Healthcare Systems and European Harmonization

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Executive summary

European Member states are finding themselves under increased pressure to implement safe, successful and interoperable eHealthcare services, while for the time being, only limited resources are being allocated to European interoperability. Nevertheless, the European eHealth Action Plan published by the European Commission will help to ensure that eHealth does not stop at geographical borders.

However, unsolved interoperability problems of identification management impose an imminent threat to seamless pan-European healthcare delivery. Moreover, it is a distinct possibility that future cross-border eHealthcare scenarios will add further complexity to existing translation difficulties.

Therefore, there is an urgent need to create an independent and secure digital healthcare IT infrastructure, one which takes all requirements into account, and one which offers concrete mobility for European citizens. This document proposes a set of recommendations for such a European eHealth infrastructure and its associated interoperability.

Introduction

In September 2006, the European Commission decided to launch a public consultation on how to ensure legal certainty regarding cross-border health services under Community law, and to support cooperation between the healthcare systems of the Member States. The consultation is based on a communication to be drawn up by the European Health and Consumer Protection Directorate – General, setting out ideas for a European framework for safe, high-quality and efficient healthcare services. The first step is a consultation on issues such as:

- The kinds of cross-border healthcare that must be authorized and paid for, and the provision of information to patients about treatments available in other member states
- Deciding which healthcare authority is responsible for supervising cross-border healthcare in different circumstances
- Responsibility for any harm resulting from treatment and relevant compensation
- Patient rights
- Data privacy protection
- Supporting healthcare systems through European co-operation

To achieve these objectives of cross-border health services, health, social carers and other providers must no longer work in isolation, but need to collaborate as a team. It is vital that these parties can access and share securely up-to-date information on a citizen's health status – data which they can understand and act on.

Without an appropriate information and communication technologies-based infrastructure, this goal cannot be reached. Full interoperability is the key to success.

The member states themselves and the various Commission services, working through an informal inter-service mechanism, are developing this program of activities.

This white paper gives a brief overview of the eHealthcare domain and the advantages of using smart cards for interoperable systems, followed by some recommendations on how to reach this essential interoperability on a European level.

Healthcare as an eco-system

Healthcare and its associated social system is an eco-system in any national economy. Even if the objective is to secure the health of citizen in the most efficient manner, it is a key cost center for national competitiveness, involving budgets in the billions of euros. In a challenging worldwide eco-system, healthcare and social systems need to be better controlled with reduced costs. The basic need remains the same across all countries and there are four main drivers for introducing an electronic healthcare solution:

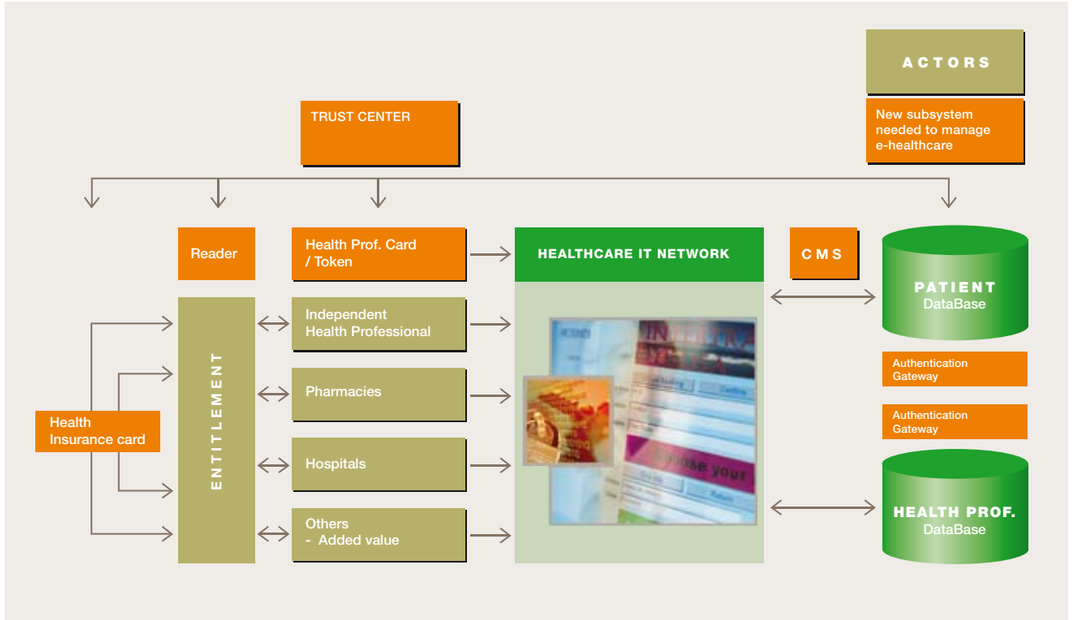
1. Cost reduction
2. Cutting application fraud
3. Improving management of eHealth services
4. Distribution of social funding

Overview of eHealth

An early foray into the world of electronic healthcare took place in the mid-90s, in France, Germany, Belgium and Slovenia. And a faster migration from a non-digital paper-based system to an eHealth approach is fast approaching. Many initiatives have been already started around the world, in countries like France, Germany, Slovenia, Poland, Finland and Belgium in Europe; Algeria and Morocco in Africa; China, Taiwan and the Philippines in Asia; and Mexico and Brazil in America.

A typical healthcare IT infrastructure could be represented as follows:

Figure 1: Typical healthcare IT infrastructure and actors.



Standardization process

The standardization process exists through the International Organization for Standardization (ISO) and the European Committee for Standardization (CEN) in order to federate common views and definitions regarding eHealth needs, like schemes, smart cards, healthcare electronic documents, and personal medical records. These processes would seem a little late compared to existing systems already deployed or under deployment.

Nevertheless, the voluntary use of open and formal standards by industrial actors could contribute tremendously to eHealth interoperability. Standardization is an integral part of the European Union's policies to increase business competitiveness and remove trade barriers. This was confirmed by the European Parliament in 1999 and by the Council both in its resolution of October 28, 1999 and its conclusions of March 1, 2002 on the role of standardization in Europe.

In the eHealth area, the 2005 report from the CEN/Information Society Standardization System eHealth Standardization Focus Group (March 14, 2005), emphasises that health information standards are essential to achieving the goals of eHealth in Europe. The report recommends the creation of an interoperability platform. Among other tasks, this platform would establish a Europe-wide view on the requirements for eHealth standardization and its implementation, in collaboration with standardization organizations, and this should be based on input from relevant stakeholders' communities.

That means that current efforts must be pursued in all domains connected with eHealthcare.

Smart Card use for eHealth

The healthcare market must respond to security, privacy, and cost efficiency requirements, and is motivated by very high budgets a vailable. Smart cards are the best proven technology to respond to such needs.

Unlike easily-forgeable paper documents, smart cards are in practice impossible to forge or unlawfully manipulate. They benefit from inherent high levels of security used in other applications, such as banking, telecoms and identity. The same security mechanisms as used in banking sector, like PIN codes and biometry, limit the unlawful use of lost or stolen cards to gain access to healthcare.

Dematerialization of the medical prescription from paper to an electronic format helps organisations reduce costs and increase efficiency.

Smart cards solutions enable the pre-authorization of health transactions by storing information regarding the validity of the patient's rights.

In addition to the chip and the security features of the operating system, the card body itself becomes a secure tool when the user's picture is added along with extra security features, such as guilloches, rainbows and hidden words, all of which have been previously developed for banknotes and ID applications and can be easily re-employed in eHealthcare systems.

Finally, the smart card enables the ultimate privacy protection by filtering access to sensitive data – only authorized people can read it, such as the smart card holder and their authorized doctor.

As such, a complete digital security approach based on a wide range of flexible, personalized smart cards solutions could be delivered for eHealthcare. A variety of solutions for patients and professionals are available, including:

- eHealthcare insurance smart cards and/or European Healthcare Insurance Cards, for patients
- Secure web access to medical services for patients
- eHealth professional smart cards for health workers
- Secure access control, both physical to buildings and offices, and logical to computers for professionals
- Authentication solutions for connection to medical applications
- Set readers adapted to every need, such as PC-connected readers, standalone units or tokens

The following eHealth solutions are also available for issuance organizations like governments and health insurance companies:

- Enrolment of patient data
- Personalization of cards including data preparation
- Packaging and direct mailing according to specific customer requirements
- Healthcare portal authentication gateways

Smart card technology is the trusted personal eID device for all European citizens. It is independent of the infrastructure and already shows a high level of adoption in other domains such as mobile telephony, pay-TV and banking applications. A trusted personal device in a smart card presents undeniable advantages in terms of interoperability, acceptability, mobility and security. It can be the legal, most cost-efficient and most secure proof of a citizens' digital identity while protecting their privacy. It is clearly the best combination of an ID document, a personal portable tool and a secure access to eHealthcare services in one.

EU interoperability

Nevertheless, each healthcare system is unique and has its own local specificities. IT could be managed at a national level as it is in France, or managed locally as in Germany where each “länder” manages its own regional healthcare system. Due to existing schemes and current deployments, we need to ensure interoperability at the infrastructure level. This interoperability is motivated by different factors:

- Each European citizen has the right to be covered by their own national or regional health insurance system within the European landscape
- The ease of mobility for European citizens
- On-line verification and authentication in order to guarantee the inter-clearing compensation between European healthcare systems

The requested interoperability could be reached via a range of different approaches. These include:

- Creating a complete brand new system
- Interconnecting existing systems
- Interconnecting existing systems and standardizing a full system for future eHealthcare IT deployments within the EU

The first approach is very exciting in term of conception and in terms of homogeneity between systems. In theory, it would probably be easy to define because the objectives for using an eHealthcare approach are motivated by the same arguments. But it would almost certainly be very difficult to find a consensus between all European countries due to the specificity of each one in term of culture, techniques and ethics. And as some national systems are already deployed, it seems unfeasible to create a complete brand new system.

The interconnection of existing systems proposed in the second approach offers more simplicity due to the limited number of existing systems in Europe. It should be easily accepted by countries having their own deployed system. But how to integrate newcomers? How to enlarge the number of national eHealthcare systems? And how to maintain the common interconnection? There are several options. For example, one of the existing deployed systems could be selected for newcomers, or the overall interconnection could be reworked in order to enter the specificities of the newcomers. The maintenance complexity with additional new systems would clearly stand in the way of such an approach which in reality, could not be really implemented.

The last approach combines the two previous solutions. It offers an opportunity to interconnect existing systems and to standardize a solution for future implementations. It is clearly open to new systems based on a unique approach. Such a common approach should easier to define due to the limited numbers of countries involved. As such, it would be supported by a large number of eHealthcare players.

Our recommendation is for the last solution involving the interconnection of existing systems and the standardization of a full system for future eHealthcare IT deployments within the EU. This standardized approach should be based on the NET@CARDS (http://www.netcards-project.com) project for European infrastructure, and on the CEN standards for smart cards (CEN TC224) and for healthcare electronic documents definition (CEN TC251).

Table: Pro & Cons of different approaches for full interoperability between national eHealthcare systems.

	Create a complete brand new system	Interconnect the existing systems	Interconnect the existing systems and prepare the spec for future Healthcare IT
PROS	• Easy to define (in theory!)	• Accepted by THE existing systems • Easy to define? • Fast thanks to the limited number of existing systems	• Accepted by the existing systems • Open to further new systems • Easy to define? • Interoperability guaranteed • Support from a large number of e-healthcare players • Techno open
CONS	• Not deployable • Hard to find a consensus • Costly • Unrealistic • Too late	• How and who to manage new comers for the future? • Maintenance complexity with additional new systems	• Maintenance?

> European Citizen Card Platform (E.C.C.)

The proposal for a standard by CEN/TC224/WG15 is a key opportunity for European governments. It is the only way to guarantee a high level of trust and confidence within authorities and partners by providing a reference backed up by smart card leaders. Target applications that meet with EC (European Commission) standards mainly involve e-Government and will depend on the European and national regulations

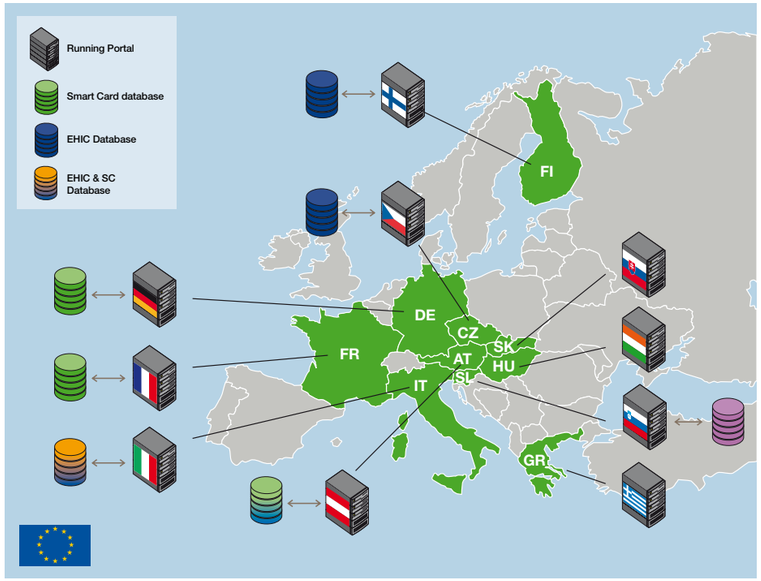
This new technical standard:

- Ensures all citizens that their privacy will be correctly preserved
- Ensures a truly interoperable and highly secure eID smart card platform for internal country usage (homeland) and cross-border usage (i.e. within the EU)
- Ensures common, transparent and state-of-the-art specifications and a consistent program for updates and maintenance of such specifications

- Presents an clear, cost-effective advantage that will be very easy to maintain because the smart card is a proven industry backed by major actors
- Allows European countries to take worldwide leadership with a competitive and exportable technology. Member states will be able to accelerate the deployment of their programmes and to reach significant economies of scale for administrations budgets
- Can harmonize the technology and its application in the European arena. The adoption of this standard by bigger countries as their platform solution will encourage governments of smaller countries to adopt this technology also.

This ECC standard proposal is a central element for an interoperable eID management system as requested by the eHealthcare IT system. It is a key enabler for the achievement of the i2010 objectives proposed by the European Commission. It gives power to local governments while promoting European industry and means holding on to or creating new jobs.

Figure 2: NETC@RDS on-line infrastructure



> NETC@RDS

The NETC@RDS Project aims to improve access for mobile European citizens to different national healthcare systems using advanced smart card technology. It also aims to implement and evaluate technical solutions for the European Health Insurance Card electronification and for improving additional services such as the inter-European health costs clearing/billing processing. The consortium includes partners from Austria, the Czech Republic, Finland, France, Germany, Greece, Hungary, Italy, Lichtenstein, Norway, Netherlands, Romania, Slovakia, Slovenia, Poland and sub-contractors and/or supporters in many of the participating countries.

A large number of NETC@RDS pilot implementations have been set up in 15 E.U member-states participating in the NETC@RDS project. The systems are used for visiting European citizens in case of emergency during their stay in these countries, with satisfying results regarding acceptance, ease of use and usefulness of the NETC@RDS service.

Conclusions

Interoperability is a key element in European eHealthcare because mobility within the EU is a reality for European citizens. But member states have realized that implementing eHealth interoperability is a long-term process requiring sustained commitment with respect to political involvement and resources. Achieving interoperability is seen as a goal that can be achieved only gradually – application by application.

The success of interoperability is crucial for Europe. Member states must satisfy their citizens' requirements in terms of user-friendliness, quality of services including mobility, and cost reduction based on increased efficiency and fraud reduction.

Because the task is not an easy one, the Commission recommends the necessary steps to reach these goals for the benefit of Europe, its citizens and societies, thereby supporting the long-term objectives of the Lisbon Strategy. These cover the domains of political, social, and regulatory issues. They also cover appropriate processes and structures to achieve eHealth interoperability, technical standardizations, semantic interoperability, and certification and authentication processes. This must be done in accordance with existing eHealthcare schemes already deployed.

We therefore clearly recommend to interconnect existing systems, and to standardize a full common system for future EU eHealthcare IT deployments. Some opportunities already exist regarding standardization and harmonization. Thus, we propose to build the future European approach on these opportunities:

- The European Citizen Card standard with a specific profile for eHealthcare is the right support for eHealthcare smart cards and confirms that the smart card is the most appropriate tool for security and privacy requirements in relation to eID, and in particular for healthcare.
- This opportunity could be completed with the NET@CARDS approach which is a good option regarding the technical infrastructure itself.

The emerging pan-European eHealthcare IT infrastructure is an opportunity to improve European citizens' lifestyles. But the European eHealthcare approach must be developed and deployed in harmony with Europe.

This solution offers a real business case which would clearly promote European jobs. And its success in Europe could be widely repeated outside Europe as was the case with GSM in the 1990s.

About Gemalto

Gemalto is a leader in digital security with pro forma 2006 annual revenues of €1.7 billion, operations in about 100 countries and over 10,000 employees including 1,500 R&D engineers.
Gemalto was formed in June 2006 by the combination of Axalto and Gemplus.
In Heallthcare, Gemalto is the trusted partner in several countries around the world and contributes to more efficient national healthcare systems for the benefit of patients, health insurances and health professionals.
Gemalto's eHealthcare IT solutions mean better control and services. Providing the complete eHealthcare IT solution or part of it, Gemalto is the digital security expert for protecting personal health data while securely connecting all actors.
Gemalto offers a complete set of flexible, personalized solutions to meet all requirements and suit your needs:

- Complete eHealthcare IT system
- Personalized health insurance card
- Health professional cards & tokens
- Health readers
- Authentication gateway
- Card Management System
- Trust center technology

With references in Algeria, Belgium, Germany, China, Finland, France, Mexico, Puerto Rico, Slovenia and on the European Health card, Gemalto is a strong and reliable partner.

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