross-border health care provision,
- ⇨ cross-border use of 'benefits in kind' – without additional costs for the insured,
- ⇨ simple and quick access through simple administration,
- ⇨ without costly approval procedures with hundreds of forms,
- ⇨ simplification of the billing system between Member States,
- ⇨ information and transparency.

This is achieved by cross-border services in all branches of the CZ Groep and AOK Rheinland in the 'Euregio' Meuse – Rhine, especially in the AOK Branch in Vaals (NL).

Many years of cooperation between the insurers AOK Rheinland and CZ Groep make possible the implementation of this project, which is based on a contract defining procedures and mutual guarantees.

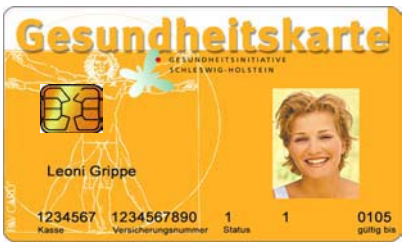
This cooperation is also a good foundation for activities in other projects for cross-border health care provision, to improve the position of the insured. Meanwhile, cross-border health care provision has been firmly established in the activities of health insurance companies in the border region.

Currently (end 2002) there have been around 11,300 cards issued for CZ – insured and around 3,000 cards for AOK-insured

More information/contact: Heike Au, AOK Rheinland - Die Gesundheitskasse
Kasernenstr. 61, 40213 Düsseldorf
Telefon (02 11) 87 91 11 55, Telefax (02 11) 87 91 12 32
heike.au@rla.aok.de

8.6.5 Health Card (Gesundheitskarte) Schleswig-Holstein (PDC)

The Health Card Schleswig-Holstein is an initiative in the north of Germany. It is planned to start with a pilot in the city of Flensburg in Spring 2003, involving 15 physicians' offices, two hospitals and a small number of pharmacies.



The card is intended to improve the quality of services as well as communication between family doctors and specialists on the one hand and physicians and hospitals on the other hand. In the long run a gain of more transparency of services and costs is also expected. The use of the card is voluntary for the patient and will help to strengthen his/her position in the health care system.

Technically the card is a development of the currently used nationwide health insurance card, which is a simple memory card and merely contains administrative data. In contrast, this new card is a smart card with additional data, i.e. emergency data (blood group, allergies, implants, vaccinations) and references and pointers. Technically it could be used with an electronic prescription or medication passport.

Under the leadership of the Ministry of Social Affairs of Schleswig-Holstein, this initiative unites the efforts of the Association of Office based Physicians, the Physicians´ Chamber, the Association of Pharmacists, as well as health insurances (AOK), the General Hospital Diakonissenanstalt Flensburg, the Teaching Hospital of the Kiel University and the Flensburg University of Appplied Sciences (Department of Health Care). The vendors' side is represented by ORGA Card systems, PAV CARD Kartenkommunikation / Paul-Albrechts-Verlag, and MediSoftware, Computer Systems for Physicians.

More information/contact: Ministerium für Arbeit, Soziales, Gesundheit und Verbraucherschutz
Adolf-Westphal-Straße 4, 24143 Kiel
Tel: 0431-988-5482
Fax: 0431-988 5478
Bettina.Neke@sozmi.landsh.de

8.6.6 Netlink – French – German pilot (PDC/HPC) (see also France)

The Netlink pilot region was, on the German side originated in the cities of Achern and Offenburg in the state of Baden-Wuertemberg with approx. 60.000 inhabitants and on the French side in Strasbourg. It is still running, although the NETLINK-project itself finished at the end of 2000.

For several reasons, mainly because dialysis centres across borders may be closer to their homes, French patients come to Germany regularly for dialysis.

In this pilot, the structure for these patients of the reimbursement process between the German physicians, the physicians' association, the German health insurance fund and the French insurance company, as well as the entitlement of the patient to receive the requested service, is handled by electronic communications. This is done using cards and secure cross border networking.

Today, the whole reimbursement process takes approximately two years, starting with the patient attending at the insurance office to receive a paper insurance form, by presenting his paper E 112 form, then receiving the service 'in kind' via reimbursement of the physician through his regional association, and afterwards the collection of all forms by the dif-

ferent service providers and ending with the reimbursement process between the German and French insurances via the national liaison offices.

To optimise this unsatisfactory process, a data set of reimbursement suitable for electronic exchange was defined on the basis of the present reimbursement forms within social health insurance in European Union (forms E 112). While the electronic form of E 125 is developed by the TESS-project the definition of the E112 (Certificate of Entitlement to Benefits in Kind During A Stay in a Member State) is in its work programme but is not defined yet . Therefore a card storable definition of the E 112 data content was developed within the scope of the French-German NETLINK pilots and the storage of this data is implemented in the French Vitale microprocessor card. In this regard, a bilateral protocol agreement has been signed between the French and German Health Insurance as well as by the (German) National Association of Statutory Health Insurance Physicians. Thus, the NETLINK French-German pilot is providing cross-border procedure simplification in the area of regulation. The French insured patients from the area of Alsace may prove their entitlement to receive dialysis treatment in German dialysis centres by presenting their Vitale card updated with E112 dataset. The German physician is well-equipped with reader and software that can read the Vitale card and print out the E112 form for the purpose of further cross-border reimbursement procedures.

French patients are only allowed to receive dialyses treatment in Germany. With any other disease they have to contact a French physician. In this case it is very important for the physician to know the latest data of the patient because he might not have seen him for several month. Therefore a remote access by a French physician to the data of the patient stored on a German dialyses centre system is implemented. Ideally the French physician will have access to the data by presenting his Health Professional card and authenticating himself to the system. To implement this solution a stepwise concept is set up:

In the first phase, the data on the French patients is stored on a separate mail server which can be accessed by a software certificate provided by the German network provider.

In the second phase, this certificate will be replaced by the Health Professional card.

The software used is a product by Control Data GmbH, Frankfurt, Germany called 'Cipher Suite'. It facilitates the creation of a directory-based security infrastructure, allowing a flexible, client independent, application for e-mail, Web-services and other internet applications. The information for personal authentication is stored on the smart cards by default. All other administrative settings are handled through a central directory service.

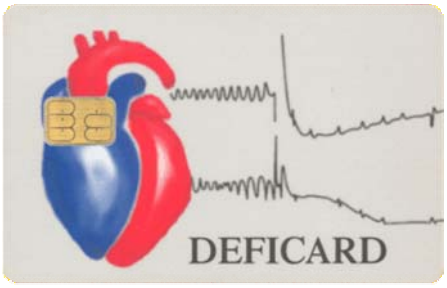
Public Key Infrastructures are created by a set of security modules. These offer an LDAP-compliant address service and serve as a repository for certificates, security policies and local client configurations. The secure identification and authorisation of the French physician can be done through the use of chip cards or soft-PSE (1st phase)

The system uses strong encryption, based on international standards, and is in line with the recommendations of the Netlink-WP02 deliverable, e.g. LDAPv3, X.509v3, PC(SC), RSA 1024, SHA1 etc.

8.6.7 Former projects

After the successful introduction of the health insurance card in Germany, card projects were initiated all over the country, mainly to extend the administrative data by adding medical data, which had to be on an additional card (because the data set of the existing card had been fixed by law). During 1995/1996 this development reached its peak with 13 different health card projects nationwide. Here a selection of those worth mentioning.

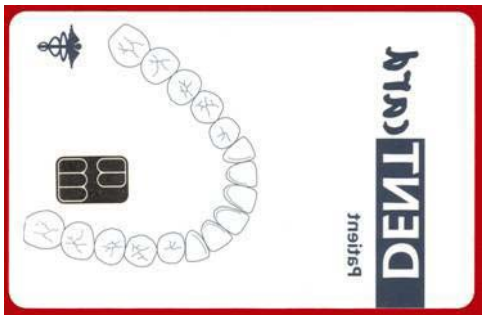
8.6.7.1 Deficard (PDC)



The first historically viable PDC in Germany was begun in 1993, the so-called "DefiCard". This card was developed for the approximately 70,000 patients in Germany with implanted defibrillating devices. It contained data relating to the device selected, as well pre- and post- operative patient data, specifically information on the basic illness and therapeutic intentions. During the 1996 project phase in Hannover, about 100 of these cards were issued, validating the usefulness of the information contained for post-treatment purposes. This card already contained the so-called G7-interoperability data set, a standardised set of minimal patient information, thus paving the way for future interoperable applications in an international, European setting.

More information/contact: Universitätsklinik Marienhospital Ruhr
Prof. Dr. med. Hans-Joachim Trappe
Hölkeskampring 40, 44625 Herne
Tel. +492323/499-1600/1
Fax: +492323/499-301

8.6.7.2 DentCard (PDC/HPC)



Another large project which went into production in 1998, with an evaluation of over 1000 cards by over 20 dentists in Brühl, was the "DentCard", a set of patient data cards together with an access 'professional card' for the transfer of dental data between patient, dentist and dental laboratory. This card contains data specific to the patient's dental status and ongoing therapy, and is accessed using the PIN-protected professional card.

More information/contact: http://www.orga.com/gesundheit/index.html

8.6.7.3 DIABCARD (PDC)

One of the European funded projects was carried out by a consortium of GSF-Medis (National Research Centre for Environment and Health, ZI (Central Research Institute), Diabeteszentrum Bogenhausen, Hospital de la Santa Creu I Sant Pau Barcelona, Instituto di Patologia Speciale Medica e Metodologia Clinica, Perugia, University of Linz, Institut für Pflege- und Gesundheitsforschung, Linz, Boehringer Mannheim, IBM Germany, Siemens and Schlumberger. The "DIABCARD", which started in 1992. These cards contained the so-called ´DIABCARD diabetes data set´ and were first tested in Italy, Greece and Spain. In 1996 the third phase of this project was initiated with pilots in Barcelona, Umbria, Thessaloniki, Athens, Corbeil, Vienna and Munich and Kassel. Around 700 cards were issued and pilot tested, 500 in Kassel. The focus of these cards was medical records for diabetes care and communication between treating physicians. This card contained administrative data, an emergency data subset (interoperable to the G7 data set) and medical data.

More information/contact: http://medis.gsf.de
http://www-mi.gsf.de/diabcard/
Rolf Engelbrecht, GSF – München, engel@gsf.de
Claudia Hildebrand, GSF – München, hildebra@gsf.de

8.6.7.4 MPK/-A Card (PDC)

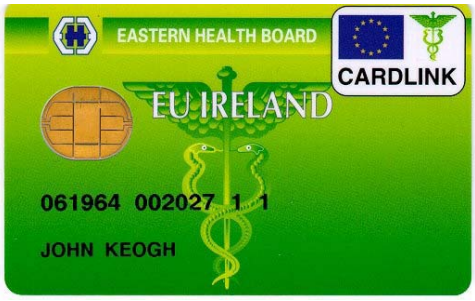
A major project was jointly developed by the German Association of Pharmacists and the Association of Office Based Physicians and issued to over 5000 patients of selected physicians in the region of Koblenz, the "MPK/-A Card". This card contained a standardised version of clinical data, the last 40 medications and / or vaccinations in addition to administrative data. Each physician and pharmacist could read or write relevant data.

This region was also a test site for the CARDLINK – project (see also 'Ireland", below)

More information/contact: http://zi-koeln.de/service/andere/brenner/brenn-03.zip (Cardlink)
http://www.zi-koeln.de/service/andere/brenner/bren-15.zip (MPK)

8.7 Ireland

8.7.1 Cardlink (PDC)



Ireland (Eastern Health Board) was the main contractor of the Cardlink project called "A patient held portable record for particular application in cases of medical emergency", supported by the European Commission DG XIII from 1.3.1996 to 30.6.1999.

The aim of CARDLINK was to demonstrate the nation-wide interoperability of emergency data. CARDLINK-test sites were: Saint-Nazaire (France), Koblenz/Neuwied (Germany), Amaroussion (Greece), Dublin (Ireland), Brescia (Italy), Rome (Italy), Delft (Netherlands), Lisbon (Portugal) and Valencia (Spain).

The CARDLINK project demonstrated the European and national aspects of interoperability. European interoperability aimed to find solutions where a patient card issued and personalised in country A may be accessed in country B.

An interoperable data set was agreed between the CARDLINK partners on the basis of the G8-interoperable emergency data set (http://www.sesam-vitale.fr/html/projets/g8).

More information/contact: http://intercare.imsgrp.net/cardlink.htm

8.8 Italy

8.8.1 Netlink – pilot (PDC/HPC) (see also France)

Italy actively participated in the NETLINK project and issued Netlink-compliant cards in Imperia, Pinerolo, Bolzano and Trento.

The project implemented demonstration plate-forms for cross-border entitlement to health services by using E111 electronic forms issued from the PDC in medical emergency situations abroad.

The Italian PDC contains E111 information useful for procedure simplification as specified in the NETLINK project. French VITALE cards are able to provide electronic authentication and administrative data so that a E111 form (for administrative registration) could be built up when the French patients went to Italian pilot sites for medical assistance in an emergency situation. A similar procedure could be applied for Italian Health Cardholders when they went to a French pilot site. Thus, the French VITALE Health Card would replace the E-111 paper form as well as the Italian Card would do

In the French–Italian pilot, for interoperability, both NETLINK-compliant Italian PDCs and French experimental PDCs contain an emergency medical data set.

The Italian call for tender requested, for PDC´s and HPC´s, smart cards with at least 8 KB of EEPROM, ISO 7816-4 compliant, class '00' commands, capable of mutual symmetric authentication (3DES). Part of the HPC is equipped with RSA private keys for digital signature and deciphering.

The Italian PDC is accepted in selected emergency hospitals, USL's (local health centres) and family doctors' surgeries in the pilot areas.

The mutual use of health cards in Italy and France could lead to a pilot of bilateral acceptance of electronic media, whether cards or networks, as a first step towards cross-border communication and entitlement to health services in Europe.

In the Regione Lombardia, 320,000 PDC´s have been issued to simplify diagnostic procedure and to improve the efficiency of Italian health systems.

Patient Data Cards compliant with Netlink requirements contain the card data (i.e. cardholder data), emergency data in 'clear' mode (i.e. blood group) and administrative and clinical data (e.g. hospital admissions).

More information/contact: Alessandra Pastorino, blena1@interfree.it

8.8.2 "Carta Nazionale dei Servizi" (CNS): Recent Italian Smart Card Project

An experimental smart card pilot project CNS "Carta Nazionale dei Servizi"® is underway. The card is going to be tested in some Italian Regions by mid 2003. It will initially provide both health and fiscal services. Later additional services will be implemented.

The smart card provided to each citizen does contain

- ⇨ A unique ID code (fiscal code) consisting in a self generating alphanumerical code
- ⇨ Registry data
- ⇨ A set of emergency data
- ⇨ Electronic (digital) certificate.

Qualified persons will be provided with a special card, named CNS/O Carta Nazionale dei Servizi/Operatore, which will allow them to have access both to health data stored in the citizens card and to NHIS. However citizen may (or not) authorize the access to his/her health data, excluding in the case of emergency.

The system is designed to:

- ⇨ Provide secure access to services
- ⇨ Facilitate citizens administrative (health and fiscal) fulfilments
- ⇨ Optimize the flow of the organizational process within the Public Administration
- ⇨ Facilitate a better control of the health expenses.

8.9 Netherlands

8.9.1 The Healthcard project ("the Eemland pilot") (PDC)

On the initiative of the national umbrella organisations of care consumers, care providers and care insurers and the Netherlands Ministry of Health, a trial concerned with the Healthcare Information Network and the Healthcare Card was conducted in the district of Eemland (Amersfoort and surrounding area). The trial started in May 2001 and ran for exactly one year. Now that the results have been evaluated, the network has been used since September 2002 for other applications, such as electronic letters of referral from general practitioners to specialists. The pilot applications and the use of the Healthcare Card have been terminated.

In mid-2001, the insured in the district around Amersfoort (about 375,000) were given a personal healthcare card with a chip and some 200 care practices, about 50% of that region, were provided with a computer and a card reader. For the period of one year, care providers had access, via the network, to the most recent name/address and insurance data of their patients. In this way, a test was carried out of the development, the linking-up, and the use in practice of a health care Information Network with Healthcare Cards.

In addition health care consumers could also read and write a small amount of data on the card: specifically "first aid information". This reading and writing could be done at a small number of locations like hospitals, two libraries, a health care centre etc.

The results of the trial were encouraging. Support for the use of a safe network in which messages could be exchanged electronically appeared to be considerable:

- ⇨ the care providers stated that although the network operated rather slowly and the possibilities were limited, they wished to proceed further with electronic communication;
- ⇨ the largest care insurers in the district stated that the network contributed to an improvement of insurance data and that the trial revealed the necessity for far-reaching standardisation of data;
- ⇨ although the network used for testing appeared to give few advantages to care consumers, they nevertheless considered the electronic exchange of data, as such, to be practical.

The network in Eemland has continued in a modified form, giving more emphasis to mutual communication between care providers. Already in September 2002, a test has been started with general practitioners and specialists at the Meander Medisch Centrum (formerly known as the Ziekenhuis Eemland and Medisch Centrum Molendael). General practitioners are, for example, now able to send a letter of referral to the specialist electronically, instead of giving it to the patient, to read the feed-back letter from the specialist in the same way, view laboratory results, and call up radiology reports.

Work will be done within the district to add other possibilities.

The Healthcare Card, originally used only for checking insurance entitlement, is not necessary for communication between care providers. There are alternatives available for enabling care providers to check the insurance entitlement of their patients electronically without use of a Card. For this reason, the use of the card as proof of entitlement was cancelled on 1st September 2002.

More information/contact: Zorgpasgroep (Care Card Group), tel: (030) 210 64 77 or info@zorgpas.nl; on the follow-up: MCCE, tel: (033) 475 74 50 or mcce@meandermc.nl

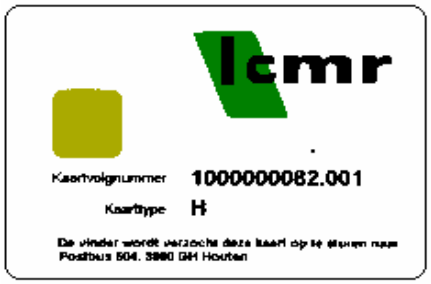
8.9.2 Health card for drug addicts (PDC)

Drug addicts and homeless people in the Netherlands have to identify themselves with a special pass in order to obtain health care. In October 2002 Heerlen, a town in the southern part of the Netherlands, started a pilot project, in which the Ministry of Health is taking a close interest. According to the council of Heerlen, the pass is intended to certify which of the addicted and homeless population are entitled to care (and which are not). The pass is also used to track the use of care and to see who is a citizen of the town of Heerlen and who is not. The first 50 Health cards were given to a group of Heerlen drug addicts and homeless who are entitled to day and night care. As well as this group (who get a 'green' card), there are other categories of homeless. For those groups, it is still unclear what care they may be entitled to - when that is established other Health cards will be distributed.

More information/contact: http://www.heerlen.nl

8.9.3 LCMR – Card (PDC)

The National Central Medicine Registration (NCMR -LCMR in Dutch) is an information system supporting practitioners, helping them to assure the correct dose of prescription medicines to authorised addicted cardholders.



The use of biometry and chip cards guarantees that access to the system is restricted to people authorised to use it - this applies to both patients and health care professionals. The main objective of the NCMR is to help healthcare professionals who prescribe substitute medicines to patients suffering from an opiate addiction to offer a qualitatively good level of care (continuity of treatment, the prevention of overdosing and double dosing), by means of a national information system. Other objectives are to combat theft and the incorrect use of medicines referred to in the Dutch Opium Act, and to obtain anonymous policy information.

The NCMR is automatically filled with information from the local registration systems on a daily basis. This information (up-to-date information about the medication prescribed to patients as part of their treatments, and up-to-date information about the healthcare professional responsible for patients' treatment) is then immediately accessible to authorised health care professionals elsewhere. The information accessible via the NCMR enables a health care professional to determine reliably whether and where someone is being treated (or has been treated). On the basis of this information, the authorised health care

professional can contact previous/other health care professionals, in order to exchange information about treatment.

With the NCMR system, those authorised to administer or dispense substitute medicines have 24-hour access to up-to-date and reliable information about each patient receiving substitute medicines as part of his/her treatment, without leaving their desks.

The use of biometry and chip cards makes it possible (temporarily) to continue to administer/dispense substitute medicines elsewhere. It also becomes possible for the patient, in consultation with his/her personal doctor, to collect the substitute medicines from his/her own pharmacist, using a biometrically-protected chip card, on which prescriptions have been recorded.

More information/contact: http://www.sivz.nl

8.9.4 The Parkinson Pass (PDC/HPC)

In recent years much work has been done on the development of a smart card for Parkinson patients, incorporating biometric identification.

The background for development of such a card is that people with chronic illness often receive treatment from more than one physician or therapist, and these specialists also need to know about their colleagues´ therapies and treatment methods. The 'Parkinson Pass' therefore creates a basis for an Electronic Patient Dossier and provides a practical, quick and easy to use key for that dossier. The use of the key is exclusive to the patients and their care providers. Without one of the two keys there can be no access to the data stored in the pass.

The Parkinson Pass contains both a built-in memory chip and a processor chip, the former linked to a sensor for biometric identification (fingerprint).

Information from the medical dossier which is stored on the card is only made available if the fingerprint corresponds to the one registered on the card. In addition, smart cards are also issued to all care providers. Only if both cards are used simultaneously can data from the card be made accessible. So the final decision about who may access his medical data is always with the patient.

The pass serves mainly as a medication alarm for Parkinson patients. Information stored on the card includes the medication used and the progress of the disorder. Neurologists can add new prescriptions to the card along with a timetable for taking the medication. Pharmacists are also able to read the prescription and then input details of what prescription has been purchased.

One of the objectives of the Parkinson Smart Card has been to provide help to this group of patients in taking their medication. One way to do this is to facilitate an exchange of information and data. Parkinson patients are extensive medication users and often take a wide range of medicines. It is often necessary to adjust the timetable for taking medication.

In order to improve patient compliance, each Parkinson patient who takes part in the test is given a special little gadget called “Ex Libris” – specially designed for this purpose – to enable them to read out the medication and other details from the chip. An acoustic, light or vibrating signal from the device tells the patient that it is time to take their medication. At the same time, an LCD display shows which specific medicine has to be taken.

About 95% of pharmacies in the Leiden area are able from the technical point of view to participate in the pilot and it is intended that about 500 patients living in that area will test the pass in practice.

The project has been developed from real needs and in close cooperation with patient organisations such as the Dutch Parkinson Association.

Technically it uses two chips (which will be integrated into one chip in the future development). The biometric sensor has been developed by Infinion Technologies and the thickness of the pass complies with ISO standard 7816.

The project started in early 2001 with a roll out of about 100 cards to Parkinson patients registered at the Leiden University Medical Centre and the Deaconess Hospital in Leiden.

Initially it was also intended to make the Parkinson Card fully readable by card readers used in the “Eemland project” (see above, chapter 7.9.1). This unfortunately was not possible because of the necessity of having readers with two heads.

Nevertheless a lot of development and innovation has been done within this project, which is the only project in health care in Europe using biometric identification on a patient card.

More information/contact: http://www.zorgenzekerheid.nl

8.10 Norway

8.10.1 Pregnancy Card (PDC)

A “Helsekort for Gravide” (pregnancy card) will have been issued to 200 pregnant women in the region of Innlandet by the end of 2002.

This is one component of a smart card-supported system for collection of medical data related to pregnancy and delivery, developed by a consortium consisting of the Medical Birth Registry of Norway (MBRN), the Norwegian Centre for Medical Informatics and ErgoSolutions.

This smart card stores securely the medical journal of the mother during her pregnancy. It is used to identify the patient when consulting health services; the chip card is also used to store information as the pregnancy develops. The card ensures correct and rapid identification, retrieval and storage by different systems: the hospital journal system, patient registration system, the national population registry, medical support systems, registration of live birth, statistical reports.

The main purpose is to avoid the keying of information many times, and thereby to secure data quality and to reduce the administrative workload of health personnel.

The developers were challenged by high security requirements and by the need for user-friendliness; the system has been designed to match such constraints and certified technical solutions have been applied.

Instead of carrying the paper journal, the mother can use her pregnancy smart card. At each consultation the practitioner or the health visitor reads the journal prior to examination, and writes the new consultation data to the card after the examination. The journal data is protected by the mother's PIN code. A smart card medical journal simplifies the back-end systems providing electronic data instead of the old paper journals. When arriving at a hospital for birth registration she can easily present her smart card, authorise the hospital for access to her journal and feel safe to be taken care of. The Pregnancy Card is the key to effectiveness in the value chain of birth information, also simplifying and securing reports to Public Registration Office, Social Security Office and Medical Registry of Birth Information.

The card life-time (equals guarantee from the health service) is 9 months.

The project is supported by the following application suppliers; PROFDOC, INFODOC and HIADATA.

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tel. +47 24 163 232
tone.bringedal@shdir.no
or
Mr Asbjorn Hovsto
ErgoSolutions, tel. +47 611 35 906
asbjorn.hovsto@ergo.no

8.11 Slovenia

8.11.1 Health Insurance Card (PDC/HPC)

Following a four-year period of design and development, the introduction of the health insurance card in Slovene health care was completed in October 2000. Through this project, the entire Slovene health care system relies on electronic documents certifying health insurance (the health insurance card - 'HIC'), with a virtual network interconnecting health insurers and all health care service providers. The HIC system, which effectively combines smart card technology and network services, consists of the following technological components: insured person's cards, health professional cards, health care service providers' data processing environment, and an on-line network of self-service terminals.

The system has been 'up and running' in all regions since its introduction. The evaluation results of monitoring this new mode of work have demonstrated that the card has been accepted by the insured, health care professionals, and the staff of insurance providers as a normal mode of routine work. Empirical measurements of acceptance, conducted in September 2000, demonstrate high rates of content with the system among insured and health care professionals (the substitution of the health care booklet with the card was 'strongly

approved' or 'approved' by 82.6% of the insured population). The degree of satisfaction and recognition of system benefits for the health care professionals has been growing as the system is used.

The goals set for the projects´ first phase have been achieved. The insured, physicians, pharmacists, health care professionals and the insurance providers are interconnected by an electronic system providing fast and user-friendly communication, as well as a higher degree of identification and accountability. The system offers opportunities for advanced organisation of operations, as well as neat and controlled individualisation of services in the health care sector - these are preconditions for well-regulated and transparent operation.

Business benefits brought by the HIC system:

- ⇨ Reliable insureds' identification at all health care points,
- ⇨ Facilitated communications between all actors (insured person, health service provider, insurance company),
- ⇨ Simplification and speed of administrative procedures,
- ⇨ Enhanced data security,
- ⇨ Promotion of the insureds' responsibility and care for her/his own health,
- ⇨ Raising of IT literacy among health care staff through system use.

All these benefits combine to advance the quality, efficiency and transparency of the health care services.

With the introduction of the card, the old 'health care booklet' has lost its applicability as a document to verify the validity of health insurance. The card has relieved insured of the need to update the validity of insurance with their employers' personnel departments; instead, they are assigned responsibility for the currency of their health insurance data and given autonomy to update the card data through self-service terminals. The updating of insurance validity also updates other card data (except visual data such as name, date of birth…) from data servers connected to the network of self-service terminals.

As indicated by the statistics for card updating and application in day-to-day circumstances, the insured have accepted and successfully mastered the new modes of operation. By developing and introducing the HIC system, the HIIS has constructed and established an infrastructure and built an important base of know-how and practical experience in the field of IT in health care. This opened opportunities, to Slovenia and HIIS itself, for participation in joint European developments and networks of excellence, aiming to facilitate citizens' free movement in the E.U.. Slovenian experts are now involved in the health card development workgroup under the auspices of the eEurope programme (SCC TB 11 Health), in international initiatives to promote and develop electronic prescribing of medication and smart card/ network synergies, and in the EHTEL association (European Health Telematics Association).

The HIC system has established infrastructure (technology, know-how, experience) and initiated functional enhancements and incorporation of emerging new technologies. Development is under way in several segments and directions: health insurance processes and procedures, data and functions within health service providers, scope of services from the self-service terminal network, and technology.

	October 2000 end of national roll-out	August 2002
Health insurance cards	**1.950.000**	**2.136.072 (distributed) 1.976.246 (active)**
Health professional cards	**16.700**	**17.831**
Self-service terminals	**275**	**285 + 10 by the end of 2002**
Card readers	**5.760**	**6.020**
desktop	4.900	4900 + 550 by the end of 2002
portable	630	890
keyboard integrated	230	230
Health care service providers	**1.145**	**1.263**
hospitals	26	26
health centres	64	64
pharmacies	83	92
private practicioners	972	1.081

The major projects in progress include:

a) Self-Service Terminal Network Services

Ordering of 'convention' certificates through self-service terminals, implemented in May 2001: The convention certificate warrants the right of the insured to access urgent medical services when staying abroad (similarly to the E.U. E111 form). To simplify the procedure for insured persons, HIIS introduced certificate ordering through the self-service terminal network, with the HIC serving as an access key.

b) New Health Insurance Data

Recording of data about medical technical aids issued: pilot implementation April-June 2002, national scale introduction October 2002 - February 2003: This application interconnects suppliers, doctors, insured and insurance companies. The supplier's recording of the aid issued will assist the doctor in prescribing any replacement aid when the service life of the original expires, and the patients will benefit from simplified and more equitable access on insurance account to medical technical aids. This project also serves as an introduction to the more complex process of registering medication and electronic prescribing.

The pilot trial involved one region, 200,000 insured persons, general physicians, specialists, renting outlets, pharmacies, specialised retailers and opticians. It finished successfully and the national introduction was due to start in November 2002.

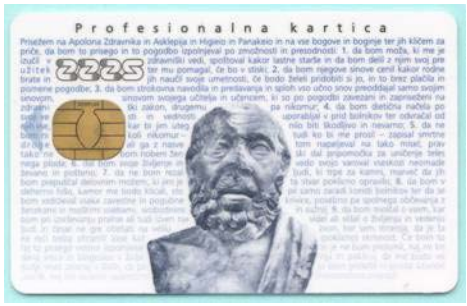
c) Recording of Selected Stable Medical Data

Recording of data on allergies and vaccination, to be implemented in 2003: The HIC will store the cardholder's stable medical data, as relevant in emergency medical aid situations. The first data set of stable medical data is due to be implemented on the HIC, comprising data on life threatening allergies. Later data will be included on relevant vaccinations and risk factors. The project was launched in September 2001 and is steered by the Ministry of Health.

Another project in this group is the recording of the cardholder's voluntary commitment to donate organs and tissues for transplants. This personal declaration is securely recorded in the card memory and accessible in controlled settings. The project is run by HIIS and by Slovenija Transplant, a partner of Euro Transplant.

d) HIC System Technology

PKI and electronic signature, to be implemented in 2004: The main current technological enhancement of the HIC system is the progressive incorporation of public key infrastructure (PKI). Comprehensive activities have already been launched, and the health professional card (HPC) will be upgraded first, by 2004. The reliability of the identification/authentication tools residing on the patient's and health professional's card will facilitate citizen's trust in privacy protection when his/her health data are to be made available to him/her and to authorised health professionals through the Internet.



The electronic signature will support electronic business operations and optimisation of processes, by providing and managing the following electronic information:

- ⇨ electronic prescribing of medical technical aids;
- ⇨ electronic prescription (assistance in prescribing and issuing medication, a combination of the local and Internet databases).

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9 Annexes

9.1 ISO TC 215 “Health Informatics” WG 5 “Health Cards”: Overview

Since August 1998 international Standards for ”Health Informatics" have been prepared by ISO TC 215 and its five working groups. Working group 5 on “Health Cards” was set up in April 1999. The kick-off meeting of this group took place in October the same year and discussed possible work items. Meanwhile after eight meetings, the latest held in April 2002 in Pretoria, four work items have been officially approved and are already well advanced – others are in different development stages.

9.1.1 ISO TC 215 W5 Scope and Experts

Currently 49 experts from 18 different nations have been nominated by their national Standards bodies. The working group currently comprises the following members:

Nation	Delegates	Nation	Delegates
Austria	1	Japan	6
Australia	3	Korea	2
Belgium	1	Netherlands	2
Canada	4	Russia	1
Finland	3	South Africa	2
France	3	Sweden	1
Germany	5	Turkey	2
Ireland	1	United Kingdom	9
Italy	1	USA	2

The WG 5 kick-off-meeting was held in October 1999 during the international conference ”Health Cards 99”. The following scope of the working group was adopted by the ISO TC in November 1999 at its 3rd meeting in Tokyo.

9.1.2 Scope of ISO TC215 Health Informatics Working Group 5 ”Health Cards”

- ⇨ ISO/TC 215/WG 5 shall produce standards in the field of healthcare usage of machine readable cards compliant with the physical characteristics, including dimensions, defined in ISO/IEC 7810. The WG shall place special emphasis on technology independent data structures leading to interoperability and compatibility including the communication of data.
- ⇨ WG 5 shall focus on cards used to identify both patients and healthcare providers both as individuals to information systems and in terms of record linkage. It shall also focus on patient data cards intended to convey a healthcare data set of medical importance that may not be immediately available or useable by other means.
- ⇨ WG 5 shall not produce standards which apply to medical devices. Machine readable cards are not interpreted by the WG to be medical devices.
- ⇨ WG 5 wishes to co-operate with other working groups in relation to data structures and shall not produce data models where such data models already exist.
- ⇨ WG 5 will also co-operate with other TC 215 working groups where there are areas of common interest and shall appoint liaison members from within its membership.

From this scope it is obvious, that the emphasis is on Standards for the content of cards and not on techniques. The latter is covered by other groups, such as the ISO JTC1/SC 17 ”Information Technology – Identification Cards and Related Devices”, which among others produces the Standards series 7816.

On the European level the currently inactive CEN TC 224 WG 12 ”Machine Readable Cards, Related Device Interfaces and Operations – Health Applications” also has to be mentioned as well as the CEN TC 251 ”Health Informatics” Task Force on Cards.

As well as what is explicitly stated above, the Standards are to be 'technique independent'. However, the group will only consider cards according to ISO/IEC 7810, i.e. only cards which are the size of a credit card.

During its first meetings the group discussed five possible new work items which in the meantime have been specified and also revised several times. The current status is as follows:

1. Extension of European Registration Standards to cards
2. Technical report for the usage of cards in health care
3. Electronic prescription on cards
4. References and Record Linkage (Links)
5. Patient Healthcard Data

9.1.3 Extension of European registration Standards to cards

This work specifies identification cards and the extension of the two European standards EN 1387 “Machine readable cards – Health care applications – Cards: General characteristics” and EN 1867 “Machine readable cards – Health care applications – Numbering system and registration procedure for issuer identifiers”. The problem is the absence of a registration authority. On the ISO-level there exists the standard 7826. These two Standards had been accepted as Working Drafts in March 2001 and several experts were nominated. Japan chairs this group of experts, aiming to modify the old European Standards and hopefully to have them adopted as International standards soon.

9.1.4 Technical report for the usage of cards in health care

This proposal was made by the USA in the first meeting, recommending a technical report on the use of cards in health care. This was supported by all nations. Subsequently the group decided that this is not a topic suitable for a 'Standard', but it will be worked on voluntarily inside the group.

9.1.5 Electronic prescription on cards

One of the major topics from the beginning was electronic prescription. During the discussions it soon became obvious however that many national definitions already exist, e.g. in Australia. Therefore, it was agreed to start with an investigation of already existing Standards and decide after that, whether a specific format for an electronic prescription on cards is needed. It was also agreed that, particularly in this case, a close link to the working group 1 “Health Records and Modelling Coordination” had to be established.

During the third meeting the group then decided to go for a Standard but to integrate the electronic prescription into the Patient Healthcard Data Standard. The meeting in April 2002 discussed whether to have a comprehensive electronic prescription including medical history or “merely medication data”. This part 7 of the overall “Patient Healthcard Data” Standard has recently been adopted as CD (Committee Draft).

9.1.6 References and Record linkage

There were long debates about whether there is any 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 go for an extra Standard and to consider each and every possible link into networks.

The group was aware that this is not a topic specific only to cards, but they are 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 Healthcard Data. This will be out for ballot as a New Work Item Proposal (NWIP).

9.1.7 Patient Healthcard Data

Another natural work item 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 there is also the internationally-agreed G7 – interoperability-data-set, which had been enhanced together with the NETLINK-project during 1999 and 2000.

The new Standard is to be mainly based 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 as an 'emergency data set'.

Because of the decision to have the electronic prescription and the linkage information integrated in this Standard it now has become an eight part work item. In detail these parts are:

- ⇨ Health informatics - Patient healthcard data - Part 1: General structure
- ⇨ Health informatics - Patient healthcard data - Part 2: Common objects
- ⇨ Health informatics - Patient healthcard data - Part 3: Limited clinical data
- ⇨ Health informatics - Patient healthcard data - Part 4: Extended clinical data
- ⇨ Health informatics - Patient healthcard data - Part 5: Identification data
- ⇨ Health informatics - Patient healthcard data - Part 6: Administrative data
- ⇨ Health informatics - Patient healthcard data – Part 7: Electronic prescription
- ⇨ Health informatics - Patient healthcard data – Part 8: Links

The status of the different parts according to their stage of development is the following:

- ⇨ Parts 1,2,3 are sent out for DIS-ballot (Draft International Standard), i.e. that they could already be ISO standards by April 2003 (deadline 14-04-2003).
- ⇨ Part 7 has been adopted as CD with some comments.
- ⇨ Part 4 was issued for NWIP-ballot. It failed not because it was voted down (11Yes, 0 No, 3 Abstention), but because under ISO rules at least five countries must support the proposal by 'nomination of experts', and there were only four. Most likely there will be another attempt because of this inconclusive result.
- ⇨ Part 5 and 8 will be sent out for NWIP-ballot. Part 8 is already listed as Preliminary Work Item.
- ⇨ Part 6 is under preparation for the New Work Item Proposal procedure.

9.2 IT Opportunities having potential synergy with smart card use

Medical Devices			
***	Wearable devices with integrated sensors, communications, and processing	***	Non invasive, light-weight sensors for continuous data acquisition (trend data)
***	Smart, self-aware sensors	*	Micro machines for sensors, enabling cure with minimum incisions
**	Remote, non-contact sensors	*	Sensors for airborne agents, particulates
**	Surrogate diagnostics	**	Emergency event detectors
*	Light-based sensors		
***	Low-power sensors	*	Hand-held units with diagnostic capabilities
**	Small sensors	*	Low-cost, high-resolution cameras
***	Self-calibrating sensors	**	Embedded Object Request Brokers and Java applets
Patient Records			
***	Distributed electronic patient record repositories	***	Wearable or portable devices for storing EPR information
**	Terminology translators	*	Longitudinal EPR construction utilities
***	EPR software in the home	**	Patient identification services
***	Data mining and search engines	***	Better memory storage
	Updating the EPR via the internet		
	Disease management		Patient identification services
Communications			
***	Low-power telemetry technology	*	High-bandwidth infrastructures
***	Home-based repeater networks	*	Data/voice synchronisation technology
*	Fast, effective compression / decompression algorithms and chips	**	Patient locator technology
*	Better tele-consultation technology	***	'Body LAN's uniting autonomous sensors and wearable devices
User Interface			
**	Vocal password parameters	**	Facial recognition parameters (and flags for on-screen natural and sign languages)

Processing			
***	Intelligent software agents	***	Trend data analysis tools
***	Automated diagnosis algorithms	**	Demographic analysis tools (statistical routines to analyse demographic profiles and to indicate correlations)
***	Knowledge assimilation techniques for state-of-health determination	**	Advanced filtering (e.g., signal extraction) and waveform analysis tools
***	Artificial intelligence algorithms for care decisions	***	Information reduction and interpretation tools to avoid physician information overload
***	Neural network and fuzzy logic technology for decision making	**	Techniques for collating non-health sensor data with physiological data for determining patient state of health
***	On-chip or on-device decision support tools		
Protocols			
***	Evaluation procedures	**	Mechanistic activities for directing the medical instruments (instruction sets for automated devices)
'Back plane'			
***	Standard device descriptions	***	List of resources for establishing context
Information Security and confidentiality			
***	New biometric algorithms	*	High-speed, low-power encryption chips
***	Owner-aware sensors	**	Audit trails for the home
***	Health databases with role-based permissions	*	Procedural guidelines
***	Role-based access control standards		
Standards			
***	Information architectures	***	Storage
***	Security	***	Nomenclature
***	Plug-and-play hardware	***	Protocols
***	Communication	***	Diagnostic procedures
***	Messaging	***	Device descriptions

9.3 Glossary[30]

Access Provider	The Access Provider is the entity in charge of managing the infrastructure (i.e. the card readers and necessary drivers, communication network and servers) to be used by the card holder accessing the offered services.
AES	Advanced Encryption Standard
API	Application Programming Interface
ATM	Automated Teller Machine
Authentication	Authentication is the process through which a data or access provider can obtain trustable proof through a trusted third party about whom the requester claims to be (identification) OR what the requester is capable of or authorized to do (attributes).
B2A	Business to Administration (communication), a modality of e-commerce
Biometrics	Facilities provided on or in association with a card for authenticating a user by non-invasive reference to their biological characteristics, e.g. fingerprint, hand print, iris pattern, vocal dynamics or facial recognition.
Bluetooth	Bluetooth is an open specification for wireless open short-range communication of data (including voice) between devices.
C2G	Citizen to Government (communication)
Card Holder	The Card Holder or user is a physical person (in the legal sense, i.e. an individual human being not a company/legal structure) who has been issued a smart card by a card issuer.
Card Issuer	The role of the Card Issuer is to issue smart cards to card holders.
CEC	Commission of the European Communities
CEN	Comité Européen de Normalisation: European Standardisation Committee

[30] (References are drawn preferentially from:

Telemedicine Glossary 4th Edition, 2002 Working Document, ed. L. Beolchi, DG InFSO-B1, Brussels, 2002

Global Interoperability Framework for Identification, Authentication and electronic Signature with Smart Cards, Part 1, version 2.0 of 28 June 2002)

Content Provider	The Content Provider is the entity in charge of keeping the content of the service provider up-to-date.
CVD	cardiovascular disease
CWA	CEN Workshop Agreement: consensus-based specification, drawn up in an open CEN Workshop environment .
DIABCARD	Improved Communication in Diabetes Care based on Chip Card Technology. An R&D project co-funded by the European Commission (Health Telematics Application - Telematics Application programme) through the 3rd-4th Framework Programme for Research & development (1994-1998)
Digital Certificate	A public key directory entry signed or validated by a certification authority. Digital certificates are used to verify digital signatures.
DIS	Draft International Standard
DSA	Digital Signature Algorithm
ECDSA	Elliptic Curve Digital Signature Algorithm
eEurope	The e-Europe initiative was launched in December 1999 with a view to stimulating the development of the internet and the new economy in Europe and enabling every individual to participate in the information society. At the European Council in Lisbon on 23 and 24th March 2000 the Heads of State or Governments of the European Union set themselves the target of making Europe a competitive and dynamic economy. In the meantime the action plan eEurope 2005 has been published, following the action plan eEurope 2002. See also www.europarl.eu.int or http://europa.eu.int
EEC	European Economic Community
E111, E112, E128	Administrative forms designed for citizens of EC, EEA and other Treaty countries to request medical care in a non-resident country
e-Gov	electronic Government services and processes
e-Prescribing	electronic prescribing enables physicians electronically to write, order and renew prescriptions and to renew information related to the selected drug on a real-time basis
e-Lab	electronic laboratory services
EHCR	Electronic Healthcare record
e-health	electronic health
e-social	internet-based technologies for social services
FCR	FINREAD Card Reader

FCRA	Java TM application, signed by the appropriate entity, that may be downloaded by the FCR. When an FCRA is activated, the FCR operates in secure mode
FINREAD	Project funded by the European Commission which aims to establish an industry standard for technical specifications related to a secure financial transactional IC card reader to be used primarily, but non-exclusively, in Electronic Commerce and home banking applications. Technical Specification issued July 2001
G2G	Government to Government (communication)
GIF	Global Interoperability Framework for Identification, Authentication and electronic Signature with Smart Cards. The Framework is a document in 4 parts: ⇨ GIF Part 1: Contextual and conceptual modelling (i.e. this document) an in-depth modelling of the smart card, its environment and interoperability issues with regards to identification, authentication and electronic signature; ⇨ GIF Part 2: Requirements for IAS functional interoperability, a list of functional requirements and interoperability prerequisites to be used together with Part 1 for establishing a set of specifications for interoperability at IAS level; ⇨ GIF Part 3: Recommendation for IOP specifications, guidance for enabling, implementing and operating IAS inter-operability; ⇨ GIF Part 4: Deployment strategies for generic IAS, an overview of business plan elements, organisation issues, and system development processes for mass deployment strategies.
GPRS	General Packet Radio Service allows mobile devices to be connected via IP addresses
G.P.	General Practitioner (Primary Care specialist, 'family doctor')
GSM	Global System for Mobile Communication
HW	Hardware
ICT	Information and Communication Technology
ID	Identification
Identification	Identification is the process of obtaining information about whom the requester claims to be without considering the “trustability” of this information.
IOP	Interoperability
IP	Internet protocol
ISSS	Information Society Standardisation System

ISO	International Standards Organisation
ISO TC 251 WG5	Technical Committee on Health Informatics – Health Cards Working Group
IT	Information technology
JEFF	Execution of Java code direct from memory (e.g. on a card)
LAN	Local Area Network
MMI	Man-Machine Interface
Netc@rds	Project aiming to replace the European health insured entitlement paper-form (E111, E128) by electronic forms stored in health insurance smart card or downloaded from server. Netc@rds is co-funded by the European Commission DG INFSO E-TEN programme. Preparation of the Business Plan and Market Validation Phase A is planned year 2002-2003 while next Phase B (initial deploymen)t is planned 2004-5.
Netlink:	Project for validation and co-ordination of implementation of interoperable data card systems and intranet solutions before nationwide implementation. An R&TD project co-funded by the European Commission (Health Telematics Application - Telematics Application programme) through the 4th Framework Programme for Research & development (1994-1998)
NICSS	Next Generation IC Card System Study Group. An initiative of a Japanese Government funded organisation which aims to develop contactless multiple application smart cards for use by local Japanese authorities and to create an infrastructure for IOP smart cards using the Web for distributing new services
NWIP	New Work Item Proposal
ORB	Object Request Broker: a middleware technology that manages communication and data exchange between objects
OS	Operating System
PDA	Personal Digital Assistant
PC/SC	Personal Computer/Smart Card standard
PDC	Patient Data Card
PIN	Personal Identification Number

PKI	Public Key Infrastructure: Data Transmission Infrastructure which handles security, confidentiality, integrity, availability, authentication, non repudiation and certification features
POS terminal	Point-Of-Sale Terminal
SAM	Secure Application Module
Service Provider	The role of the service provider is to provide business services to the card holder using the smart card as an IAS token and/or as a support for a specific on-card application.
SIM	Semantic Inter-operability Mediator, e.g. as in mobile phone SIMcard
SCC	Smart Card Charter
STIP	Small Terminal Interoperability Platform
SW	Software
TB	Trailblazer (a working group of the SCC initiative)
TC	Technical Committee
Transcards	R&D project co-funded by the European Commission, DG EMPLOYMENT and SOCIAL Affairs (1998-2000).
WAP	Wireless Application Protocol
WLAN	Wireless Local Area Networks using electromagnetic waves
WPAN	Wireless Personal Area Network

9.4 TB 11 White Paper: Document History

Name/function	Action	Circulation	Version
Marc Lange	Document structure definition	TB 11	v. 0.0
Marc Lange	Inclusion of comments from meeting of 25/04	Tomas Trpisovsky and Noel Nader	v. 0.1
Marc Lange	Inclusion of comments on v. 0.1	TB 11	v. 0.2
Marc Lange	Inclusion of comments from meeting 11/06 / Assignment section ownership	TB 11	v. 0.3
E. Vellidou and N. Nader	Contributions included in section 4 and 5	TB11	v. 04
N. Nader	Contribution included in section 5	TB11 of 15 February	v. 05
P. Angelidis & T. Trpisovsky J. Schäfer	Contribution included in section 6 Comment on sect. 1-5	TB11 of 15 February	v. 051
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SH. Schug	Review/Include External Comments	TB 11, eESC, Public	v. 1.1.0