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A EUROPEAN HEALTH CARD

Final Study

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A European Health Card
FINAL REPORT

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A European Health Card

FINAL REPORT

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PART ONE – INTRODUCTION ON HEALTH CARDS
CHAPTER I – INTRODUCTION

1.1 Description of a health card

The health card is a medium containing health care references.

A health card may either contain health data about its holder or the key to access such a data when it is stored on a remote computer, or both.

Developing a study on a health card involves the analysis of several issues such as: data format, legal issues related to data storing and reading, interoperability, security.

At the moment, health cards are mostly implemented on smart cards although there is an increasing interest in alternative technologies like laser cards.

A smart card is a credit-card sized plastic card with an embedded computer chip that can be memory or also include a microprocessor. They are less expensive than microprocessor cards but with a corresponding decrease in data management security. A microprocessor chip can instead add, delete and otherwise manipulate information in its memory and hence offer complex data security schemes. Smart cards are used world-wide: GSM mobile phone cards, satellite TV cards, credit cards. Remarkable examples of their use as health cards are several projects implemented during the last years, such as the 10.5 million smart cards issued for the Belgian Health Coverage, the 78 million for the German Health Insurance and the 58 million for the French Sesam Vitale 2.

1.2 Key factors

1.2.1 National and EU legislation

EU Member States' legislation and EU laws on data privacy, security, and access rights, should be the basis for the security requisites of the European health card. Moreover, it should conform to health record processing rules enacted at national and EU level.

1.2.2 Acceptance

In order to be effective, a European health card initiative needs to be well accepted by all the agents involved: the public, physicians, health care institutions and pharmacists. It must also be user-friendly if it is to be disseminated widely.

1.2.3 Technology

Technology is an important factor to enhance user-friendliness and data security which greatly influences the overall acceptance of the health card. Technology is evolving extremely fast, so that a specific smart card technology might become obsolete in the short period of few years.

1.2.4 Interoperability

Interoperability refers to attributes of software that bear on its ability to interact with specified systems. It's the understanding of data and its context among different operators. The use of standards alone does not ensure interoperability since independent applications may not implement all optional parts of a standard or may implement different subsets of a standard. It is vitally important therefore to define application conformance profiles which delimit those optional parts of standards which need to be supported for a particular application class. Devices are interoperable when in addition to communicating with each other, they can also execute a common task together. This requires additional standards like APIs (Applications Programme Interface). Interoperability is one of the most critical issues for disseminating a European Health card.

PART TWO - EXECUTIVE SUMMARY

The adoption of a European health card aims to guarantee a quick and easy access to health and insurance data and to create an integrated system to overcome all the differences between Member States' healthcare policies. The success of such initiative depends greatly on the achievement of the interoperability, at a European level, among the healthcare systems of all the Member States to transfer and share medical healthcare data with particular regard to data confidentiality and security.

A health card system consists of health cards, health data and the devices and policies that regulate the access to the health information on the basis of what is recorded on the card. There are two major technological aspects: card type and data organisation. All current studies propose technological solutions based on cards of the smart card type (like phone cards, "electronic" credit cards) with some data organised on the card and some in databases. Data confidentiality and security is then ensured by public key cryptography and access authentication schemes although access rights vary on the basis of the national laws of the nation in which the study was carried out.

Interoperability among health card systems greatly relies on technology compatibility since it cannot be achieved without having one health card system being able to make use of and/or update computer readable data held on the health cards issued by another health card system.

Many experiments were conducted in Europe to introduce smart cards in the health system. The cards used in the health system are similar to those used in communication and banking: The two specialist application segments of health and transport still remain quite small compared to telephone and banking, because of their reliance on small numbers of major projects. Still the growth is massive: health cards jumped by 71% to a total of 60 million in the last year, driven largely by the nation-wide roll-out of the French patient cards. Just two suppliers, Schlumberger and Gemplus, account now for over two-thirds of phone card production, as well as health cards.

CHAPTER II - SUMMARY OF EU PROJECTS FOR HEALTH CARD

Several European projects are the practical demonstration of how policy and technological options can integrate themselves:

CARDLINK 2 (Ireland, Germany, Holland, Spain, Greece, Portugal, France, Italy, Finland) to implement and demonstrate a health card for patients in cases of medical emergency.

DIABCARD (Spain, Greece, Italy) to developed a diabetic health card. Its architecture could be implemented within existing informative systems and network environments and could be improved with technological devices.

ISHTAR to create a group of legal, medical and technical experts. The goal of the project was to provide data protection guidelines and evaluate the user-friendliness of health cards.

NETLINK (France, Germany, Italy, Canada) to promote interoperability between nation-wide Information systems for the benefit of patients, health professionals, governments and health insurance funds by establishing technical and functional recommendations for interoperable network and smart card based health system solutions and demonstrating the viability of the selected solutions through cross-border pilot sites.

TRUSTHEALTH (Belgium, France, Germany, Norway, Sweden, UK) to show how telematic projects can be settled down using modern secure methods.

G-8 HEALTHCARE DATA CARD PROJECT (France, Germany, Italy, Canada, UK, USA, Japan, Russia) to develop an international emergency card that would provide the essential medical information that is vital for an emergency situation as well as an international harmonised administrative data set and an international professional card that will allow the secure identification of healthcare professionals when accessing medical data and network services.

AIM EUROCARDS (Canada, UK, Germany) to offer essential information which could improve the effectiveness of a ready care for a patient and to introduce a system specification which could be implemented and used in a European country without any language problem.

CHAPTER III - HIGHLIGHTS OF THE SURVEY

- *“The card should not be used primarily for data storage; perhaps emergency data may be on it and these should probably be well accessible. It would then mainly be used as a means to access information stored elsewhere. This certainly will make strong protection essential”*
- *“I think that the first test should be very simple in order to save costs. If its success brings risks, then the further step should consider the security problem of data”*
- *“The European health card should have the maximum data, especially, health, emergency and administrative data. The emergency data should be coded so there is no language problem according to the G8 rules as it was done in Slovenia”*
- *“A European health card is a logical step to take in a federal system such as the United States of Europe. But it is utopic too”*
- *“I don’t think there’s a need of a European health card. There’s a need for a European identity card”*
- *“To guarantee the interoperability of the card it is needed to codify the diseases and especially emergency data. A software then would translate automatically into the languages of the national system, so there would not be any language skill needed for the user”*
- *“It’s necessary to obtain financing to spur consortium - making between private and public institutions in order to disseminate a European health card”*
- *“An important factor is to meet the “Kohll&Decker” judgement. This would allow a wider use of healthcare services and a change in Member States’ expenses because they would be forced to pay back medical charges for care provided by another country”*

PART THREE – ILLUSTRATION OF APPROACH TO THE STUDY

CHAPTER IV – APPROACH TO THE STUDY

As suggested by the STOA, the study examined all main aspects about the development of a European Health Card in order to have an exhaustive assessment.

The study conducted a survey on local policy options and on current solutions adopted both in terms of service and data content. In particular by means of data gathering concerning experiences across the EU Member States and an investigation of current systems, this study wants to provide a reference for future EU actions.

The study on "A European Health Card" looks forward to actions to be taken in a medium/long term and prospects for the future.

4.1 Options

The current study analysed the range of policy and technological options that have been identified as relevant and realistic. In particular has been dedicated to:

- 4.1.1 Policy options for the European Parliament. Policy options for the Committee on the Environment, Public Health and Consumer Policy
- 4.1.2 Policy options for the European Commission
- 4.1.3 Options for other institutions
- 4.1.4 Technological options

4.2 Arguments and evidence

The study describes the health card systems in different EU Member States.

The study collected information from Health Care institutions of the European Union Member States in order to find out if health cards already exist in each Member State and, if so, to evaluate the outcomes of such experiences. The study looked at the compatibility and interoperability of the existing health card systems in terms of:

- usability and flexibility;
- what kind of information is included;
- who is authorised to input data and to have access to such information;
- the use the cards are appointed to;
- the problem of protection of medical data, confidentiality (e.g. digital signatures) and security.

Further actions consisted in collecting, through interviews, experiences and comments by organisations and interest groups such as the WHO, European institutions (e.g. CEN), doctors, pharmacists, citizens, and consumers' associations.

Finally, the study performed an assessment of technological options in order to appreciate the likely developments in this field.

CHAPTER V GANTT CHARD OF THE WORK DONE

5.1 Workplan

Workpackage 1: Policy options analysis

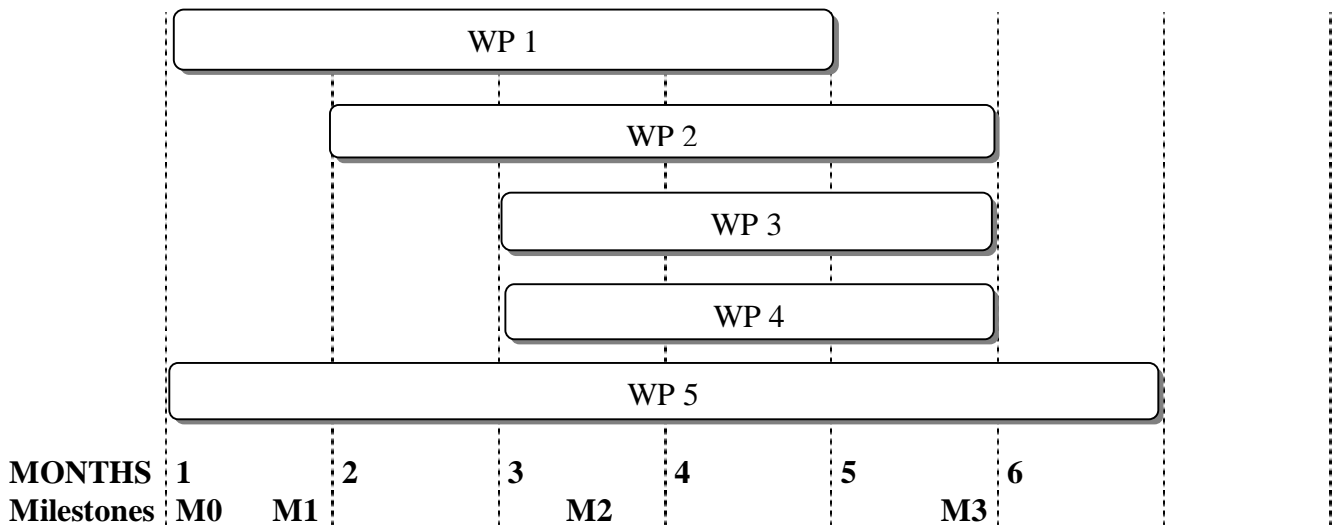
Workpackage 2: Users involved survey and acceptance analysis

Workpackage 3: EU HC card systems analysis

Workpackage 4: Technical options for health cards

Workpackage 5: Documentation and management

5.2 Gantt chart of the study on "A European Health Card"



5.3 Milestones and Deliverables

M0 (T0): Kick off: 15 September 2000,

M1 (T0 + 1): Scoping meeting report

M2 (T0 + 2,5): Interim Study Report;

M3 (T0 + 5): Completed Study;

PART FOUR – POLICY OPTIONS

CHAPTER VI – BRIEF OVERVIEW OF POLICY OPTIONS

6.1 Documents issued on the European health card

- 13/10/1981 The European Parliament expressed its opinion that a voluntary, unique European health card had to be issued only if individuals would request it.
- 21/12/1983 The European Commission submitted to the Council's consideration a recommendation for adopting an emergency health card.
- 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 a European emergency card. This resolution didn't take account of all the problems regarding data update and liability.
- 16/10/1989 The European Commission wrote down 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, developed them. The report concluded that technological improvements had to be made. The AIM Project was up to this task.
- 24/10/1995 The European Parliament and the EU Council issued a Directive about people's protection regarding personal data treatment and free data exchange.
- 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 watching.

6.2 Main reasons for the creation of a European health card

Two main necessities pushed the European Parliament and other EU institutions to suggest the adoption of a European health card:

- To guarantee quick and easy access to health and insurance data. In fact, in case of illness or accident, their lack could jeopardise an early and suitable treatment regarding in particular people affected by serious and chronic diseases.
- To create an integrated system to overcome all the differences between Member States' healthcare policies.

Other factors were added in the long run. In particular, the growing mobility of European citizens, who travel all around the EU for business or tourism, has increased the overall demand for a healthcare system able to guarantee to all the EU citizens the same medical treatment. This argument has been reinforced by two judgements rendered by the European Court of Justice in 1998. In Case C-120/95 *Decker* [1998] ECR I-1831 and Case C-158/96 *Kohll* [1998] ECR I- 1931, the Court held that health care is not, in principle, exempted from the EC Treaty's rules on the free movement of goods and services, respectively. Consequently, patients receiving health care in other Member States can be entitled to be reimbursed by their national health insurance.

Furthermore, such a device could bring about important cost savings and make it easier for physicians to know all the clinical information of their patients, as highlighted by the European Council within its recommendation project about the adoption of a European emergency health card.

Another important task of the European Parliament and the European Council has been to promote interoperability, at a European level, of the healthcare systems of all the member States by creating telematic instruments.

This is confirmed by the decision adopted in 1997 regarding the adoption of a European programme about the supervision of European healthcare systems. It stated as its main aim to fix medical guidebooks with a data critical examination, suitable methods elaboration and the creation of a European network to transfer and share medical healthcare data with particular regard to data confidentiality and security.

All the adopted recommendations have always taken account of two basic moral issues: the self-determination of the people involved and their consensus in order to introduce data into the card. Nevertheless, the problem of the legal regulation of personal information protection remained without a solution till the European Parliament and the EU Commission introduced Directive 95/46 regarding the treatment of personal data and their dissemination. The Directive obliges Member States to protect all citizens' rights to privacy with respect to the processing of personal data. Processing of data concerning health is only allowed in where 'processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.'

PART FIVE – TECHNOLOGICAL OPTIONS

CHAPTER VII – ILLUSTRATION OF TECHNOLOGICAL OPTIONS

7.1 Health card systems

A health card system consists of:

- *Workstations* which are computers with networking capabilities.
- *Health Cards*, containing computer-readable data, which may be smart cards (like a credit or mobile phone card) or Universal Serial Bus (USB) token. They may also have an optical strip to increase the card's storing capacity. The optical strip is made of a reflective optical recording medium on which data is stored and cannot be rewritten.
- *Card Access Systems* that can read and/or write the computer-readable data on health cards. They are made by:
 - A card terminal device capable of communicating with a health card in case of a smart card. To read USB tokens, it is sufficient that a computer has USB port. Which is standard port in both PC's and Mac's like serial or the parallel ones.
 - Additional hardware and/or software to allow card data to be read and/or updated.
- *Card Databases* with copies of the data on the health cards for administrative use and for card duplication.
- *Health Databases* containing patient health data that may be located everywhere.

7.2 Technological options

There are two major technological aspects: card type and data organisation.

The first is the choice between smart cards and USB tokens. Smart cards require a card read/write device to be attached to the computer while USB token don't require additional hardware but they are generally more expensive. Another important choice is the card architecture:

- memory size,
- presence and size of the write once area,
- processor.

The card architecture influences:

- the amount and the type of information stored on it,
- the compatible security schemes,
- the type of card reader to be used.

For instance there exist multifunctional cards that have a smart card chip, optical and magnetic strips. Data organisation is instead crucial for data updating and accessing. If for example all health data is stored on the card then data changes must be recorded directly on the card, and data security is totally implemented on the card. If instead the card is only a means to access information located on databases then data can be changed in the database, security can be implemented both at database access and at card levels, data can be accessed only if there is a network connection to the database. All current studies propose technological solutions based on smart cards with some of the health data on the card and some on databases.

7.3 Data set and encoding options

How to organise and encode the health data is another important question because it affects flexibility, storage optimisation, multilingual representation of the information. It has also a big impact on the cost of changes in the data set and encoding, when they must be changed. If all data is on databases then it will be sufficient to change their content, by adding information or modifying data codes, and to adapt the software accessing them. If, instead, all data is on the card then the content of each card would have to be modified.

7.4 Security Technology options

All studies consider basically the same security technologies of public key cryptography and access authentication. They differ very much instead on the data read/write rights scheme because they reflect national legislation. They may give different access rights depending for example if the physician is a medical doctor or a dentist.

7.5 Functional Interoperability between Health card systems

It allows the functions of one health card system to make use of and/or update computer readable data held on the health cards issued by another health card system. It has advantages in many fields:

7.5.1 Healthcare administration

- Simplification of administrative procedures for the patient.
- Identification of the healthcare professional usually responsible for care of the patient to allow information to be requested to assist in treatment.
- Use of the health card to authorise access to patient records by network.

7.5.2 Clinical healthcare

- Access to accurate emergency and other clinical information held on the health card when and where it is needed (rather than just in the issuing system).
- Reduction of delays to treatment of patients due to delays in accessing relevant clinical information about the patient.

7.5.3 Health economics

- More efficient administrative procedures when treating a patient covered by another health card system.
- Simplification of billing or claiming for services provided to a patient participating in another health card system.
- A standard health card system specification would reduce the cost of development, implementation, support and training.
- An interoperable health card system may form a basis for improved internetworking between other patient-centred information systems.
- Similar health card systems will facilitate the mobility of staff between different hospitals or organisations.

7.5.4 Politics

- Interoperable health card systems crossing national boundaries would be a practical demonstration of co-operation within the European Union and with other countries.
- Benefits to healthcare services and industrial partners in all Member States through creation of a more stable market for health card system products.

7.5.5 Commerce

- Increased sales of health cards, card terminals and health card system services based on a common specification.
- Simpler maintenance of healthcare applications that only have to support a single health card interface.

PART SIX – MARKET STATUS

CHAPTER VIII – INDUSTRY AND MARKET SITUATION

8.1 Industry situation

Many experiments were conducted in Europe to introduce smart cards in the health system. The cards used in the health system are similar to those used in other sectors, especially in telephone and banking. When a smart card is used in the health system we will refer to it as a “health card”. The health card can take advantage of investments and success achieved in other sectors, such as WAP compliance and 32 bit capacity. The smart card market is growing very fast. Banking and retail cards continue to grow strongly with a 29% jump in volumes, but this market remains almost universally based on proprietary, country-specific, smart cards products.

Token cards for payphone applications – based on sophisticated memory chips – remain the largest single segment, with a total market volume approaching a billion cards in 1999, but there has been considerable consolidation on the supply side. Just two suppliers, Schlumberger and Gemplus, account now for over two-thirds of phone card production, as well as health cards. Schlumberger attributes this dominance to the expert knowledge that mass producers can bring to bear to maximise yields and keep costs down – a crucial factor in this commodity market as the costs of chips escalated over the last year.

The two specialist application segments of health and transport still remain quite small compared to telephone and banking, because of their reliance on small numbers of major projects. Still the growth is massive: health cards jumped by 71% to a total of 60 million in the last year, driven largely by the

nation-wide roll-out of the French patient cards.

8.2 Market devices in Europe

8.2.1 GIE Sesam Vitale

The most complete project in the health field is the Sesam Vitale project: this card system aims to replace one billion paper treatment forms by paperless electronic forms; to facilitate relations between patients, medical professionals and the health insurance organisations while incorporating a high level of security; to offer the patient high quality service, with simplified administrative procedures and faster reimbursement; to facilitate medical control of developments in health expenditure by a more reliable system for collection of data which will facilitate its analysis. The consortium GIE SESAM-VITALE was formed in 1993 by different health insurance schemes in France. It is also part of the international project called NETLINK whose other members are France, Germany, Italy and Quebec. Experiments are conducted in many countries including the Czech Republic and Russia.

8.2.2 France and Germany

The biggest health card markets in Europe are mostly in France and Germany thanks to the size of population and because those countries already implemented the systems. Belgium, Italy and the UK are also starting projects on a smaller scale. In France, already in 1995, Schlumberger provided 10.000 cards to employees of RATP (French subways company) which depend on a private healthcare system. This company had decided to implement a complete system based on two microprocessor smart cards, one for the health professionals and the other one for the employees.

The patient card, called “Carte Clè Espace Santé”, was considered as an access key to the RATP health information system which manages all employee medical insurance schemes. In 1996, about 100.000 cards had been supplied by Schlumberger/Solaic for a health insurance company that wants to provide to its members a specific service of quick healthcare reimbursing, RMS.

The Santal programme consists of a two microprocessor smart cards system and the goal of this pilot project was to experiment the use of identification and medical data storage in a smart card.

Schlumberger/Solaic with Santal organisation have defined the way to store securely medical data in the smart card. Today more than 40.000 3Kbytes smart cards are used in Saint-Nazaire (France) to test this concept. The result of this project will be used to design the VIM (Volet d’Informations Medicales = Medical Data Folder) in the Vitale 2 card.

8.2.3 Schlumberger

Schlumberger has been selected to design the CPS mask. This card is based on a new generation of microprocessor smart cards and uses a crypto processor component to perform a public key algorithm (RSA). This provides a high level of security in data storage and has the capability to do digital signature and authentication towards patient cards and towards the French health system.

CPS received in October 1998 ITSEC E3 advanced security certification, which covers both the performance of the card and its resistance to external attacks. ITSEC E3 represents the highest category ever achieved for such a high capability smart card.

DENTCard is the German first smart card for dental patients. The DENTCard integrates elements of the work performed by the most important users in the dental sector, including patients, dentists and even laboratories and their suppliers. The basic demands placed on a

patient information system for a dental practice are summarised in the terms diagnosis, therapy and recall. The modular design of the DENTCard was built to satisfy these demands. The system is structured around seven registers, which satisfy all of the requirements requested by dentists. DENTCard was developed in co-operation with Built Informationstechnologie AG, DENTCard AG, the Dentists Initiative in Buhl/Baden e.V (IZB) and ORGA Kartensysteme GmbH. The partners set up a test market in 1996 and supported it until 1998. In actual practice, and given the changing health policy environment, it was found that the master files of patient dataHS: Automatic transfer of data through the dental practice's software is planned in 1999 through the integration of "Open Data" and the VDDS export interface. In the meantime 32-bit versions are available in German, English and Cyrillic.

8.2.4 ORGA

ORGA has launched a smart card based mobile office for use in healthcare in the UK in 1999. The system provides a completely portable data collection and records system and is expected to be of particular benefit in community care. People receiving care at home and at regional health centres are issued with a smart card that stores relevant personal information and treatment records on the card's micro-chip. Visiting healthcare practitioners are equipped with Mobile Office, a compact unit incorporating a mobile printer and ORGA's handy smart card reader. Prior to treatment or consultation, data from the patient's smart card is output onto appropriate pre-printed forms, such as prescription, treatment guidelines and assessment, sick note or accident report. This eliminates the tedious filling in of forms. The system, which is housed in a leather shoulder bag, will also connect to laptop and desktop PC's. Diagnosis, treatment, prescription and other details can be written onto the smart card. This enables up-to-date records to be held on the card at all times, accessible only by authorised healthcare practitioners. The system also connects to central healthcare systems so data from each visit can be stored centrally. Actions may be required following visits, such as letters to GP's and consultants. The system can also automatically record the start and end of treatments to provide a complete time and attendance record.

8.3 Different experiences in Europe and USA

8.3.1 Belgium

The main project performed was the health/welfare card issued for 12 millions citizens with also 35000 healthcare facilities equipped with terminals connected to the network: la Carte d'Identité Sociale Belge (CIS). This project is based on a two smart cards system: one for the professionals, the other one for the citizens.

For the patient this is a 1 Kbytes memory card, secured with a PIN and distributed nationwide. Information relative to the patient is encrypted in the chip and only a microprocessor professional card will have the authorisation and the capability to access this information. Also the Fédération des Mutualités Socialistes du Brabant (FMSB), one of the five Mutualities in Belgium, has its additional health card as identification to the mutuality.

The 1 Kb chip content is about the same as the one for the national card but data stored are dedicated to the private healthcare insurance scheme. Schlumberger supplied 360000 health cards and 250 terminals for FMSB in 1997/98. Gemplus was the main supplier.

8.3.2 Finland

In Finland the development of a health card is not very far advanced. There are some macro pilot studies which are a regional health care improvement scheme utilizing data technology and regional data bases in connection with a chip-equipped personal identification card.

The basic solution selected in Finland seems to be a combination of a personal identification and health card with data bases accessible using that personal card. It's thought that this combination has the advantage of storing some permanent data on the card and giving the opportunity of looking at all data and changing data online or by wireless technology.

8.3.3 France

One of the most complete projects in the health field is the Sesam Vitale project: this card system aims to replace one billion paper treatment forms by paperless electronic forms; to facilitate relations between patients, medical professionals and the health insurance organisations while incorporating a high level of security; to offer the patient high quality service, with simplified administrative procedures and faster reimbursement; to facilitate medical control of developments in health expenditure by a more reliable system for collection of data which will facilitate its analysis. The consortium GIE SESAM-VITALE was formed in 1993 by different health insurance schemes in France. It is also part of the international project called NETLINK whose other members are France, Germany, Italy and Quebec. Experiments are conducted in many countries including Czech Republic and Russia. More than 40 million cards were issued and according to the CNAM 46,79% of the doctors send data through the network today.

The Sesam Vitale system is based on secure exchange of electronic data between professionals in health services and the social insurance organisations through a microprocessor-based Vitale card.

Vitale 1 card, first generation of Vitale card, is a family card and contains exclusively administrative information. It is a microprocessor card with EEPROM 3-4 K. Roll out was completed (37 million units) in June 1999. Schlumberger has been selected as major supplier for these Vitale 1 cards. Other suppliers were Gemplus, Orga and FCO.

The second generation Vitale 2 card is planned to be issued in year 2003 (60 million units). This personal card will contain both administrative (base and additional insurance data) and medical information. It could be a microprocessor card with EEPROM 8K. Schlumberger and Gemplus will produce and personalise most of these cards.

8.3.4 Germany

Germany was also a forerunner in introducing a healthcare smart card. Since 1994, all members of the statutory health insurance funds or permitted substitutes for them have received a healthcare smart card. The following functions are fulfilled by this card: it identifies patients to the doctor and has their signature on the rear. The paper-based health insurance ticket is replaced by it. The statutory health insurance funds financed the 80 million healthcare smart cards and the necessary infrastructure.

The patient's master data can be read electronically and error-free during processing and printed directly on various standard forms. The data can be processed in paperless form using conventional data transfer methods. The reduction of these "mountains of paper" and the associated elimination of time-consuming data input and scanning processes entails a huge potential for saving. In addition, health insurance tickets no longer need to be sent by post, i.e. postage and printing costs are saved. There is no medical data on the card, but only administrative. Confidential information or information not known to the patient may likewise not be stored on the card. Since then, ORGA's multifunctional card terminal replaced its first-generation card readers, which have been in regular use in German medical practices ever since the health insurance card was first introduced. The new terminal's basic functionality is 100% compatible with card readers of the first generation, but presents the possibility for digital signature, which offers the option of supplementing device software with additional

programs obtained via certified download.

DENTcard is the German first smart card for dental patients mainly done by ORGA. The DENTcard integrates elements of the work performed by the most important users in the dental sector, including patients, dentists and even laboratories and their suppliers. The basic demands placed on a patient information system for a dental practice are summarised in the terms diagnosis, therapy and recall. The modular design of the DENTcard was built to satisfy these demands. The system is structured around seven registers, which satisfy all of the requirements requested by dentists. DENTcard was developed in co-operation with Built Informationstechnologie AG, DENTcard AG, the Dentists Initiative in Buhl/Baden and ORGA Kartensysteme GmbH. The partners set up a test market in 1996 and supported it until 1998. In actual practice and given the changing health policy environment, it was found that the master files of patient data. Automatic transfer of data through the dental practice's software is planned in 1999 through the integration of "Open Data" and the VDDS export interface. In the meantime 32-bit versions are available in German, English and Cyrillic.

8.3.5 Italy

Italy is starting a project for the creation of a digital identity card which will also contain medical data. The project will develop in the following 6 years and during the first 2 years several pilot projects will be carried out in some Italian sites.

There's also a health card project come out directly from the NETLINK project.

Two basic aspects are:

- The installation. It must be possible on Windows 95,98, NT and the installation procedure has to be automatic.
- General aspects. Health professionals' PIN must be requested by the application only one time for each session with the HPC card. The patient's PIN has to be requested only one time for each session with the PDC card. Before every kind of updating on the PDC card, the cardholder has to be verified to be the same working on the database package.

Three scenarios must be managed:

- 1) GP patient, already existing on database package: in case of the first card upload, the package must be able to copy in an automatic way on the health card the following basic data:
 - Emergency: emergency clinical category, clinical code, free text on clinical diagnosis, blood-group, Rhesus factor, blood-transfusion indicator, immunization factor, therapy category, therapy code, therapy name, ophthalmologic prescription, pregnancy details, implants
 - Pointers: healthcare events (date of admission of hospital, paper number, hospital name, free text)

In case of patient health card update, facing some inconsistencies about the clinical file, the package must be able to manage all the variations onto the card related to all the basic data.

Furthermore it is important to take care that the pointers can be put in the card by the GP or the hospital manager after a stay in hospital. So it's important that all the pointers are filled in the database.

- 2) GP patient not existing on the database package: the database package upload starts from the patient health card. Visualisation and printing of data filled in the card don't request the patient PIN. The package must record on his database the data mentioned above, so it can reload a new patient card if the card is lost by a patient.
- 3) Incidental patient not existing on the database package: Visualisation and printing

of data filled in the card don't request the patient PIN. The basic visible data are:

- Free administrative data: name, surname, date of birth, health card validity, GP name and regional code, Azienda Sanitaria Locale (ASL), GP, organs donor
- Free emergency data
- Protected emergency data
- Pointers

There's a wide usage of the card:

- a) During a GP visit: with the HPC the physician can transfer the basic healthcare data from the clinical file to the PDC
- b) During a physician visit: every citizen has his basic clinical file and data related to E111 onto his Health card. On the other side the physician has the key to read the data and communicate by Internet with the patient's GP onto his HPC.
- c) At the ASL: the health card put in the reader links immediately the citizen to his administrative data. The ASL employee can update them with his professional card (in particular: patient ID, SSN administrative data, GP basic data, address, people to be contacted in emergency cases, language, abroad assistance, organs and tissues donation, ticket exemption, prosthesis right, dietician products right).
- d) At the CUP: the health card is the identification and access key to the healthcare services
- e) In ambulance: in emergency cases the health card gives all the information needed to opportunely intervene already in the ambulance (patient identification, clinical details, immunization details, usual therapy)
- f) In hospital: the health card simplifies all the admission to hospital operations, because patient data are automatically read and transferred to administrative databases and, in emergency cases, in order to immediately intervene.

8.3.6 Slovenia

The most recent and complete operation in health card is in Slovenia. Between 1998 and 2000, 2 million citizens received health insurance and medical smart cards and 6500 healthcare facilities were equipped with terminals connected to the network.

In the first phase a card with administrative functions has been introduced, providing the support to the procedures of the selection of personal physicians. The health insurance card is designed for the communications between the insured person, the physician, the health centre, the hospital, the health insurance provider, the pharmacy and other stakeholders in the system. The system design strictly follows the European Union recommendations regarding card technologies. This guarantees the compliance to relevant standards and opens the door to harmonisation with health care and health insurance systems around Europe.

The card microprocessor stores data readable only by means of a card reader, in the presence of a health professional card. In this way the card data are protected against unauthorised access. The following data are stored on the card:

- Details of the insured person (name and family name, address, sex, date of birth...)
- Details of the contribution obligor (registration number, name or title, address...)
- Data concerning compulsory health insurance (date of updating, validity of insurance policy)
- Data concerning voluntary health insurance (type of policy, date of updating, validity of insurance)
- Details of the selected personal physicians (general physician/paediatrician, dentist,

gynaecologist)

- Details concerning the personal commitment as a donor of organs and tissues for transplants after death

Any storage of data onto the card or their modification is controlled. The Institute, in its role as the competent institution, manages and maintains the central database in accordance with regulations in force. The card merely stores a copy of those data. Upon any modification of data, the new data are copied from the central database to the card chip. Automatic verification, updating of data from the central database and confirmation of validity of health insurance are the responsibility of the insured person, by means of a self-service terminal. Each insured person is to decide, on a voluntary basis, regarding the set of data to be stored at their own card.

The introduction of electronic prescription and electronic medical technical aid order form is to represent the next step in the implementation of the chip card technology in the health care sector in Slovenia. In the future, the electronic prescription is envisaged to bring a range of benefits to physicians, pharmacists and insured persons, to advance the transparency of the prescribing and consumption of drugs, to reduce the administrative chores and to reduce the errors, to advance the quality of drug prescription and issuing and to advance the level of service quality in general.

The health insurance card data meets the requirements of the Slovene legislation and is provided at several levels. The card micro-chip is a miniature computer, hence the card data are protected in a manner similar to general computer data protection methods. The use of health professional cards is further secured by means of a PIN.

The Slovene card technology has several benefits:

- The card comprises a microprocessor-based circuit which supports active and controlled data interchange with the environment instead of a merely passive data storage
- It supports subsequent recording and application of an enhanced set of key medical data set

The health professional card acts as the carrier of access rights to health insurance card data. It is issued to physicians, medical nurses, reception desk administrative staff, pharmacists, physiotherapists and other health care professionals and authorised health insurance provider officers. The health insurance card is introducing a scheme of double data security where a data item cannot be read or modified without a simultaneous use of a health professional card and its personal identification number.

The health professional card issued to authorised health professionals carries the following data:

- ZZZS card holder identification number
- Card copy serial number
- Name and family name of the card holder
- Profession
- Country code
- Institute of Public Health code number
- Specialisation
- Type of access rights

In the case of the card holder not being a doctor, the following data are also present:

- Country code of the seat of the competent health care organisation
- Institute of Public Health code number of the competent health care organisation
- Title of the competent health care organisation

With the introduction of the card system, the work of the health professional card holders is

simplified and expedited. They no longer have to manually enter the insured person's data for the purposes of invoicing their services to health insurance providers. Applying the health insurance card as the medium, the data from the Institute's central database to the local service provider's database are transferred. The health professional is to insert his health professional card into a special device – card reader – and log in with his personal password. When receiving a patient, the health professional inserts the health insurance card into the second slot of the same card reader. The card reader serves to the health professional card holder to read and modify data according to this access rights. The data are displayed on the screen and, as necessary, uploaded to the local databases.

The self-service terminals for the updating of the card data validity are located in health centres, hospitals, institute regional unit headquarters and branch offices. At the completion of the project, 275 such terminals are installed throughout Slovenia. In selecting the locations, several criteria were considered, including the frequency of patient visits to a health care organisation, geographic distribution of terminals in the region, accessibility to disabled person.

In spring 1999 the Health insurance Institute of Slovenia introduced the health insurance card system into the pharmacies of the pilot region. Phased approach regarding the card function stands for the implementation of administrative card functions in the first phase. The aim is to simplify and automate the process of transfer of data to the prescription form heading. These data comprise: insurance number, selected personal physician, insured person's date of birth, contribution obligor registration number, insurance status, sex, nationality, voluntary health insurance details.

Under the pilot project, carried out in spring 1998, the health insurance cards were issued to the inhabitants of the Posavje region. Since that time, in this region, the card has been the document effectively applicable for the implementation of health care and health insurance rights.

During the three months pilot project, approximately 440 health professional cards and 70 thousand health insurance cards were distributed. As the result the cards became the effective document applicable at all the visits to the doctor's and a year later, also in the pharmacies. 21 self-service terminals were installed. The card was well accepted by insured persons, health care professionals, Institute staff and employers. The health professionals further expressed wishes for the card to be extended as soon as possible with other medical data.

After the successful pilot project, the national scale introduction of the health insurance card started on October 18 1999, in the Novo Mesto regional unit, with a ceremonial handing out of the first card. By the end of 1999 the cards were received by the inhabitants of the Celje region and of the Institute regional unit of Ravne na Koroskem. In January 2000, the cards were issued first to the inhabitants of the Murska Sobota region and then those of the Maribor region. In the next months the turn was on the Kranj, Koper, Nova Gorica and then Ljubljana. The inhabitants of the bilingual Slovene-Italian region on the Slovene Coast received their bilingual version of cards in July 2000 and so the national introduction of health insurance cards has been concluded.

The goals of the Slovene project are:

- To improve the quality of services and handling of insured persons both at the Institute and at other health care service providers.
- To simplify and improve communication between the Institute, the physicians and the health care organisations
- To cut down the number of various procedures now required during the insured persons' implementation of their rights.

- To improve the security of personal data within information processing systems
- To reduce the extent of administrative tasks and thereby achieve a higher efficiency of operation at the Institute and within the health care service
- To promote transparency of financial liabilities between subjects in health care and health insurance systems
- By way of promotion of rational operation in health care, to provide long-term economic benefits at the national economy level.

Furthermore benefits include the following:

- **Insured persons.** Improved quality of services, independence and autonomy regarding the updating of administrative data
- **Employers.** Total elimination of the issuing and confirmation of the health care identification booklets, reduced administrative tasks
- **Doctors, medical nurses, reception desk administrative staff, pharmacists, physiotherapists and other health care personnel.** Reduced administrative and paper work, more time available for quality professional tasks, electronic transfer of data onto the existing forms, electronic linking to expert information systems
- **Insurance company staff.** Improved currency and accuracy of data, rationalised data flows, reduced administrative tasks, improved quality of services, and in this way, higher efficiency in carrying out various analyses of drug prescription and consumption, as well as timely and appropriate implementation of measures addressing the field of drug consumption in Slovenia.

8.3.7 UK

In UK in 1999, ORGA has launched a smart card based mobile office for use in healthcare. The system provides a completely portable data collection and records system and is expected to be of particular benefit in community care. People receiving care at home and at regional health centres are issued with a smart card that stores relevant personal information and treatment records on the card's micro-chip. Visiting healthcare practitioners are equipped with Mobile Office, a compact unit incorporating a mobile printer and ORGA's handy smart card reader. Prior to treatment or consultation, data from the patient's smart card is output onto appropriate pre-printed forms, such as prescription, treatment guidelines and assessment, sick note or accident report. This eliminates the tedious filling in of forms. The system, which is housed in a leather shoulder bag, will also connect to laptop and desktop PC's. Diagnosis, treatment, prescription and other details can be written onto the smart card. This enables up-to-date records to be held on the card at all times and accessible only by authorised healthcare practitioners. The system also connects to central healthcare systems so data from each visit can be stored centrally. Actions may be required following visits, such as letters to GP's and consultants. The system can also automatically record the start and end of treatments to provide a complete time and attendance record.

Furthermore there's an overall plan of the NHS about the development of the health card system.

A series of targets for the implementation of electronic services in Government has been published, to deliver services to the citizen, to make government and its services more accessible, to tackle social exclusion and to use information better. This policy was set out in the White Paper "Modernising Government", published in 1999 and reinforced by a series of papers since. This has the overall objective of achieving joined-up working between the different parts of Government and providing new, efficient and convenient ways for citizens

and business to communicate with Government and receive services. To direct the strategy the e-Envoy's office has been created within the cabinet Office, driving the policy forward and reporting on progress to the Prime Minister.

Specific targets which impact on the services delivered by the NHS include:

- By 2002 25% of dealings with Government should be capable of being delivered electronically.
- By 2005 100% of dealings, covering all key Government services, including the NHS HS should be capable of being delivered electronically.

These targets are reflected in the NHS Plan, published in July 2000, building on information for Health targets which, though published in September 1998, was largely in line with e-government objectives. The key services supported include:

- Remote access health care services to patients and the public
- Better quality information to support healthcare delivery
- Administrative services for patients
- Information and knowledge to patients and healthcare professionals

Information for health

The information strategy for the NHS was issued in September 1998. Its central theme is the development of the electronic health record (EHR) which is patient-centred and aims to help health care professionals improve the delivery of services to patients. The vision is of a lifelong person-based EHR which follows patients as they move within the NHS. It is envisaged that such a record will be available to authorised clinicians in carefully prescribed circumstances on a 24-hour basis. In the context of providing access round the clock, the new strategy states that one option may involve the development of patient held records, possibly through the use of smart cards. The strategy also states that regardless of the technology used, any approach must ensure that the timing and provision of care does not rely on patients having records with them.

The NHS Plan

The main thrust of the government's policy as embodied in the NHS Plan is to provide a health service of high quality designed around the patient. The Plan's vision is to offer people fast and convenient access to services and information. The availability of accurate, timely and up-to-date information for patients and healthcare professionals is, of course, pivotal to the provision of effective and modern healthcare services. The NHS Plan develops further themes that formed part of the information strategy for the NHS.

The NHS Plan contains a strategy for the access to electronic personal records for patients. It also states that when the necessary infrastructure is in place and a full evaluation of the technical feasibility on effectiveness has taken place, smart cards for patients allowing easier access to health records will be introduced.

There are many technical, legal and cultural issues, notably issues of security and confidentiality, which need to be resolved before any wide-spread use of smart cards in health can be made. There is, therefore, no immediate plan to introduce a national smart card scheme in health. It's important to determine the purpose and scope for introducing smart cards. For this reason it is essential that pilot schemes are run to test some of these complex issues. Some piloting of the use of smart cards in health has already begun and other pilots are planned. Further piloting and trials will be necessary to establish the business case for implementing smart cards schemes, to ensure benefits are achieved and issues are addressed. The NHS has developed criteria to judge the suitability of proposals. These include questions like how the use of cards will improve services for patients and how they will improve conditions for clinicians.

Electronic Record Development and Implementation Programme (ERDIP)

The development of the electronic health record is being taken forward under the aegis of the Electronic Record Development and Implementation Programme (ERDIP). This Programme has been set up to explore a variety of electronic patient record systems in different healthcare settings. It has an interest in technologies that add value such as smart cards and web-based technologies. Smart cards could be seen as an interim means of storing limited clinical information such as alerts and medications, or as an access token to the shared electronic patient record.

South and West Devon Health Authority

The work of this ERDIP demonstrator community includes an evaluation of the use of smart cards as a storage medium for patient information. This will be part of the site's overall work on patient access. In addition, the use of smart cards as authentication and access control devices will also be investigated as part of this work. An initial evaluation will be undertaken prior to the specification of a demonstrator EHR system. This is in order to examine the opportunities for, benefits of and implications to care from patients being offered access to their EHR. This will be based upon a systematic review of local and national literature and consultation with patient access element of the South and West Devon EHR demonstrator. This aims to test the feasibility of creating a workable EHR by focussing on the management of Coronary Heart Disease.

Results from the initial evaluation are expected to be completed by the end of December 2000, but are unlikely to be available for wider dissemination until the early part of 2001.

Bradford Health Authority

Although the work on this site has yet to begin, part of the project's remit is an evaluation of smart card technology as a means of providing patient-held Electronic Health Records and as a mechanism for enabling authentication of patient identity. This will include testing read and write systems. This work is due for completion by the end of December 2000. This is however the "doing part" of the activity. The review documentation on smart cards will be included in the Project Closure Report that is due by the end of March 2001.

Latest news

The Department of Health has published its strategy document, Building the Information Core-Implementing the NHS Plan in which it pledges to have an electronic health record for every NHS patient as well as a revolutionary booking system.

Today's allocation of £533m will be made available over the next three years to get all GPs, hospitals and patient access points connected to the same network allowing them to analyse, manage and share information more effectively.

The Electronic health record proposal is supplementary to the electronic patient record (EPR) scheme currently being implemented, and will replace millions of paper records. Patients will also be given easy access to their records, which will incorporate encryption technology to ensure the security, in accordance with the Data Protection Act.

The associate director at iSoft, the company working with the NHS on a pilot for EPR, said the announcement underpins the whole NHS Plan.

Personal health systems provider LifeGard has developed a smartcard capable of holding a patient's full medical record. LifeGard claims the technology, based on multi-application operating system MULTOS, allows it to be programmed to securely hold individual patient records.

8.3.8 USA

This breakthrough health and social services programme is being initially tested in the states of Florida, Wyoming, North Dakota and Nevada. Health cards are beginning to revolutionise

healthcare in the United States by assuring the validity of claims, cutting the cost of processing claims, insuring patient privacy and keeping patient records timely and accurate. It will specifically touch on technical challenges and emotional factors that need to be addressed in any successful smart card-based application.

8.3.9 Conclusion

Thus, the biggest European Health card projects were handled by several experienced European producers: they are Gemplus, Schlumberger, who were the main actors in France, Belgium and Italy, Orga, one of the main actors in France and Germany and Italy and Giesecke&Devrient, another German producer. Also these producers are part of the so-called "SIMalliance". The four founding members Gemplus, Giesecke&Devrient, ORGA Kartensysteme and Schlumberger intend to increase the interoperability between their systems that will drive the industry as a whole.

PART SEVEN – RESULTS OF THE MAIN HEALTH CARD PROJECTS

CHAPTER IX – RESULTS OF THE MAIN EUROPEAN PROJECTS

There were, and they are nowadays, many projects which are the practical demonstration of how policy and technological options can integrate themselves.

The study provides some brief information about the main European projects developed during the last years:

9.1 ISHTAR

(starting date: February 1, 1996; ending date: October 31, 1998)

The project intended to be a further step to a stronger awareness that healthcare systems and the IV Framework Health Telematics Projects had to be considered together taking into account that telemedicine applications were improving ever more. The major participants of this project are the UK, The Netherlands, Ireland, France, Belgium, Portugal, Greece, Switzerland, Finland, Italy, and Germany. Objectives: the project's aim was to create a group of legal, medical and technical experts and to provide the data protection guidelines.

9.2 DIABCARD

(a third phase of the project started July 1, 1996 and ended July 1, 1998)

The project developed a diabetic health card. The card was part of the medical informative system. A pilot of the system was built and evaluated for three months. The DIABCARD card was flexible and suitable to different needs. Its architecture could be implemented within existing informative systems and network environments and could be improved with technological devices. A first prototype was tested in Barcelona: the prototype consisted in a data registration system computer-based (CPR). The pilot was tested in "Hospital de la Santa Creu i Sant Pau". The first implementation was one-month long, while the second one was three-months long and involved three units (endocrinology, obstetrics, nephrology). 108 patients were involved. Some of them were put in an experimental group using DIABCARD and other in a control group using traditional paper files. Data were updated every time patients went to their physician. Physicians' reactions weren't good because they were disappointed by functionality problems. On the other hand patients were happy about the project. Another prototype was tested in Perugia: the experimental phase did not get known in order to avoid undue expectations or earlier reactions about the service quality. The final aim was to create

a link between DIABCARD and the software Millennium. 5 physicians were recruited who used the Millennium system and a record of their diabetic patients was built up. The second step was the creation of DIABCARD card and its dissemination to patients. Patients transferred their data from the card to the Millennium system every time they went to their physicians. The final result was that the project maintained high physicians' motivation and patients' reaction was very good.

A third prototype was tested in *Athens*: the same model implemented in Barcelona was used but the card structure was modified to make it suitable to the Greek language and methods of working. 15 professionals and 100 patients were involved. During the trial and at the end of it physicians and patients answered to questionnaires on the system results, its influence on the day-to-day routine and its acceptability. The test was carried on at the "Red Cross Hospital" and lasted for three months. The project was well accepted by physicians and patients.

9.3 CARDLINK 2

(starting date: March 1, 1996; ending date: March 1, 1999)

The main task of the project was to implement and demonstrate, within 10 regions of 9 European countries, a health card for patients in cases of medical emergency. The card contained data within a security system and could be read and updated by general practitioners, specialists, pharmacists and the administrative staff. The card contained also pointers to allow access to hospital databases and to provide synergies within the wide healthcare network. Data architecture was suitable with the recommendations of Eurocards project. The implementation within the 10 regions intended to be interoperable in terms of administrative and emergency information. The project wanted to strengthen the results of the concerted action "Cardlink 1" and to provide a test-field for a research in the Eurocards project. The project issued 100.000 cards and produced a detailed evaluation about the user and provider of the service.

The partners involved in the project were:

IRELAND (Dublin). The Eastern Health Board was responsible for planning and delivery of primary care, hospital care and psychiatric care and a range of personal social services for the population of the three counties, Dublin, Kildare and Wicklow. The trial involved the issue of a minimum of 20.000 cards to different sectors of the Board's population including elderly people, children and individuals suffering from particular medical disabilities. The card was used in GP surgeries, hospital Accident & Emergency units, community pharmacies and ambulances. The card could be read or updated by General Practitioners and hospital medical personnel. Pharmacists had access to prescription information and could update only the dispensing section of the dataset. Cards and readers were supplied by the Philips Company.

GERMANY (Koblenz). The aim was to issue cards to a population of 50.000 people over the three year life cycle of the project. Besides emergency data and basic anamnesis data the card contained information on pharmaceuticals prescribed. The card could be issued by any of the 60 office-based physicians or in one of the 25 pharmacies established in the region. Physicians were entitled to read and enter data to the card in their offices, pharmacists were entitled to write data onto the card but reading access was restricted to pharmaceutical information. The project was supported by the companies of Siemens, Gemplus, Krone and Data Card which delivered cards, chips and readers.

HOLLAND (Delft). 25.000 cards were issued. The cards utilised carried personal data (name, address), Insurance data (coverage, risk details etc.), stable medical data (including past pregnancies), data about allergies and pharmaceutical data (the last ten medicines issued).

SPAIN (Valencia and Madrid). 20000 cards were issued with card readers deployed in primary care sites or reference hospitals in the areas of cardiology or emergency.

GREECE (National Technical University of Athens). The proposal was to implement a student health card for approximately 6.500 university students who were covered by a specific health care insurance plan. Health care services were provided to them either by the university clinic and the emergency care services of the near by hospitals, to implement child health care cards in collaboration with the Municipality of Amaroussion and State Children Hospital of Pendeli in co-ordination with a contracted insurance company, to implement health care cards for 2.500 elderly people over 65 years old in collaboration with the Municipality of Amaroussion.

PORTUGAL (Lisbon). The card was used to link primary health services, local and regional hospitals and ambulance services. The total number of cards issued during the project duration was 20.000.

FRANCE (St.Nazaire). The project was managed by Santal Association. The confidentiality of data and the access management were guaranteed by the use of a professional card. 40.000 patient cards were issued during the first phase.

ITALY (Rome). The following health care centres were involved: ASL RM C, "Fatebenefratelli" Hospital, Alitalia Medical Centre in Rome's Fiumicino International Airport, University of Rome "Tor Vergata". About 5000 patient's data cards were issued. Cards were issued to patients expected to report general or specialized medical out patients' centres equipped with card readers and persons who, because of their profession, were expected to travel throughout Europe and to come in contact with other health care centres involved in this project outside of Italy.

(Lombardia Region – City of Brescia). In agreement with the Municipality of Brescia, the city Hospital and the local health care Unit n°18 and under the sponsoring umbrella of the Lombardia Regional Authority, the Azienda Servizi Municipalizzati (ASM) co-ordinated and carried out the test. Citizens had the opportunity to use the card in 10 service access points.

FINLAND. The elderly and disabled persons were the primary client users in the pilot. The main purpose of use was the information requirements in emergency situations and the secondary supporting functions such as payment/refunding systems of transportation services for elderly and disabled persons. Most of the clients used the emergency services provided by the Helsinki University Hospital. The pilot project aimed at defining, piloting and assessing the health care smartcard system as a whole and the services provided by it for an ordinary citizen as the recipient of social welfare and health care services.

9.4 TRUSTHEALTH

(starting date: April 15, 1998; ending date: April 15, 2000)

The first aim of the project was to show as telematic projects can be settled down using modern secure methods. The project was introduced in 6 countries, Belgium, France, Germany, Norway, Sweden and UK. Within all these countries TTP services were operative and security kits were carried on with the following applications: medical messages communications for laboratory results, pharmaceutical prescriptions, digital signatures, user authentication.

The aim of the project was to provide several specifications for security services and interfaces, a service infrastructure for third parties involved and specifications publicly available. Three assertions about healthcare environment affected the work of the project on services and interfaces: PCs are the most used terminal and they will be in the future, healthcare professionals are very movable, key and

certificates control makes smart cards the best mean for recording data.

The project took the start-off from the “Trusted Health Information Systems” project which highlighted the need of defining European guidelines in order to create a Trusted Third Parties structure with a national control of every operation. The project issued three documents:

- Selection of Security Services and Interfaces. Functional requirements for security services
- Guidelines for implementation of security services and interfaces
- Functional specifications of TTP services. Functional requirements of services including name, public key and professional certification, card issue and direction services. Every user had an identification number recorded by a public recording authority. Then every user received three types of key from a key generator: one for digital signature, one for encryption and the last one for identification and authentication. Furthermore every user received public key certificates linked with each key and an electronic professional certificate.

The project put forward the usage of a hierarchical scheme of names with a certain number of trees for country to support national practices. The scheme had three attributes: unique number (UN), numeration system (D), country [C], which identify one name. To allow a good readability a common name (CN), the organisation name (O) and organisation unit (OU) had to be introduced.

9.5 NETLINK

(starting date: June 1, 1998; ending date: June 1, 2000)

It is a IV Framework R&D Project of the EC (HC 4016) partially funded by the European Commission bringing together participants of France, Germany, Italy and the Province of Quebec (Canada). The project aims to promote interoperability between nation-wide Health Information systems for the benefit of patients, health professionals, governments and health insurance funds by establishing technical and functional recommendations for interoperable network and smart card based health system solutions and demonstrating the viability of the selected solutions through cross-border pilot sites. Its most recent documents are the NETLINK requirements for interoperability (version 2.1) and the Cook-Book approved version 2.1. Project solutions involved the usage of smart cards technologies, Public Key Infrastructure (PKI). The Italian project disseminated 130000 cards to patients and 1000 cards to healthcare services providers. An Italian region implemented an innovative method for linking the health card with an existing debt account using the remote process management system of the bank. Quebec (Canada) developed a system which created an anonymous network database containing medical transactions depersonalised. Germany distributed 80 million chip cards to German citizens in 1993 and 1994. Now Germany is investigating the usage of a PKI-key access, identification and digital signature cards provider. France disseminated 42 million Vitale family insurance cards during 1998 and 1999. France is now still disseminating cards to healthcare services providers. With such a card the electronic payback has suddenly decreased to a two-days time limit and frauds have been minimised.

9.6 G-8 HEALTHCARE DATA CARD PROJECT

The G-8 members along with the European Commission decided to take the opportunity offered by the Ministerial Conference being held in Brussels on February 25-26 1995 to identify a number of selected projects where international co-operation could be an asset. The official title of this project is “International harmonisation of use of data cards in healthcare”. It deals with the development and piloting of:

- An international emergency card that would provide the essential medical information that is vital for an emergency situation as well as

- An international harmonised administrative data set and
- An international professional card that will allow the secure identification of healthcare professionals when accessing medical data and network services.

A major emphasis was being placed upon developing technical interoperability so that all cards from all participating manufacturers can read in the different participating countries.

9.7 AIM EUROCARDS

General objectives: there were substantially two main objectives:

- Offering an essential information which could improve the effectiveness of a ready care for a patient.
- Putting forward a system specification which could be implemented and used in a European country without any language problem.

There were also several likely actors:

- healthcare service providers thought that was necessary to be aware of some basic characteristics related to a patient in order to supply a better service,
- patients thought they could have a better treatment if they could have clinical information always available,
- government services expected a better management by preventing hostile reactions,
- insurance organisations expected to anticipate cost cutting by making available medical information to professionals when a patient needed a ready care.

Implementation situations: there are 4 implementation situations:

- No patient card exists. All the informative infrastructure has to be developed but this allows the obtaining of economies of scale.
- There's a paper file or magnetic card system. This allows the basic and unprotected information transfer.
- There's a medical niche implementation. An informative structure exists and an emergency card adds some costs but improves the system. Nevertheless the target population is small and this can bound the impact.
- There's a patient card administrative system. Some functions help the healthcare service in emergency cases. Data as identification number or patient data access are not included within the card.

Emergency card: there are two possible situations:

- *Life emergency.* The patient is in a life-danger situation, so he can provide no personal clinical data but the medical intervention is urgent to assure the patient survival. After the first saving-life intervention patient data are needed for the following treatments. The emergency card must provide such a data.
- *Ready care need.* Even if there's no life danger the emergency is likely to hinder to have the time needed to access patient data. So emergency card has to provide ready care.

Legitimated users can be: public servants, police in emergency cases, other emergency staff, paramedical staff, nurses and healthcare professionals, medical staff.

There are several card functions:

- *Administrative.* Patient identification is essential in order to keep his/her medical records. Furthermore the card has to show the name of the patient first medical responsible.
- *Clinical decision support.* It is possible to summary within the card several clinical information in terms of yes/no data that can be very useful. However a wide information set can

be an integration of lacking information and it would be included or transferred to an emergency card. Some data should be readable in a visual and electronic form.

Legal and ethical aspects: the first objective is to guarantee the healthcare service continuity safeguarding patients and physicians confidentiality rights. Every patient has a privacy, confidentiality and self-determination right.

Privacy is protected by the normative structure which is, basically, the same in all the medical applications related to data protection. EU recommendations and all the European normative has a final aim which is to affect the results of the improvement of every single national legislation.

European rules regard, most of all, data protection:

- *The convention for the protection of individuals with regard to automated processing of personal data.* It asks to dispose and standardise national legislation in order to satisfy data protection requirements.
- *Recommendation on the protection of medical data.*

Card content liability is up to people who insert data.

Furthermore:

- Every card application which involves data recording would have an actor responsible of it. He decides the usage purpose, he is responsible of patient data inserted and finally he is responsible of authorised access and data transfer.
- The aim of card usage should be defined in connection with the card planning (patient identification, suitable medical treatment, administrative purposes).
- Data collected within the card must be suitable, relevant and not redundant. Data must be recorded regarding to card dimension. Data must be categorised for selective access within the card for every healthcare proposal: identification numbers and data related to patient identity, administrative data, insurance data, genetic data and so on.
- Patients are the card holders. Patients may have the power to decide the data usage and dissemination. When a third party is involved in the treatment, the patient must give his assent in order to know which information can be released and he must be informed who is the third party involved.
- The patient must have the chance to decide which data can be released to strangers and which data have to be withdrawn from the card. Personal data transfer to third countries is allowed only if the country has a protection data system similar to the original country.
- Data collected must be relevant, correct, careful but not too much redundant.
- Data should be maintained only for a certain period useful to reach the aim they were collected for. If people requires it, medical data can be erased.

Security requirements: Information security is usually defined as the combination of services for: *confidentiality, integrity, availability.*

- ❖ *Confidentiality.* Information must be classified in sensitivity classes. Administrative information must not be protected. On the other hand clinical information, such as chronic diseases, need protection because their access must be allowed only to few professionals. It is not easy to shut out someone from accessing data when a different access right is requested even if technology permits it.
- ❖ *Integrity.* It relates to the necessity not to have an accidental data change which can give the wrong information to professionals. Defining the information source and authenticating it must be allowed on emergency cards. To do so, it's necessary to include attributes to data defining identity of people who has content liability.
- ❖ *Availability.* It regards to technical feasibility of a method which allows access readiness and speed. Several methods of data access are involved. One of them is the visual information which

includes a link to other information. Another alternative is to include information in more than one memory technology within the same card.

Interoperability requirements in Europe: Interoperability requests the solution of three key problems:

- *Technical aspects.* Technological basic standards have been developed regarding to ISO standards. Specific standards for health cards have been developed by CEN TC251. Nevertheless specific decisions must be taken because standards are very generic. Data representation and system interface must be based on a modern structure which allows a great flexibility for a good data interpretation. It is important that emergency card structure is flexible enough to guarantee an easy development. International healthcare scheme recording has been fixed in collaboration with WHO. Functionality analysis of an emergency card shows several different processes or functions: general administrative, specific administrative, general clinical data. Furthermore it leads to these conclusions: some data can and should be included in visual and electronic format, some other data should be freely accessible to all potential users, some other data should have an access controlled by security systems to make them accessible only to few users. Even the technology problem is involved. There are three technological classes: magnetic, IC-cards and optical memory cards. In order to make a card readable everywhere, it's necessary to draw up an agreement between European countries to standardise all the methods. The most feasible way seems to be the creation of a software interface able to read more than one technology.
- *Decision to guarantee interoperability.* It's necessary that the system has a certification of the operability regarding the fixed standards.

Projects already developed: Several trials have been carried on in the past using cards including emergency data and attempts in order to weigh the effectiveness of the system regarding to type and quality of data exchange.

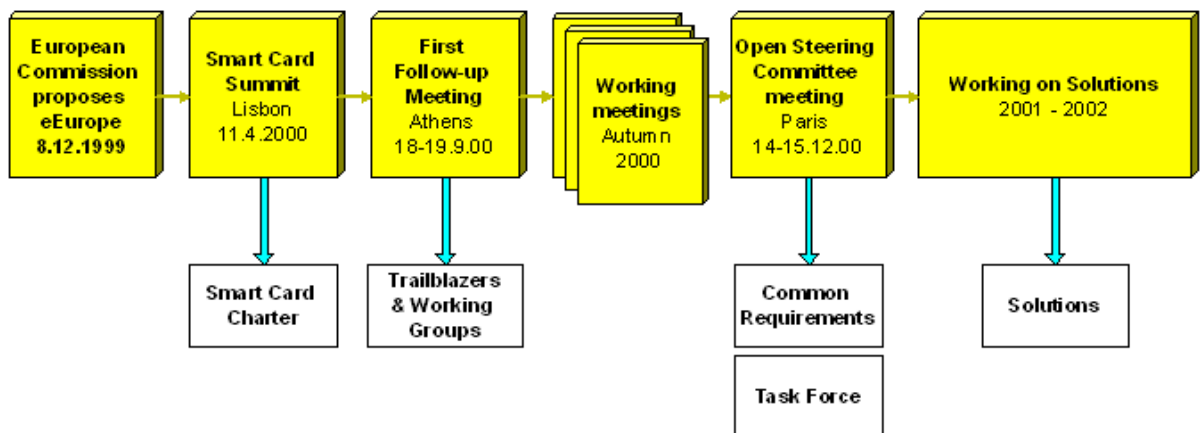
- *Mounts Bay Project.* The project was carried on by Green Shield (Canada) in the area of Mounts Bay (Ontario). Cards were issued for pensioners in order to carry an emergency information file including a medical history. The evaluation was centred on cost decrease and covered mobility.
- *Exeter Care card trial.* The project was carried on, after the request of National Health Service (NHS), in the city of Exmouth (UK). The project involved a portable medical file including an emergency information set automatically read/updated after every medical interaction.
- *German Health card implementation.* The card planned in the German project contained this kind of information: name of the illness fund issuing the card with the name abbreviation and the number, the insured person surname and name, the date of birth, the address, the card holder insurance number, month/year of expiration (if a deadline is expected).

9.8 e-Europe smart initiative

9.8.1 Introduction

In December 1999, the European Commission, proposed the eEurope initiative to accelerate the transition of the economy to the digital age. An important part of this initiative, eEurope Smart Cards is aimed at stimulating the smooth acceptance and deployment of smart cards across Europe. There's a general conviction that the smart card (a card with an embedded microprocessor) is a very promising and enabling technology that till now, has not lived up to all the high expectations. Although hundreds of millions cards are in use world-wide, the market is still fragmented and most schemes operate only on a sectorial or at best on a national level.

Nevertheless the smart card has the same promising capacities as the mobile telephone or the Internet because it can support a magnitude of services both from the Business community and from Government.



Because fragmentation and reluctance of user acceptance are considered as the main cause for the slow adoption of the smart card technology, the need was felt for an action towards more co-ordination and co-operation on a European scale.

9.8.2 Smart card charter

At the Lisbon meeting it was first decided to set up a high-level Task Force with a clear mandate to initiate and support common developments in the deployment of smart cards throughout the European Union. The aim being to accelerate progress towards greater interoperability of smart card based systems and services, and therefore towards faster developments of the digital economy in Europe. There will be co-operation with standardisation and other institutes that are active in the field of smart cards. The Task Force will build on existing activities and there will be no duplication of work that has already been done. Working groups will be installed for mobile, e-business, security and trust, electronic identification and authentication. The Task Force will report yearly on progress. The participation will be open to all, and the results will be available to all interested parties. Secondly it was agreed the contents of a Smart Card charter. This charter will be the basis of the activities that Task Force will co-ordinate to reach the goal of interoperable and easily usable smart card based systems in the near future.

The Smart Card charter has four focus points: building trust, enhancing usability, improving access and supporting the deployment of applications and services.

The following work items have been defined:

Building trust

- common set of security requirements
- common security certification procedures
- common specifications for electronic identification and authentication
- free use of cryptographic products
- transparent and fair cost conditions

Enhancing usability

- ensuring easy access, by applying design for all principles
- coherent use of contact and contactless technology
- road-map for multi application cards and terminals

Improving access

- framework for interoperability between terminals in different countries
- access to the Internet from a range of terminals using standard protocols
- have an open dialogue between the telecom industry and the finance sector
- ensure efficient electronic payments and best use of existing infrastructure

Deploying application and services

- support development of Government Applications (employing smartcards for interfacing the public administration)
- common requirements for Public transport
- common requirements for Health
- exchange experiences and define common requirements for an electronic national and cross border identification function

Building Trust

Trust and confidence are essential to the Information Society. The lack of trustworthy security services is a major obstacle to the use of information technology in private, in business as well as in public services. Trust is intimately linked to consumers' rights, like security, identification, authentication, privacy and confidentiality.

All commercial transactions in the Information Society require a high degree of security, especially in the Internet-mediated e-commerce environment where the transaction happens with no physical contact over an anonymous global network.

Smart cards will contribute to provide the strong identification, authentication and proof of transactions. Moreover a smart card is an efficient device to execute security functions like digital signature.

- To develop a common set of scalable security requirements and relevant protection profiles for hardware devices (cards and all kinds of card accepting devices)
- To define common, workable, affordable and timely security certification procedures and infrastructure for the security certification of products/devices and acceptance environments.
- To agree on a common or interoperable technical specifications for Identification and Authentication infrastructures and services across Europe
- To support the full liberalisation of the intra-community trade and use of cryptographic products and encryption
- To ensure transparent and fair cost conditions of use of smart card infrastructures
- To ensure citizen trust in the protection and use of personal data.

Enhancing usability

Usability is vital for avoiding the great divide between those who have and those who don't have access to the Information Society. The citizen must be able to use their card wherever they are and at all access points with equipment that is consistent in their operation.

The multiplicity of card and variety of user terminal interfaces, the security requirements of the terminals and the specific requirements of impaired people hamper the wide acceptance of the smart cards.

- To ensure an easy access to smart card based infrastructures by designing it for all, including disadvantaged groups. To ensure, on the terminal, an overall interface consistency, the adaptation of the interface to the user preferences, a global consistency of the operation, in one word: user-friendliness
- To ensure coherent use of contact and contactless cards

- To devise the appropriate mechanisms for seamless use of multi-application cards and terminals to optimise their utilisation

Improving access

Access means the capability of entering services and applications from any terminal, any time, anywhere including those groups that are at disadvantage.

Currently terminals are not often interoperable: national borders, terminal specialised for some applications, specific platform, all are barriers for access. At present a comprehensive set of specifications allowing the compatibility of card terminals between applications does not exist.

- To broaden access to services to the widest range of smart card terminals in different locations in different countries
- To ensure smart cards can be used as an easy way to access digital applications and services from a wide range of terminals (e.g. PC, PDA, web phone, fixed and mobile phones, set-top boxes, digital television) using existing standards (e.g. GSM, GPRS, UMTS, FINREAD)
- To reduce the risk of fragmentation of the access to mobile commerce by calling for a dialogue between the telecommunication industry and finance
- To ensure reliable and efficient smart card based electronic payments and best use of the existing infrastructure

Deploying applications&services

Once access is assured, trustworthy and consistent, a wealth of applications can open to the full deployment of the Information Society.

Smart cards are used in a number of sectors, each with their own technology choices, their way of interacting, their requirements and their view on the best approach.

The expansion of content and the cross-fertilisation of ideas and services across and among application sectors has not yet happened.

- To provide support as necessary to enable public sector applications to develop and flourish
- To define common requirements for major public services starting up with Public Transport (by the end of 2000) and Health Care (by the end of 2001)
- To exchange experiences and define common requirements regarding the deployment of smart cards for electronic identification and digital signature (e.g. Finland, Italy, Netherlands, Sweden) by the end of 2001
- The successful deployment of a wealth of applications and services will ultimately be the measure as to whether smart card technology fulfils its potential and makes its due contribution to ensuring that the citizen benefits from the information society. Therefore there is a need to continuously monitor the success of the roll out of applications and services to identify unresolved problems in the practical exploitation of smart card technology.
- European strength would be to realise electronic communication on a wide front in cooperation with commerce, the banking sector and public administration, to produce versatile that can facilitate the live of the citizen.

Trailblazers

202 members, representing a cross section of card issuers, consumer and citizen interests, as well as the smart card industry met in Athens to decide on concrete steps for implementing

the smart card charter and follow the invitation of the European council in Feira, on 19-20 June 2000.

The focus of the discussion was on user acceptance and system interoperability across Europe by bringing together platforms and application platforms.

The meeting participants agreed on seven interrelated issues (trailblazers) needing urgent attention. They concern:

- Public Identity
- Identification&Authentication
- Protection profiles, security certification
- Generalised card reader
- E-payments (including purse, credit/debit and m-commerce)
- Multi-application systems

As well as one horizontal issue:

- Contactless smart cards

And the creation of four new trailblazers:

- User interface
- Public Transport
- E-Government
- Health

For each of the seven issues, the main requirements for further work, although not being exhaustive, were discussed and agreed upon.

In addition, it was felt that some other issues needed further exploration, in particular user interfaces spanning across all issues and transport and e-government for which already three organisations are starting to investigate further work.

To organise further work, participants decided to form open working groups addressing the issues above. A preliminary list of working groups was drawn up that should closely co-operate. A steering group, consisting of the chairpersons of the working group as well as representatives of public interest, and those relevant sectors not yet represented within the working groups, will co-ordinate the activities. The membership of the steering group would not exceed 15 people.

There were a number of proposals to provide the organisational and secretarial work of the working groups and the steering committee. The European Commission will discuss with the concerned organisations the main tasks required in order to define the tasks required.

TRAILBLAZER 1 – PUBLIC IDENTITY

To create a European multi purpose citizens identity which can be:

- In a travel document
- Driving license
- Citizen card

Part of this proposal is an implementation plan for the creation of qualified signature according to EU directive and the EESSI specifications. Also biometrics for cardholder authentication will be part of the proposal

TRAILBLAZER 2 – IDENTIFICATION&AUTHENTICATION

This project aims at promoting standard specifications for interoperable and secure smart card acceptance systems, to be used for e-business and transactional information systems over the Internet.

It will assess and specify common requirements for authentication of individuals and entities

accessing the Internet, and implement a deployment project.

The requirements are to be issued with input from representatives of the overall industry: systems components suppliers (manufacturers of smart cards), network providers (Telcos and banks) and content&services providers (such as merchants, transport organisations, administrations...) and standardisation bodies.

The topic is developed in relation to an accompanying measure called SMART IS sponsored by the European Union. The WG will define a large-scale implementation of a secure smartcard system to identify and authenticate a card-based-holder, from any kind of terminal, to any kind of e-service.

In this way, different solutions will be evaluated for the European Citizen so that they will be able to access all kinds of electronic services, with the same level of security and convenience using secure authentication and identification.

TRAILBLAZER 3 – PROTECTION PROFILES, SECURITY CERTIFICATION

The objective of TB 3 is to promote and facilitate the adoption of the Common Criteria (CC) - ISO/IEC 15408 standard through the Smart Card Industry for the evaluation and the certification of products and systems, to provide trust and confidence to the smart card users. To achieve its goal the TB will elaborate a framework to facilitate the process (product development - evaluation - certification) of using the Common Criteria cost and time effective to support internationally recognised certifications.

The principal aims of this WG are:

- Turn Protection profiles into practice with security targets and actual certificates and application with real products
- Avoid proliferation of Protection profiles with ultimately a standardisation process in conjunction with tests and pilots
- Need of competent laboratories allowing Europe with equivalent knowledge of smart card security
- Creation of a registration entity of Protection profiles at the European level
- Layered approach taking into account consumer needs and industry environment
- Maintenance of security level of certified products, possible reuse of industrial building blocks
- Define and support an educational process around SMART CARD security and Protection profiles for operators and users.

TRAILBLAZER 4 – GENERALISED CARD READER

The objective of the TB is to propose an architecture and a set of technical specifications for a secure IC card reader to be used in e-commerce and related IC card based applications on open networks. Existing approaches will be used to identify minimum common requirements and define a system architecture on existing or readily available technologies as well as fast track standardisation procedures to allow a wider acceptance of the work achieved.

The emphasis will be on the development of specifications for a multi-channel FINREAD secure card reader prior to addressing the issue of a multi-sector device.

TRAILBLAZER 5 – E-PAYMENTS (including purse, credit/debit, m-commerce)

The objective of TB 5 is enable broad adoption of smart cards as a means of secure payment, and ensure interoperability across channels, sectors and borders. Its strategy will have the following main points:

1. Synchronising EMV migration across Europe

2. Encouraging e-Euro by adopting CEPS e-purse and its continental roll-out
 3. Accelerating the convergence of smart card based e & m payment methods/architectures
- Recommendations on follow-up actions:

Subject	Issues/Risks	Actions
Payments for mobile commerce	Proliferation of business models and architectures, leading to further market fragmentation across service providers and across regions. Numerous and possibly overlapping, initiatives involving often the same core players	First, contract a “state-of-play” analysis of the market situation. As appropriate, bring the key alliances and players together in order to discuss the possibility to agree on a limited set of possible architectures (banking, telecom operators and manufacturers of mobile phones in particular). The parties involved should include (but not be limited to) key members of the Global Mobile Commerce Interoperability Group, The Mobey Group, MeT initiative, Radicchio, the WAP Forum, ETSI SMG9/Smart Card platform, the GSM Association. Consider calling a high level meeting of key executives to accelerate the business dialogue between the payment industry and mobile telephony industry on m-payment deployment
	Lack of consistency of end user interface	Take stock of plans of working groups defining user interfaces for mobile payments. Ensure that consumer requirements are addressed on a pan-European level. Identifying issues related to horizontal topics of the Charter such as consistency, usability, price transparency, etc. Produce a widely agreed position paper
	Level of security of handset devices and related payment services	Define the more efficient roadmap to ensure harmonised security evaluation procedures throughout Europe for payments on mobile devices (including agreed industry-wide minimum levels of security)
Payment terminal infrastructure for smart cards	Risk of incompatibility of accepting devices (fixed and/or mobile)	Create a forum for accelerating the convergence of the common layer of technical standards regarding smart card accepting devices (EMV, CEPS, TV set-top boxes, car-embarked systems, mobile phones, PDAs...)
Internet payments (debit/credit /electronic purse)	Lack of common approach/critical mass of users for a smart card based Internet payment solution	Perform comparative analysis (including economic data) of existing solutions (Cybercomm, SET-based, mobile platform/WAP and others). Evaluate relevance of pan-European co-operation on deployment. Liaise with TB2, TB1 and TB4
Small payments in euro across borders (e-	Delayed and “non-coordinated” deployment across Member States	Monitor progress and identify barriers to the deployment of pan-European interoperable e-purses (to be performed by independent observers). Consider intervention/support of

purse)		national public authorities and facilitate cooperation between service providers.
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TRAILBLAZER 6 – CONTACTLESS SMART CARD

This trailblazer’s primary objective is to promote the use of contactless smartcard technology. The expected benefits are the use of the trailblazer deliverables by operators in m- or e-commerce as well as public transport systems as they roll out over the coming years.

- The objectives will address two key overlapping areas; the industrial offer (IO) and the end-user (EU) needs and may be broken down further into several identifiable parts as follows:
 - Promotion (IO/EU) – Overall goal, promoting contactless technology
 - Security (IO) - Threat evaluation, personal profile inputs, market perceptions
 - Interoperability (IO) - Current status, inputs to standards organisations, demonstrations
 - Certification (IO) - Conformity procedures, laboratory participation,
 - Roadmap (IO/EU) - Current status, future requirements, platform definitions and harmonisation
 - Field trials (IO/EU) - Pilot scheme specification, implementation and result evaluation guidelines
 - Deployment (EU) – Equipment and tender specs, operational issues, supplier catalogue
 - Education (EU) – Contactless advantages, projects

To achieve its goals the trailblazer aims to re-use the work and results of current projects, standards, and platforms with the aim of harmonising the existing efforts and complementing them where necessary.

This technology is fast, easy to use, reliable, better protected against vandalism and requires reduced maintenance. However, it lacks standards and interoperability. Today, transport is the driving market.

TRAILBLAZER 7 – MULTI-APPLICATION SYSTEMS

The objective of Trailblazer 7 is to enlarge Citizen’s freedom of choice in the selection and management of the ICT services they wish to access using smart cards as the generic access token. This objective to be achieved by providing a framework for open interoperable multi-application smart card platforms both in usage and service management under strong security control initiated by the card issuer. A further objective will be to aim for convergence of business models based on a common data framework and in so doing develop an environment of free competition among providers within the smart card value chain. Technically to support and promote all smart card, chip, operating system and management activities that enable the desired multi-application environment.

To link with existing actions in this area within standardisation, RTD project and industry consortia initiatives, and to build on this work without duplication to achieve the desired outcome in the fastest and most optimum manner. Key issues are to take account of all business sectors involved in multi-application programmes, to facilitate endorsement of deliverables by international organisations and take account of technology interfaces already in existence that support multi-application operation. These issues will be tackled by involving

all major business sectors, including government in the activity of the Trailblazer.

Where possible the resource of existing projects will be used to minimise cost and maximise the speed of work.

Three activities are currently going on this area:

- The Global Platform presented by Proton World
- The ETSI EP Smartcard Platform
- The ISOP1 project of the ISOP consortium

The working group will start comparing the strength of these different platforms and then define a way forward. In the end this will lead to more transparency for the card issuers and a clear view on sustainable and open platforms which can be promoted and used by large supporter groups. Test and trials will help to realise this. ETSI proposed to use its interoperability testing capabilities.

TRAILBLAZER 8 – USER INTERFACE

The objective of Trailblazer 8 is to ensure that the user interface and functionality of ICT systems employing smart card technology meet already identified requirements to support Citizen aspirations, to provide systems that are attractive to Citizens and to guarantee inclusiveness for all categories of Citizen. It is a specific objective of this Trailblazer to interact with all other Trailblazers to provide them with user requirements input. It is a further objective of this Trailblazer to interact with external representative bodies to provide a route into the Smart Card Charter activity for those bodies to express their concerns and wishes. All such interactions will be two way.

The Trailblazer will adopt two approaches in its strategy to meet the requirements placed on it, a horizontal strategy and a vertical strategy. The horizontal strategy reflects the specific objectives of the Trailblazer and is concerned with building bridges and information paths both to other Trailblazers and to external bodies. As such, Trailblazer 8 believes it will have a pivotal role in ensuring proper representation of Citizen needs and aspirations leading to the Smart card Charter meeting its goals for the two year programme. The vertical strategy enables the Trailblazer to undertake specific actions and studies to research and/or validate specific items concerning user interfaces and requirements where such information is not currently readily available.

TRAILBLAZER 9 – PUBLIC TRANSPORT

The objectives of Trailblazer 9 is to support the aspirations of the Smart card Charter in enfranchising Citizen's access to a range of ICT services supporting Public Transport utilising the smart card as the access token. Implied in the above objective is the need for interoperability between European transport ticketing systems utilising smart cards. Out of this comes the final objective of supporting all players by promoting innovation & co-operation between public transport authorities, as well as with relevant standards bodies to ensure inclusive Citizen support including consistency of user experience, and to provide operators with a credible business case model that supports the achievement of these objectives.

The Trailblazer will form multi-interest workgroups from the various business sectors involved, including the financial services sector to support ticket payments (eg. CEPS payment), which will identify and take forward individual work items for action. As much as possible use will be made of existing and completed projects, input from other Trailblazers

and ongoing de facto and de jure standardisation work to avoid duplication as well as establish a base starting point. Of most importance within this application oriented trailblazer is the task of ensuring that results and requirements are practicably implementable by operators.

The Trailblazer will also support the establishment of smart card based projects to enforce the TB objectives. The trailblazer is not intending carry out any R&D work or create new unique architectures that are not compatible with country specific architectures. The trailblazer will instead take a “modular” approach based on standard modules that can be put together in different ways to ensure that the needs of citizens can be met in a common way but suiting the needs of different national administrations.

TRAILBLAZER 10 – e-GOVERNMENT

The objective of TB 10 is to achieve definition, rationalisation and implementation of a European model for digitally performed procedures employing smart card for interfacing the Public Administration; promote more effective use of government's information resources; access to public services and simplify on line administrative procedures that use secure smart card solutions based on standards such as electronic signature , PKI infrastructure and internet.

To achieve its goal, Trailblazer 10 shall develop a methodology based on the consensus of its participating members that advances the state of the art by taking into account the requirements of the administrations agencies and the end users needs as well as all aspects of an application. The TB has defined a mode of operation based on the market requirement analysis to promote and accelerate the development of Business to Administration applications and exchange of data among administrations around Europe.

The TB will set up a co-ordination committee of the Administration bodies in order to obtain consensus and political actions on the implementation of existing standards such as Electronic signature or ask for new standards.

TRAILBLAZER 11 – HEALTHCARE

The trailblazer on healthcare should give recommendations for a European-wide interoperability of healthcare 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 healthcare/health related data and could be seen as three different cards with different functionalities, e.g. ID-card, signature card and health card, which of course could also be combined on one card.

Citizens crossing EU borders may wish to present their healthcards to help with treatment in other countries. The trailblazer will draw attention to the provisions necessary to promote crossborder interoperability in clinical, management and financial fields, where the underlying systems permit this. In the same way the outcome of this trailblazer should help Health professionals to use their ID-card to access urgently needed data of a patient from wherever they are, with the patients (electronic) consent given.

Where there are no recommendations possible it is also in the scope of the trailblazer to describe what is possible with regard to the given framework and at the same time ask for improvement. In this context it has to be clarified how data, especially references, can be stored to allow shared care, what in technical terms means shared access. It is also in the scope of this trailblazer to describe and give advice how a secure remote access to a patient's

data can be organised and under which circumstances and by whom this access may be given. In this respect, aspects of synergy between card systems and IT network based solutions should also be addressed. Electronic signatures, Certificates, Public Key Infrastructure and electronic patient consent are some of the key topics that have to be addressed.

One of the major tasks of the trailblazer healthcare is the harmonisation with most of the other trailblazers, such as "Smartcards for Internet", "Contactless smart cards", "Identification & Authentication", Public Identity", Protection Profiles, security, certification", Multi-application systems" and "Generalised card reader". Co-ordination will also be required with the TESS Programme of DG Employment who is in charge of the modernising administrative procedures for European citizens moving from one to another Member State. These trailblazers are not sector specific but have to be seen intersectoral. For example the identification and authentication procedures are not different for a citizen, a patient or health professional.

Card readers for the same purposes and with the same functionalities should be usable in banking environment as well as in transportation or in the health care sector etc. Therefore the use of generalised and non-proprietary terminals should be encouraged, in the interest of reduced infrastructure costs. The trailblazer will, with other actors, identify common usage scenarios which enable manufacturers to achieve cost efficiency and systems designers to call uniform open-source routines appropriate to applications needs. It is a very important task of this trailblazer to achieve harmonisation of smart card based infrastructures across sectors by building a consensus for compatibility.

The third field of activity is the initiative for demonstrators and pilots to show that the recommendations and harmonisation efforts published by this group and promoted to others are usable and accepted by industry as well as by the users. This developments should be based on existing work and standards and should not reinvent something already existing. Derived from this it can be stated that it is not the task of this trailblazer to initiate new developments or to engage in the field of standardisation. Topics like the electronic prescription, a minimum dataset/interoperable data set or a so called emergency data set are already work items of the international standardisation activities. The trailblazer may however identify any gaps of technical standards, where user-needs are revealed for future work in standardisation bodies.

Also the field of entitlement and reimbursement is out of the scope and is covered by other EU-projects like TESS etc, which are responsible for international solutions in this area.

TRAILBLAZER 12 – ADVANCED ELECTRONIC SIGNATURE

The objective of TB12 is to provide European Citizens with Advanced Electronic Signature use, as per the European Directive, through a Smartcard based system for Internet.

- Identify minimum common requirements and define a system architecture using existing or readily available technologies. This will allow European Citizens to carry out transactions on open networks, such as the Internet, with confidence, in multiple domains.
- Identify projects, and bring together the necessary skills and technologies to start deployment of such a system by or before the end of 2002, and within a number of European countries.

Evaluate the deployment and improve the architecture specifications. Such an architecture should be : based on the use of smartcards and PKI, conform to standards and use non proprietary solutions, « Web Access Device » independent e.g. mobile, Webphone, Set Top Box, PC Reader,interoperable, multi-application

PART EIGHT - VIEWS AND COMMENTS BY ORGANISATIONS AND INTEREST GROUPS

CHAPTER X – DESIGN OF THE EUROPEAN HEALTH CARD

Our study has been completed by interviewing people dealing with the topic of health card systems, such as physicians, National Health Service officers, managers of companies involved in health card projects.

10.1 Information to be included on the European health card

Quite all the sources interviewed agree that there's the need of a European health card: only one source said there's no need of such a card because he thinks there's a need for a European identity card. All the other sources said yes and specified their opinions. They underlined that there are several problems to be resolved regarding legal and cultural issues, notably issues of security and confidentiality. So these are the reasons why it can be difficult implementing a European health card, but it would have the great role of benefiting healthcare workers and patients and of facilitating free travel of European citizens.

All the sources gave different answers. This confirms that there are different points of view about the card content. Most of them said emergency care, health records and all the aspects regarding health services and emergency data are the most important elements to be inserted onto the card. Three sources highlighted that the card has to contain also administrative data in order to guarantee a secure patient identification and to resolve the problem of digital signature.

10.2 Use of the European health card

10.2.1 Emergency situations

Most of the sources said that the card must contain any health information, included emergency data, and, in some cases, administrative data. The French sources strongly believe that the card should contain the maximum data. One Italian source said that the card should contain data in order to fill up a clinical file. This is the reason why administrative data must not be contained in the card.

10.2.2 Medical and social insurance fields

Most of the sources said that administrative data must not be present in the card because they are not urgent. Only a PIN for identifying the patient and/or the physician is necessary. Only the card issued in Germany was an insurance card, while all the others were not dealing with such an argument.

10.3 Protection of the medical data, confidentiality and security for the patient

Most of the sources said that the issue of data privacy and security have to be of special concern and that all data stored on the card or on a remote database have to be encrypted by methods protecting both access and manipulation. One Italian source instead said that, taking account of the Italian situation, it could be possible to simplify the first card exploitation in order to save costs and only if the success of the card generates risks then security procedures have to be implemented. Another Italian source said that the data encryption is not essential because the card contains only emergency data, so a PIN and PDC/HPC authentication are sufficient.

Another problem often discussed is who should issue, manage, insert/update data. All the sources agreed that whoever manages or issues the card the problem of information security is the most important. So many sources said that only national bodies, independent trust centers, territorial healthcare structures can issue and manage data stored in the card. On the other hand it's possible that GPs manage clinical information and city officials manage administrative data (this is a distinction remarked by French sources). Nevertheless patient should have influence on the way it's managed: updating and adding data only with consent of the patient.

10.4 Languages used/to be used

One of the principal problems related to interoperability is the language used in storing data onto the card. The problem is that for using only one language (e.g.English), it's necessary that every physician or patient in Europe is able to understand it. But it's very difficult to obtain it. Furthermore many European countries have already implemented national health cards, so they are not likely to give up what they have built. (for example, the Greek health card would have data stored in Greek types, so a translation is needed for a European usage).

10.5 Questionnaire grid

The sources interviewed are 15 : Three for France and Italy, two for Netherlands and UK, one for Germany, Ireland, Norway, Finland, Sweden

QUESTIONS	ANSWERS	N°	%	NOTES
1) Do you believe there is a need of a European health card?	<u>Yes:</u>	14	93%	
	<u>No:</u>	1	7%	
	<u>Not answered:</u>	0	0%	
2)What kind of use should it have? (it's possible more than one answer for source)	<u>Emergency care:</u>	5	21%	
	<u>Health records:</u>	5	21%	
	<u>Health service:</u>	1	4%	
	<u>Everything:</u>	7	29%	
	<u>Identification:</u>	1	4%	
	<u>Patient/clinician's digital signature:</u>	1	4%	
	<u>Key access to web services :</u>	1	4%	
	<u>Administrative data:</u>	3	13%	
3a)Do you think the issue of data privacy and security should be of special concern?	3a) <u>Yes:</u>	13	86%	
	<u>No:</u>	1	7%	
	<u>Not answered:</u>	1	7%	
	<u>Don't know:</u>	0	0%	
3b)Do you think for example that all data stored on the card or on a remote database should be encrypted by methods which strongly protect both access and manipulation?	3b) <u>Yes:</u>	13	86%	
	<u>No:</u>	1	7%	
	<u>Not answered:</u>	1	7%	

	<u>Don't know:</u>	0	0%
4a)What health information should be on it? (it's possible more than one answer for source) 4b) What should not be on it? (it's possible more than one answer for source)	4a) <u>Any health information:</u>	5	31%
	<u>Only information about special disorders (e.g.diabetes):</u>	2	13%
	<u>All kind of information:</u>	2	13%
	<u>Clinical file:</u>	1	6%
	<u>Emergency data:</u>	4	25%
	<u>First relevant clinical data, then detailed information about it:</u>	1	6%
	<u>Not answered:</u>	1	6%
	4b) <u>Administrative data:</u>	1	7%
	<u>Not answered:</u>	14	93%
5a)Who should issue and manage it? 5b) Who should insert/update data stored on the card?	5a) <u>A national body:</u>	3	16%
	<u>Independent trust center:</u>	1	5%
	<u>All territorial healthcare structures:</u>	3	16%
	<u>National Health Service:</u>	1	5%
	<u>GP (only for clinical information):</u>	4	21%
	<u>City officials (only for administrative data):</u>	2	11%
	<u>Private service companies:</u>	1	5%
	<u>Not answered:</u>	4	21%
	5b) <u>A formal body:</u>	1	5%
	<u>Health professional, patient:</u>	1	5%
	<u>GP:</u>	6	32%
	<u>City officials:</u>	2	11%
	<u>Territorial structures:</u>	1	5%
<u>Not answered:</u>	8	42%	
6a)Should it be natural EU extension of national health systems cards? 6b) Something similar to the EU driving license, identity card, etc...?	6a) <u>Yes:</u>	11	74%
	<u>No:</u>	2	13%
	<u>Not answered:</u>	0	0%
	<u>Don't know:</u>	2	13%
	6b) <u>Yes:</u>	12	80%
	<u>No:</u>	2	13%

	<u>Not answered:</u>	0	0%
	<u>Don't know:</u>	1	7%
7)Should it look like a card or could it be some kind of electronic key to be plugged in a computer?	<u>Card:</u>	12	80%
	<u>Electronic key:</u>	0	0%
	<u>Don't know:</u>	1	7%
	<u>Not answered:</u>	2	13%
8)How hard do you think it will be to find a solution that will guarantee interoperability?	<u>Very hard:</u>	1	6,5%
	<u>hard:</u>	6	40,25%
	<u>Not hard:</u>	6	40,25%
	<u>Don't know:</u>	1	6,5%
	<u>Not answered:</u>	1	6,5%
9)Are there any steps which should be taken before introducing a European health card, for example legislation, data and technical standardisation, consortia making? (it's possible more than one answer for source)	<u>Legislation:</u>	2	10%
	<u>Data&technical standardisation:</u>	4	20%
	<u>Consortia making:</u>	2	10%
	<u>Gathering experience in pilot projects:</u>	1	5%
	<u>Standard on identification:</u>	1	5%
	<u>Feasibility study:</u>	1	5%
	<u>Introduction in small countries (such as Luxembourg)and then extension to bigger countries:</u>	1	5%
	<u>Approach to security and confidentiality:</u>	1	5%
	<u>Acknowledgement of smart card validity:</u>	1	5%
<u>Harmonise the rules at European level:</u>	6	30%	

10)Are there other health card initiatives we should consider in our study?	<u>Yes:</u>	8	57%	<p>The initiatives suggested are:</p> <ul style="list-style-type: none"> • The Slovenia experience (1) • French laws (article 36 loi n°99-641 27/7/1999, Code Securité Sociale article L161 31, L162-1-6) (1) • NHS Plan (1) • Netlink (1) • Canada Experience (1) • Not specified (1) • Eurocards (1)
	<u>No:</u>	2	14%	
	<u>Not answered:</u>	4	29%	
11)Are you involved in the policy making or specification of an health card?	<u>Yes:</u>	8	50%	<p>The involvements are:</p> <ul style="list-style-type: none"> • The Slovenia card (1) • Consultant in security issues (1) • Policy development on smart cards (1) • Italian electronic identity card (1) • Responsible of Sesam-Vitale project in France (3) • Not specified (1)
	<u>No:</u>	4	25%	
	<u>Not answered:</u>	4	25%	

CHAPTER XI – FUTURE OPTIONS IN THE CONTEXT OF CO-OPERATION BETWEEN MEMBER STATES

11.1 Actions to be taken

11.1.1 At present

12 sources of 13 interviewed said that the European health card should be the natural extension of national health system cards. Only one source said that the right approach is to settle interoperability requirements leaving each country free to make its personal choice: such requirements are already defined in the Netlink project.

Furthermore all the sources agree that data should be stored into the card rather than on a database server in order of two reasons: it's a more familiar format to physicians and patients and it's a more secure tool.

All these elements affect the problem of card interoperability. Most of the sources said it could be not hard or, at least, quite hard to stretch this point. Those who said it could be not hard answered that it would depend on political issues and wills, technical rules that are already defined by Netlink project and CEN TC 251. One French source remarked that the basic device is a software able to translate automatically into the languages of every national system. On the other hand, those who said it could be quite hard answered that the strongest obstacles are the harmonisation of legislation and EU commitments.

11.1.2 In the medium term

After these regards it's vital to understand what are the steps to be taken before introducing a European health card. Five sources said that it's necessary to harmonise the rules in a general sense. The other sources gave a more detailed answer because they think there are specific ways to follow such as legislation integration, data and technical standardisation, acknowledgement of smart card validity. One source insisted on the importance of obtaining financing to spur consortia making between private initiatives and public structures. Another source said that it would be very important to understand the consequences of the "Kohll&Decker" judgements. These cases regard compulsory repayments of medical expenses met in another Member State. It has the immediate consequence of increasing competition and economic impact on each Member State that could be forced to repay medical spending for healthcare services provided by another healthcare system and not issued before in emergency cases.

11.2 Orientations for further research

As a result of this survey it's possible to identify some topics to study thoroughly that can be considered good starting point for further studies.

Taking for granted that there are technical requirements already fixed by past experiences (e.g. Netlink and G8), legal rules that guarantee data security, the problem that needs to be resolved in a definitive way is the interoperability issue. In that respect, the Slovene health card is the essential experience to consider.

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