



European countries on their journey towards national eHealth infrastructures

**eHealth Strategies Report
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Final European progress report

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About eHealth Strategies and this report

The eHealth Strategies study analyses policy development, planning, implementation measures and progress achieved with respect to national and regional eHealth solutions in EU and EEA Member States, with emphasis on barriers and enablers beyond technology. The focus is on infrastructure elements and selected solutions emphasised in the European eHealth Action Plan of 2004.

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Results from this report should only be used as guidelines or generic strategy advice. For detailed advice on policy drafting, strategy development or implementation support, the services of a professional should be obtained.

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This report is available for download at: www.ehealth-strategies.eu/report/report.html.
Individual reports on eHealth developments in all countries covered can be found at www.ehealth-strategies.eu/database/database.html

Foreword



Europe, its Member States, stakeholder groups and citizens are all actively engaged in realising the European eHealth vision. The *eHealth Action Plan*, which was endorsed by the *European Council* in 2004, was the first formal commitment expressed by all Member States to cooperate more closely in the area of eHealth.

A lot has happened since then:

- Every year health ministries and high level national officials have met during an eHealth Ministerial Conference and agreed on a set of measures and actions to bring eHealth implementation forward in line with Action Plan objectives.
- The *epSOS* (Smart Open Services for European Patients) large scale pilot project has assembled by now 23 Member States and other European countries to bring forward cross-border eHealth interoperability for the benefit of every citizen by exploring patient summary and ePrescription services at the pan-European level. The vendor community is also actively involved.
- *RenewingHealth*, another large scale pilot the EC is co-funding, is pooling together the expertise of European experts and the know-how of local and regional healthcare providers who deliver telehealth services. This project is one of the largest multi-centric clinical trial-type exercise across Europe in the field of telemonitoring and telecare services; it will fundamentally enhance the body of evidence on the effectiveness of such services. It involves nine countries, and is expected to cover eventually about 8,000 patients.

These types of projects are a concrete sign that Europe is experiencing a strong political momentum to advance eHealth solutions for the benefit of both its citizens and health systems. Political support for such initiatives has been well formulated by the European Council of Ministers responsible for eHealth, which adopted in December of 2009 a set of Conclusions underlining the key role of eHealth for better, safer and more efficient healthcare systems.¹ The Ministers also endorsed the *European eHealth Governance Initiative*, a new mechanisms to facilitate cooperation between Member States, the European Commission and key stakeholder groups, and to work more closely together in bringing eHealth forward.

All this indicates that Europe is enjoying a very favourable political context for health system related information and communications technologies (ICT). But supportive politics is not enough as Europe is emerging from a very challenging socio-economic crisis. However, history has taught that challenging situations trigger major innovations. The European Commission, in its recent *Europe 2020 Strategy*, has identified Smart Growth as a key target domain. Here *European Innovation Partnerships*,² like in the field of 'active and healthy ageing', have been identified for upcoming *Flagship Initiatives*. In other words, the

¹ Council of the European Union (2009). Council Conclusions on Safe and efficient healthcare through eHealth. 2980th EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS Council meeting. Brussels, 1 December 2009.

² European Commission (2010). Europe 2020 Flagship Initiative - Innovation Union, Brussels, 06.10.2010, COM(2010) 546 final, pp. 40 – 42.

European Union is counting on innovations to help overcome the current economic challenges. The Commission believes that eHealth is well placed to deliver innovative solutions.

The recommendations for further actions submitted in this study are based on a thorough analysis of eHealth strategies and implementation activities in European countries as well as the results of a validation workshop in the fall of 2010 in Brussels, which was attended by: representatives of Member States and other European countries, national health authorities and competence centres, stakeholder associations, vendors, and European health policy and eHealth experts. Now the challenge is to cooperatively address the issues identified.

Brussels, January 2011

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Executive Summary

Introduction

Europe's countries have made substantial progress towards modern eHealth infrastructures and implementations, thereby leading the rest of the world. Following the Communication of the European Commission (EC) on "eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area" (eH-AP),³ Member States of the European Union (EU) committed themselves "to develop a national or regional roadmap for e-Health." Various non-Union European countries also followed this vision.

Key activities and progress

Overview: As surveyed by the *eHealth ERA*⁴ project, by the end of 2006 most European Union Member States had published only high level official policy documents on their eHealth implementation strategy. Today, almost all have detailed documents outlining concrete eHealth goals, implementation measures, and sometimes also already past achievements. In line with eH-AP objectives, "health authorities leadership" is visible across the EU. Table 1 identifies key fields of national level activities and the sometimes considerable increase recorded between 2006 and today:⁵

Table 1: Key fields of national level eHealth activities in the EU27 countries, 2006 and 2010

Reported eHealth activities	Total 2006 eHealth ERA	Total 2010 eHealth Strategies	Delta
Legal activities	14	22	8
Evaluation	5	21	16
EHR Patient Summary	27	27	0
ePrescription	16	22	6
Telehealth	23	27	4
Patient ID	24	26	2
Professional ID	13	22	9
Citizen card	22	25	3
Professional card	7	18	9
Standards (technical/semantic)	19	27	8

Source: eHealth Strategies study, 2010

Patient summary or electronic health record (EHR)-like systems were a priority already in 2006 for all Member States. On the other hand, in 2006 only five reported assessment

³ European Commission (2004). eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area. Brussels: COM(2004)356 final.

⁴ Available at: <http://www.ehealth-era.org/>

⁵ Only the 27 Member States of the European Union are compared here, because the 2007 data refer only to these countries, not to the additional 4 countries (Iceland, Norway, Switzerland and Turkey) covered by the present study. The data of England, Northern Ireland, Scotland and Wales were aggregated into the United Kingdom.

and evaluation activities, which by 2010 grew to 21 - the largest increase (+ 16) in attention of all topics surveyed. Further solutions high on the agenda are the electronic transfer of prescriptions – an increase by six from 16 to 22, and the provision of telehealth services (e.g. for chronically ill patients living at home), by now also a key topic in all EU Member States - an increase by four since 2006.

National competence centres: Another indication of the strong political commitment at the national policy level is the growing establishment of permanent administrative support structures. National competence centres such as gematik (Society for Telematics Applications of the Health Card) in Germany, ASIP - Agence des Systèmes d' Information de Santé Partagés in France, or THL National Institute for Health and Welfare in Finland are increasingly being created or expanded to also cover eHealth infrastructure requirements.

EHR-like systems: The eHealth Action Plan set the objective to “focus on deploying eHealth systems, setting targets for interoperability and the use of electronic health records.” Such systems are a prominent element in virtually all national strategies and roadmaps. But usually they are not well defined, often (implicitly) referring only to a patient summary or basic electronic patient record. EHR-like systems have been implemented or are under development in many healthcare provider organisations, and also in various regional healthcare systems. They cover patient data from within own organisational or regional boundaries. However, in larger European countries there exist hardly any at the national level. Recently, the urgent clinical need for large-scale *national* sharing of complex patient data is sometimes questioned.⁶

The European epSOS (Smart Open Services for European Patients) project undertaken by 23 countries pursues a more limited approach.⁷ It pilots interoperable cross-border services for the exchange of basic patient summary data and electronic prescriptions only - not a complete EHR. Eventually, it is expected to provide the treating professional in her/his own language with basic information on a foreign patient. With this activity, Member States implement the eH-AP target to “identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts” as well as the objectives to achieve “a seamless exchange of health information across Europe” and thereby to support “patient mobility.”

At the national level, progress can also be registered, but the majority (20 of 34) of European countries surveyed are still at the planning stage. This is not a surprising result because their full implementation presupposes the availability of various infrastructure components. The current implementation stage is summarised in Table 2.

Table 2: Deployment stage of patient summary and EHR-like projects in European countries, 2010

Planning	Implementation	Pilots	Routine	Sum
20	5	2	7	34

Source: eHealth Strategies study, 2010

⁶ Robertson, Ann et al. (2010). Implementation and adoption of nationwide electronic health records in secondary care in England: qualitative analysis of interim results from a prospective national evaluation. *BMJ* 341:c4564 doi:10.1136/bmj.c4564.

⁷ epSOS Smart Open Services for European Patients – Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription. Details available at www.epsos.eu/about-epsos.html

ePrescribing: This is another key application which 22 (+ 6 since 2006) Member States mention as a part of their national eHealth strategy, fully in line with the eH-AP objective that “European health organisations and health regions (communities, counties, districts) should be able to provide online services such as ... e-prescription.” ePrescribing means the electronic capture and then transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the medicine by the patient, and the recording of dispensation in the patient’s record. However, up till now, only a few countries have indeed implemented a fully operational national system (see Table 3), and these are mainly in primary care, i.e. exclude medications dispensed in hospitals.

Table 3: State of ePrescribing in European countries, 2010

	eCapture	eTransfer	eDispensation
Currently available	15	9	7
Planned for near future	5	8	6
Unavailable	12	15	19

Source: eHealth Strategies study, 2010

Up till now, patients rarely have access to their own medication profiles or are able to re-order certain repeat medications themselves, e.g. via the web. This is expected to increase considerably in the future in those countries where it would be within the constraints of regulatory boundaries.

Stakeholder engagement: In line with the requirement of a “common understanding and concerted efforts by all stakeholders” (eH-AP), many countries have by now established advisory bodies involving e.g. professional associations, patient representatives, third party payers or care providers as part of their eHealth governance structures.

Telehealth: “Telemedicine services such as ... telecare (the home monitoring of patients)” were mentioned in the eH-AP as an example for “health information networks link[ing] hospitals, laboratories, pharmacies, primary care and social centres.” All countries surveyed report at least small local telehealth or telemedicine experiments, or plan to undertake such pilots – a small increase by four since 2006. Perhaps the largest, still experimental implementation is reported for England. Its “Whole System Demonstrator (WSD) programme is a two year research project funded by the Department of Health to find out how technology can help people manage their own health while maintaining their independence. The WSD programme is believed to be the largest randomised control trial of telecare and telehealth in the world to date.”⁸ It covers various aspects of support for independent living at home as well as health and social care. However, the wider use of such services at the national level is still the exception.

Electronic identifiers: The Action Plan noted that “the need to identify a person unambiguously is an important component” of any national or regional eHealth infrastructure. This applies not only to citizens/patients and healthcare professionals, but also to healthcare providers and pharmacies. It is a central requirement to assure patient safety. Whereas patient identifiers (ID) were an element of eHealth strategies in most countries (24) in 2006 already and increased to 26 by now, the challenge of professional IDs was somewhat neglected till recently (mentioned by 13 countries only in 2006), but is now an acknowledged topic in 22 countries.

⁸ See: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_100947.pdf

However, virtually all citizen cards issued so far by European countries to be used in an eHealth context are only electronic health *insurance* cards, not eHealth cards in the proper sense of carrying medical information. They are often based on or equivalent to multipurpose eCards for eGovernment services, including healthcare. The interest to use eCards as a token for professional ID and as access means to eHealth systems has increased considerably in recent times, from only 7 countries reporting such activities in 2006 to 18 in 2010. In nine European countries, smartcard systems for healthcare professional identification are already in place. An essential prerequisite for a functioning healthcare professional identifier is an operational system of healthcare professional registration, which is not always located at the national, but also at the regional level.

Standardisation: The Action Plan noted that “the need for future standards is clearly emphasised so as to solve interoperability concerns in a way which will benefit all stakeholders.” As part of their efforts to provide EHR-like and ePrescription services, a considerable increase in standards-related activities from 19 in 2006 to 27, i.e. for all Union countries, can be reported. It is witness to the increased awareness of the pivotal role of standardisation.

Legal and regulatory issues: “Legal and regulatory issues” (eH-AP) are among the most challenging aspects of eHealth. Privacy, confidentiality, data protection, and liability challenges all need to be addressed in order to enable a sustainable implementation and use of eHealth applications. Rarely does a country report on a coherent set of laws specifically designed to address these diverse aspects. Rather, in most countries the use of eHealth is currently regulated only by the general legal framework, in particular by laws on patient rights and data protection, and by regulations on professional conduct. New legislation is often still in the process of being drafted. Here also a considerable increase (+ 8) in attention to this topic can be noted, from 14 countries mentioning such issues in their national documents in 2006 to 22 in 2010.

Financial resources and reimbursement: When looking at financing sources for the development and investment in eHealth infrastructures and applications, a mixed picture emerges. Across Europe, the primary sources of funding are government or quasi-public sources, e.g. the general budget for health, as well as dedicated ICT budgets or special levies on statutory health insurances. Considering that individual service providers usually do not have an incentive to establish eHealth infrastructures for all, this result is not surprising. To compensate for market failure and allow a network effect to kick in, adopting a ‘public good’ perspective of eHealth infrastructure seems warranted.

Recurring public budgets dedicated specifically to “the reimbursement of eHealth services” (eH-AP) are still the exception, whereas there is widespread use of projects-based sourcing. Sometimes private and public insurance companies or public technology or innovation agencies are involved in temporary financing. Among the international sources of funding mentioned, EC RTD project co-financing as well as funding from European Structural and Regional Funds and the European Investment Bank were mentioned.

Socio-economic impact assessment and evaluation: “eHealth should be supported by the widespread dissemination of best practices. These should include the impact on access to healthcare and on its quality, assessments of cost benefits and productivity gains.” (eH-AP) Not surprisingly, countries with more advanced eHealth infrastructures and services have a higher propensity to carry out assessments of the benefits of their eHealth investments and the challenges encountered. Around one-half of the 34 countries surveyed (including the four home countries of the UK) mention a specific body of one form or another as being responsible for evaluation activities. In Switzerland, the federal government commissioned a Regulatory Impact Assessment (RIA) of pending eHealth legislation. The United Kingdom has undertaken regular evaluations of the National Programme for Information Technology (NPfIT) of the National Health Service in England by a wide variety of actors. Germany regulated the testing, piloting and assessment of acceptance of core elements of its eHealth strategy.

Synthesising European experience

The impetus of the eHealth Action Plan of 2004 and the clear identification of common challenges there has initiated and massively contributed to a heightened degree of activities in Member States. Across Europe eHealth has matured from a policy debate to a very tangible, implementation oriented endeavour. From this experience, seven key success factors can be identified.

Leadership: Politicians must assure a comprehensive health policy dialogue leading to clearly defined goals specifying where eHealth solutions can substantially contribute. Reaching agreement about eHealth strategies and, even much more so, implementing them has almost everywhere proven to be considerably more complex and time-consuming than initially anticipated. The complexity of eHealth as a management challenge was vastly underestimated.

Focus on health professional and stakeholder engagement and needs: As part of their eHealth governance structures, many countries have established advisory bodies involving e.g. professional associations, patient representatives, third party payers, and care providers. Careful planning, organisational setup, and stakeholder involvement are key success factors for eHealth (infrastructure) projects. Such bodies in part resolve the challenge of potentially ambiguous or distributed responsibilities for eHealth. Although they are not a sufficient condition for success, it seems they are a necessary ingredient.

Establishment of trust: Closely related and complementary is the need to assure strong trust by all into eHealth infrastructures and applications. This requires legal and regulatory certainty, challenges which are among the most demanding aspects of eHealth. Privacy, confidentiality, data protection and liability issues are involved.

Regional rather than national focus: It seems that the complexity of national EHR systems cannot be centrally managed in larger countries. European experience so far suggests that countries with more than around 10m inhabitants tend to fail to implement nation-wide applications. In decentralised healthcare systems a focus on interoperability and connectivity of regional systems seems to be more successful. It is also increasingly evident that clinicians' enthusiasm for comprehensive electronic health records does focus on connecting diverse systems at the local level rather than nation-wide connectivity as they perceive benefits in their immediate surroundings.

Reliable infrastructure: Infrastructure elements concern items like governance rules and processes, competence centres, unique electronic identifiers for patients, health professionals and service provider entities, security and data privacy, regulation of technical and semantic standards, and payment/reimbursement issues. They allow for a network effect to kick in, also known as user externality. Unless a single (public) regional or national health institution exists, service providers usually do not have an incentive to establish such an infrastructure, i.e. we have a market failure situation which should be solved by government intervention.

Training: Qualified human resources are another key ingredient for success. Education, training and continuous professional development for all, including for those citizens and patients which are capable and motivated to become engaged in their own care, must be strongly promoted. "The most important part of eHealth investment that needs expanding is the eHealth skills and knowledge of healthcare staff and ICT suppliers' staff. An expanded capability is essential to achieve more success and so help to boost eHealth investment."⁹

⁹ Dobrev, Alexander, Jones, Tom, Stroetmann, Veli N. et al. (2008) Sources of financing and policy recommendations to Member States and the European Commission on boosting eHealth investment. Final report of the Financing eHealth study. Bonn/Brussels, empirica Dec. 2008. http://www.financing-ehealth.eu/downloads/documents/FeH_D5_3_final_study_report.pdf

Impact assessment and evaluation: European experience shows that the chance of success will be greater the more precise the foreseen implementation measures and applications indeed meet a concrete health policy objective and benefit the needs of key actors. Socio-economic and financial assessments allow to select optimal policy measures, help to develop rational business cases, guide implementation processes, and allow to continuously monitor and validate outcomes.

Recommendations

The results of the eHealth Strategies Study were discussed and validated at a workshop in the fall of 2010 in Brussels. Participants underlined that, to become even more successful, it will be mandatory to better mainstream and align eHealth implementations with strategic health policy goals. eHealth should not be the objective of a standalone strategy, but become fully integrated into overall health policies.

The ten recommendations to follow are mainly addressed to the European Commission, the Member States, or both. However, depending on the domain of concern, also stakeholders, experts, and researchers need to become involved.

1. Cross sector cooperation, integrated care

In the context of health system development, Member States should improve ICT-facilitated cooperation *beyond core healthcare service providers* towards an *integrated well-being and care* approach which includes social care providers, ambient assisted living (AAL) initiatives, prevention, and wellbeing services. At the same time, together creating *trust* across different regions, languages, authorities, as well as regulatory and professional cultures is a key requirement for enhanced European success.

2. Learning together, trans-European exchange of experience

In spite of the structural differences across regional and national health service systems, *diffusion* of eHealth solutions should be accelerated through *further improved cooperation* between the EC and Member States, among Member States and between their national competent centres. An exchange of experience gained, also from failures, and lessons learned may prove particularly beneficial.

3. eHealth governance

The EC-facilitated *eHealth Governance Initiative* of Member States is considered a good opportunity to associate eHealth strategies with the mainstream of health policy objectives. Relevant health system priorities include the safety and quality of healthcare/social care; provision of appropriate information to patients; patient empowerment; patient choice; and cross-border relations that support continuity of care.

The *Governance Initiative* also provides a powerful chance for Member States to collaboratively design the future European eHealth strategy and infrastructure. Countries are experiencing similar challenges and the same pressure on health system and societal resources; they should cooperatively build on exemplary, successful eHealth practice.

4. Industrial and stakeholder involvement

Representatives of the eHealth industry and other stakeholder groups would be keen to see an approach which assures for co-shaping in developing and implementing eHealth strategies. A governance process should be initiated where, e.g., companies and patients are encouraged to examine the availability and analysis of personal data for the common good and not purely out of self-interest.

5. Invest in training and education

There is a strong felt need to improve eHealth training and education for professionals, but also to focus on reducing the asymmetry in capabilities, information and knowledge between health professionals and patients, and thereby strengthen stakeholder engagement.

6. Standardisation

The strong felt requirement for further standardisation and, in particular, specification and certification efforts is evident. Such common initiatives should focus on well defined and bounded data models and applications, like in epSOS, and they need to closely engage health professionals to assure that their needs are met.

7. Evaluation and impact assessment

The issues involved in monitoring/benchmarking and socio-economic impact assessment are another increasingly important topic. While the EC-initiated 2004 eHealth Action Plan insisted on the importance of monitoring progress, this is also a crucial time to look ahead over a 5-10 year time-horizon and to explore approaches helping to prioritise actions to be considered in forthcoming national or European action plans.

8. Re-use of individual patient health data

A largely neglected domain in national eHealth roadmaps is the re-use of patient data in anonymised form. To reap further benefits from eHealth solutions for public health, clinical research, and patient safety, this topic needs heightened attention.

9. Financing challenges

There is no agreement on how relevant financial challenges indeed are. Perhaps financing issues are less important than sometimes considered; on the other hand, a number of newcomer countries to eHealth do see the dominant challenge as a financial one - issues to be followed up upon. Another relevant issue concerns the procuring of eHealth services and solutions in a timely and effective manner via more homogenous and efficient procedures.

10. Improve support for citizens and patients

Finally, with the support of the EC and Member States, health system actors should explore together how to deliver innovative eHealth solutions to better respond to the changing and diverse needs of Europe's citizens and patients, depending on their individual health and social situation, capabilities, and motivation to become actively involved in their own treatment. The *Digital Agenda*, a European Flagship Initiative in the context of the Europe 2020 Strategy may provide the appropriate base for such activities.

Approach and data gathering

The methodological approach applied to structure this research conceptualises the health system as a *value system* of a wide variety of co-operating health services. To provide comprehensive, seamless care ranging from prevention, diagnosis, and treatment to long-term care, they must co-operate as a health service delivery system consisting of interrelated value chains of individual health service providers. To realise high quality, safe and efficient healthcare, appropriate supporting eHealth infrastructure elements as discussed here will be indispensable.

The study covers the 27 Member States of the European Union, including the United Kingdom with its four home countries England, Northern Ireland, Scotland, and Wales and their respective national health services (NHS), plus Iceland, Norway, Switzerland and Turkey.

In order to create a baseline for the assessment of progress, data from 2006 *eHealth ERA* project reports were revisited. Next, study team experts and national correspondents filled in templates on post-2006 developments in the respective countries, and drafted individual country reports from this material. Finally, all of this information was integrated and synthesised. All results were checked, revised where necessary, and validated. In addition to internal quality review procedures, all country reports were reviewed by national ministerial representatives and/or national experts.

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1 Charting the status quo and progress of national eHealth strategies and roadmaps across Europe

As introduction to the empirical results to be reported, this chapter briefly reviews the European Union eHealth policy background on monitoring and charting eHealth policies and implementation strategies across Member States, outlines the study methodology and provides an overview of what follows.

1.1 The European Union eHealth policy background

Following the *Communication* of the European Commission (EC) on “eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area”¹⁰ Member States of the European Union (EU) have committed themselves to develop and issue national eHealth strategies and implementation roadmaps – plans for the deployment of eHealth applications addressing policy actions identified in this eHealth Action Plan. Various non-Union European countries also followed this vision.

The *2004 eHealth Action Plan* directed the Commission to also *regularly monitor* the state of the art in deployment of eHealth, the progress made in agreeing on and updating national eHealth roadmaps, and to facilitate the exchange of good practices. Furthermore, in December 2006 the EU Competitiveness Council agreed to launch the *Lead Market Initiative*¹¹ as a new policy approach aimed at creating markets with high economic and social value, in which European companies could develop a globally leading role. Following this impetus, the European roadmap for implementation of the “eHealth Task Force Lead Market Initiative” identified better coordination and exchange of good practices in eHealth as a way to reduce market fragmentation and lack of interoperability.¹²

On the more specific aspects of electronic health record (EHR) systems, the recent *EC Recommendation on cross-border interoperability of electronic health record systems*¹³ notes under “Monitoring and Evaluation”, that “*in order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should: consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems.*” This *eHealth Strategies* study is a contribution to monitoring the progress made in establishing national/regional EHR systems in Member States and other European countries. It also provides analytical information and support to current efforts by the European Large Scale Pilot (LSP) on cross-border Patient Summary and ePrescription services, the epSOS - Smart Open Services for European pa-

¹⁰ European Commission (2004). eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area. Brussels: COM(2004)356 final.

¹¹ European Commission Communication (2007). Lead Market Initiative for Europe. Brussels: COM(2007)860 final, 21.12.2007.

¹² eHealth Task Force Report (2007). Accelerating the Development of the eHealth market in Europe, Brussels: European Communities. Available at: http://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm

¹³ European Commission (2008). Commission Recommendation on cross-border interoperability of electronic health record systems COM(2008)3282 final, 02.07.2008.

tients - project.¹⁴ With the involvement of almost all Member States and three non-Union countries, its goal is to define and implement a European-wide standard for such applications at the interface between national health systems.

Earlier, in line with the requirement to regularly monitor the state of the art in deployment of eHealth, the EC funded a first project to map national eHealth strategies – the *eHealth ERA Coordination Action "Towards the establishment of a European eHealth Research Area"*¹⁵ – as well as a project on "Good eHealth: Study on the exchange of good practices in eHealth"¹⁶. Both of these studies provided valuable input to the present *eHealth Strategies* work and its reports. Member States' representatives and eHealth stakeholders, e.g. in the context of the *i2010 Subgroup on eHealth* and the annual European High Level eHealth Conferences, have underlined the importance of this work and the need to regularly update it.

This report summarises the main findings and provides an assessment of progress made towards realising key objectives of the eHealth Action Plan across Europe. It presents good practice examples and lessons learned from national eHealth programmes and related planning and implementation efforts. Finally, it identifies key challenges for accelerating the wider diffusion of regional and national eHealth systems and solutions and provides recommendations on where cooperation among countries, their competent centres and various stakeholders may be most beneficial.

1.2 Study methodology

1.2.1 The health value system as interrelated value chains of health service providers

The methodological approach conceptualises the health(care) system as a *value system* of a wide variety of cooperating health service providers, each of which has to manage its own health value chain.¹⁷ At the core lies the generic health service delivery system as depicted in Figure 1, which consists of interrelated value chains of individual health service providers. Together they 'produce' and sustain health by promoting good health and well-being, supporting disease prevention, undertaking diagnostic and therapeutic interventions, providing healthcare, rehabilitation and long-term care services. To enable health delivery, supporting processes as well as facilitating tools and services are necessary, connected to and interconnecting the core processes. Only as a complex, dynamic ecosystem of interrelated processes all of these effectively lead to health for all citizens.

For purposes of this study, the supporting information and communications technologies (ICT) infrastructure, tools and services are of key relevance. Other supporting services such as training and education, scientific and clinical research, public health etc. also are

¹⁴ epSOS Smart Open Services for European Patients – Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription. Details available at: www.epsos.eu/about-epsos.html

¹⁵ Report available at: www.ehealth-era.org (2007). For country reports, references and national documents, see: <http://www.ehealth-era.org/database/database.html>

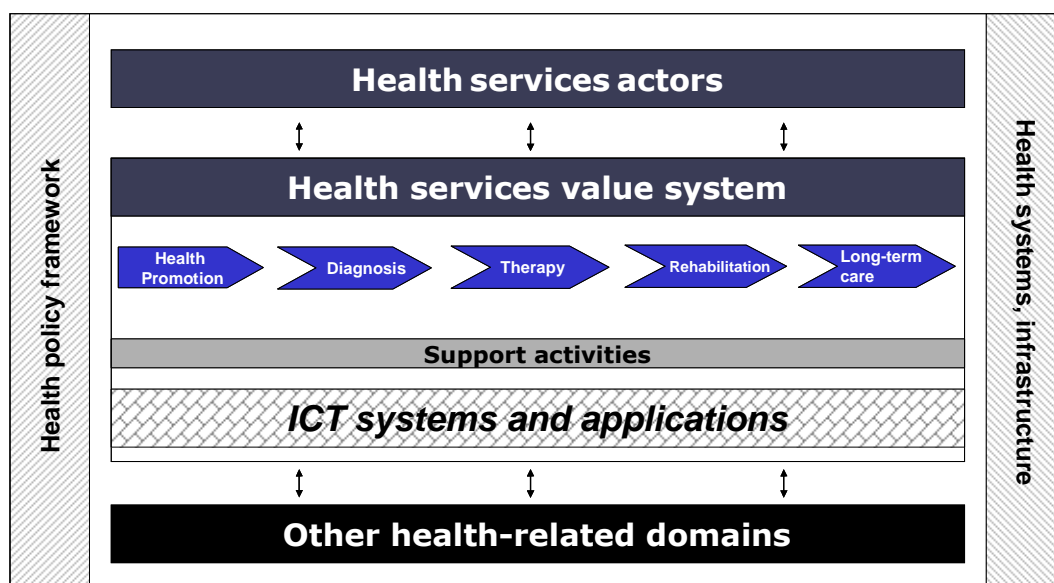
¹⁶ Results available at: www.good-ehealth.org (2009).

¹⁷ On the concept of *value system* cf. Porter, Michael (1985). *Competitive Advantage*. New York: The Free Press, p. 34: "Gaining and sustaining competitive advantage depends on understanding not only a firm's value chain but how the firm fits in the overall value system. ... Competitive advantage is increasingly a function of how well a company [here: a healthcare provider] can manage this entire system. Linkages not only connect activities inside a company but also create interdependencies between a firm and its suppliers and channels."

in need of ICT systems and solutions. Furthermore, all of these are embedded in the respective national and/or regional health policy context and their regulatory and financial frameworks. Figure 1 below illustrates this overall framework.

Based on this conceptual work, for the purposes of this study **eHealth** was defined as the application of ICT-facilitated systems, services and solutions which benefit health, be it at the level of the individual person, public health or society.

Figure 1: Conceptual model of the overall eHealth ecosystem



Source: © empirica 2006

1.2.2 Countries covered by this study

Besides the 27 Member States of the European Union

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland

- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom with its four home countries *England, Northern Ireland, Scotland and Wales*,

the following European countries are also covered by this study:

- Iceland
- Norway
- Switzerland¹⁸
- Turkey¹⁹

Individual reports on eHealth developments in all of these countries can be found at <http://www.ehealth-strategies.eu/database/database.html>

1.2.3 Collecting data and information

As an initial step, key objectives, applications and challenges as outlined in the European eHealth Action Plan of 2004 were identified and, with the support of the conceptual model, defined and grouped.

Next, national level information was collected through a Europe-wide network of national correspondents. The key tool used to collect this information was an online survey template. It contained six sections:

1. National eHealth strategy
2. eHealth implementations
3. Legal and regulatory facilitators
4. Administrative and process support
5. Financing and reimbursement issues
6. Evaluation

Under each of these six sections, a range of questions was formulated and drop-down menus provided for specified answer options. Free text fields allowed for further qualified input.

The drop-down menus were designed for two purposes: to capture dates and stages of development (planning/implementation/routine operation); and to focus the number of possible answering options on key topics, for example with regard to issues included in a strategy document or specific telemedicine services. This limit on the number of options also allows for a more uniform comparison across countries.

Under Section 2 of the template on eHealth implementations, questions regarding the following applications were formulated: existence and deployment of patient and healthcare provider identifiers, eCards, electronic health record (EHR)-like systems, patient summaries, ePrescription, standards, telemonitoring and telecare.

Data gathering followed a step-wise approach. In order to create a baseline for the assessment of progress, the *empirica* team filled in the questionnaire by using data from earlier *eHealth ERA* reports and various case studies to the extent meaningfully possible.

¹⁸ An optional summary report was drafted for Switzerland. See footnote 21 below.

¹⁹ An optional summary report was also drafted for Turkey. See footnote 21 below.

Most of this information was from 2006 (and some of early 2007). In a next step, the study team experts and national correspondents filled in the template on post-2006 developments in the health(care) sector of the corresponding country.

All results were checked, revised where necessary and validated. In addition to the internal quality review procedures within the study team, the country reports were validated by the European level i2010 subgroup on eHealth²⁰ representatives of all 34 countries reported on, and/or by respective national experts.²¹ Their great and sometimes enthusiastic, but also critical engagement in this process is gratefully acknowledged. Without their support, the study and the individual country reports would not have achieved the quality aspired.

The empirical results presented in this synthesis are based on detailed analyses and integration of data from individual country reports by the study team. This involved a preliminary assembly of structured qualitative and quantitative data into spreadsheets, followed by internal meetings and workshops to arrive at a common interpretation of the data collected. Furthermore, information available in the grey and white literature, feedback received from country representatives and experts as well as the knowledge and experience of the study team all contributed to this report.

In spite of all these efforts to provide balanced results derived from research attempting to adhere to high methodological standards, we have to be aware that a fundamental problem of the work undertaken is that the results presented will nevertheless be subjective and disputable, both by theoretical necessity and empirical insufficiency, including limited resources to undertake such comprehensive, far reaching research. Unlike in physics the study of social systems will always be prone to subjective measurements and interpretations.²²

1.3 Outline

The structure of this report reflects that of individual country briefs. It discusses health-care governance issues and eHealth policy as well as strategic and implementation actions. The chapter on administrative support structures, competence centres and governance also includes a synthesis of key legal issues. Survey results on the deployment of eHealth applications in fields such as patient summary and electronic health record (EHR)-like systems, ePrescription or telehealth are synthesised. Technical aspects of implementation focus on unique identification of patients and healthcare professionals, the role of eCards and the regulation of and adoption of standards. Furthermore, financing

²⁰ The i2010 subgroup on eHealth, active till 2010, was born in 2005, known then as eHealth working group. It adapted its name following the launch of the i2010 initiative in 2006. "Its mandate is to provide expert eHealth-related advice to the overarching i2010 High-Level Group. The main objectives are to improve quality and access to healthcare, while bolstering the cost-effectiveness of health systems and services, stimulating European industry, and supporting European patient mobility. It facilitates and contributes to the implementation of the eHealth action plan." See: http://ec.europa.eu/information_society/activities/health/policy/i2010subgroup/index_en.htm

²¹ The 34 countries are 26 EU Member States plus the four home countries of the UK with separate national health services (England, Northern Ireland, Scotland and Wales), and Iceland, Norway, Switzerland and Turkey. The results of the non-EU countries were not integrated into the overview tables on progress due to missing data for 2007.

²² On these issues cf. e.g. Luhmann, Niklas (1995). *Social Systems* (J. Bednarz, Jr. with D. Baecker, Trans.). Stanford: Stanford University Press. (Original work published 1984), and Luhmann, Niklas (1997). *Die Gesellschaft der Gesellschaft*. Frankfurt: Suhrkamp. Cf. also: http://en.wikibooks.org/wiki/Communication_Theory/Sociological_Systems

and reimbursement issues, and finally evaluation plans and activities are also summarised.

As legal and regulatory aspects are relevant for and permeate all other fields, they are also discussed in some detail, including the legal challenges of patient summaries/EHR systems, ePrescription and telehealth.

The report concludes with a summary outlook and recommendations, which are partially based on input collected during the validation workshop of the study, held on September 16th 2010 in Brussels. It was attended by about 120 senior level political representatives from European Ministries of Health, representatives of stakeholder associations and European policy institutions. The workshop also showcased good practice cases of Member States eHealth strategies and highlighted the overall trends across Europe with regards to eHealth initiatives and implementations.

Good practice examples and short case reports

Intermittently in box inserts, good practice examples and short cases are reported upon to further illuminate the points raised in the discussions. The cases illustrate developments and activities which may be of interest to other countries and regions in order to identify and transfer specific experience and lessons learned.

2 eHealth policy progress in European countries

Whereas about 4 years ago, mostly high level policy documents or roadmaps were available, today most European countries surveyed have more detailed documents published outlining concrete policies/strategies on eHealth goals, measures and/or implementation objectives and achievements. Based on such documents, the following overview identifies key fields of national level eHealth activities and demonstrates the considerable increase recorded between 2006 and 2010²³.

Table 1: Key fields of national level eHealth activities in the EU27 countries, 2006 and 2010

Reported eHealth activities	Total 2007 eHealth ERA	Total 2010 eHealth Strategies	Delta
Legal activities	14	22	8
Evaluation	5	21	16
EHR Patient Summary	27	27	0
ePrescription	16	22	6
Telehealth	23	27	4
Patient ID	24	26	2
Professional ID	13	22	9
Citizen card	22	25	3
Professional card	7	18	9
Standards (technical/semantic)	19	27	8

Source: eHealth Strategies study, 2010

Whereas patient summary and electronic health record (EHR)-like systems have already been high on the agenda for quite some time, most Member States (+16) by now realise the urgent need of evaluation activities to better prepare for and control policy progress and learn from experience.

Further services high on the agenda are the electronic transfer of prescriptions or the provision of telehealth services, e.g. for doctors and patients in remote regions or for chronically ill patients at home. These are among the key activities identified in the EC's 2004 eHealth Action Plan. It seems that the development of this Lead Market²⁴, which the EC has supported for many years, is gaining momentum.

²³ The table covers the EU 27 Member States only, in order to allow for comparison with the previous eHealth ERA study. Note that this present eHealth Strategies study analysed the EU27 and European Economic Area (EEA – to which Iceland, Lichtenstein and Norway belong, but Lichtenstein is not covered by this survey) countries, including the four home countries of the United Kingdom. In addition, experts from Switzerland and Turkey contributed on a voluntary basis country reports structured according to the generic template supplied, which is gratefully acknowledged.

²⁴ See footnotes 11 and 12 above.

Several countries have updated their older eHealth strategy documents, the most recent being Bulgaria (“Concept on E-health”, 2011). In the case of countries with a longer track-record of eHealth – such as some Nordic countries – eHealth documents are no longer published as strategies, but rather as updates on implementation progress. This is the case in Sweden, for example.²⁵

In countries where the responsibility for the provision of healthcare is decentralised, i.e. delegated to the regional level, strategy documents regarding eHealth have also been published by regional authorities. Typical examples of such a situation can be found in Spain.²⁶

Case 1: Sweden - a detailed eHealth policy document

The Swedish “National Strategy for eHealth” is an example of a policy document that encompasses not only the political objectives to be pursued, but also a detailed set of action areas and clear statements on governance and stakeholder involvement as well as financing. The action areas mentioned in the document are:

1. Bringing laws and regulations into line with extended ICT use
2. Creating a common information structure
3. Creating a common technical infrastructure
4. Facilitating interoperable, supportive ICT systems
5. Facilitating access to information across organisational boundaries
6. Making information and services easily accessible to citizens.

Slovak Republic is a Member State which recently has developed a very detailed strategy and implementation plan, based on a comprehensive needs analysis for eHealth implementation.²⁷ Four strategic goals concern the creation of a legislative and normative framework, a secure IT infrastructure, informatisation of healthcare services, and finally the development of new health service delivery processes facilitated by eHealth applications. A catalogue of stakeholders’ eHealth needs and requirements consisting of more than 1,640 items was prepared, which served as a basis for the procurement of eHealth solutions and input to iterative software development processes.

Not all eHealth strategies are labelled as such. Some countries have published a more generic eGovernment or Information Society policy document which refers to an ICT strategy in the healthcare sector as one of several priorities. Other countries such as Germany and France have enshrined their central eHealth activities in legislation governing the healthcare sector. In Germany, it is the 2003 Law on the Modernisation of Healthcare, whereas in France the introduction of an electronic medical record was included in a 2004 law concerning social security.

²⁵ Swedish Ministry of Health and Social Affairs (2009). Status Report 2009, Swedish Strategy for eHealth Safe and accessible information in health and social care. Stockholm.

²⁶ Junta de Andalucía (2004). Plan de Calidad del Sistema Sanitario Público de Andalucía [Plan for a High Quality Public Health System in Andalucía] 2005-2008; Available at: http://www.juntadeandalucia.es/salud/export/sites/csalud/galerias/documentos/c_1_c_6_planes_estrategias/II_plan_calidad/II_plan_calidad_profesionales.pdf. See also Generalitat de Catalunya (2007). Pla Estratègic SITIC 2008-2011 [Strategic Plan for Health ICT 2008-2011]. Available at: <http://www.gencat.cat/salut/ticsalut/html/ca/dir1772/dd17201/plaestratic.pdf>

²⁷ Cf. Ministry of Health (2008). Strategic targets of eHealth - key tool of public governance informatization in frame of healthcare in Slovakia. Bratislava. 25.06.2008, http://data.nczisk.sk/ehealth/strategicke_ciele_en.pdf; National Health Information Centre (NHIC) (2009). eHealth: new dimension of health care. Bratislava, 2009, www.epsos.eu/fileadmin/content/pdf/Slovak_eHealth_brochure.pdf

3 Governance - institutional structures, stakeholder involvement, legal, reimbursement and evaluation issues

This chapter reports on governance issues, focusing particularly on institutional structures, competence centres, a synthesis of key legal and reimbursement issues as well as on evaluation activities, all of which are key for meaningful investment and use.

As legal and regulatory aspects are relevant for and permeate all application fields, they are also discussed later in the respective context in some detail, such as the legal challenges of patient summaries/EHR systems, ePrescription and telehealth.

3.1 Administrative responsibility and competence centres

Allocation of responsibility for eHealth strategy development and their implementation is not uniform in EU Member States. In the majority of countries responsibility lies largely with the Ministry of Health. In others (e.g., Estonia, Ireland, Italy, Hungary or the Netherlands), responsibility is more widespread across several ministries and/or agencies, such as those responsible for new technologies, innovation and/or telecommunications. In countries with decentralised health systems (Finland, Italy, Spain), or in countries where several ministries (Belgium, Italy) are involved, there is a strong need for a concerted official eHealth strategy with common goals that are agreed among these different institutions.

Case 2: eHealth authorities in France

In 2004, France enacted legislation on the implementation of a “Dossier Médical Personnel” (DMP). After a thorough review in 2008 of the challenges encountered by this endeavour, a new eHealth Competent Authority was established with a comprehensive remit. Set up by decree in September 2009, ASIP Santé (Agence des Systèmes d’Information Partagés de Santé - Agency for Shared Healthcare Information Systems), under the guidance of the ministerial “Direction de la Stratégie des Systèmes d’Information de Santé” (DSSIS) works towards

- Implementing the general health information infrastructure addressing the medical, technical and legal requirements in the field, and encouraging its use
- Producing and promoting domestic and international guidelines, particularly in the area of interoperability (technical and semantic) and security
- Designing and deploying shared healthcare IT systems such as the DMP (Dossier Médical Personnel).

By now, more than a dozen countries have established legal entities as specific consultative bodies or competent authorities under ministerial supervision. Their role is to develop, oversee and monitor the country’s strategic goals, and/or implement and manage eHealth infrastructure and application projects. In the Slovak Republic, the National Health Information Centre (NHIC) was established as an eHealth “think-tank” body. In Germany, the “gematik” organisation has been given the responsibility for nationwide eHealth activities by law. England is another illustrative case. Here the NHS Connecting for Health (CfH) is an agency of the UK Department of Health that is specifically responsible for delivering the National Programme for IT for the National Health Service in Eng-

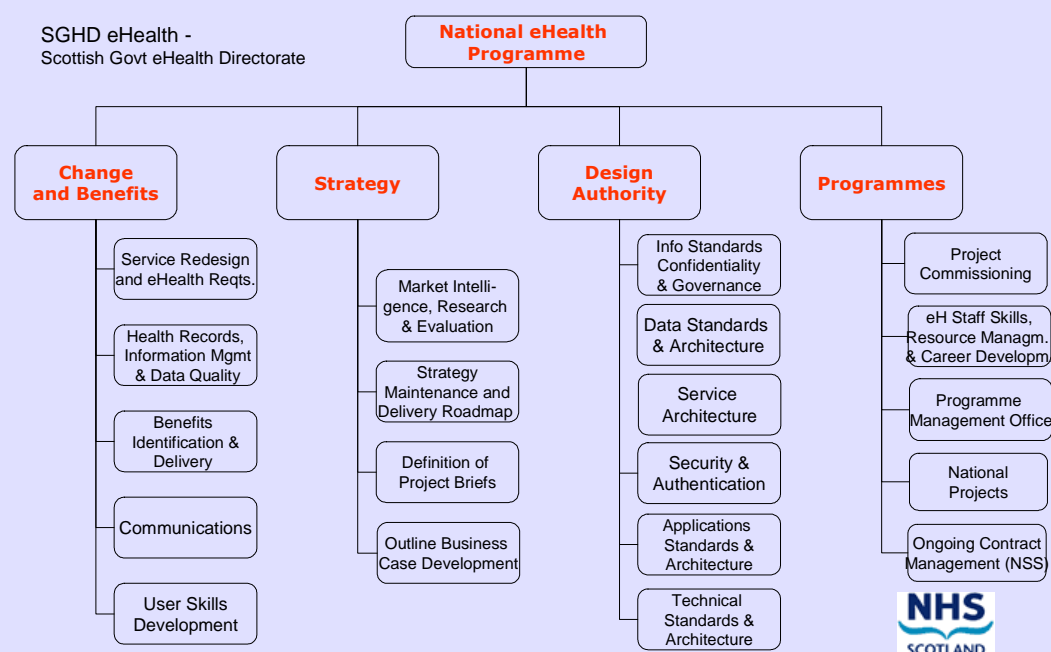
land (NPfIT)²⁸, whereas the three other home countries Northern Ireland, Scotland and Wales have their own separately administered and organised health services with responsibility also for eHealth. Even in a country as small as Luxembourg a similar organisation will be established.

Case 3: The Scottish eHealth Directorate

As part of the Scottish Government Health Department, the eHealth Directorate delivers the national eHealth programme. It aims to change the way in which information and related technology are used within NHS Scotland in order to improve the quality of patient care. This directorate is an example of a well thought through, comprehensive structure for delivering eHealth, consisting of 4 main blocks:

1. Change and benefits realisation (service redesign, EHRs, data quality, user skills, etc.)
2. Strategy (incl. research and evaluation, business case development)
3. Design authority (standards, architecture, security, authentication, etc.)
4. National and local programmes & projects (incl. commissioning, resource management, etc.)

In particular the change and benefits group and the programmes group are remarkable in that they take into account issues that are frequently neglected or under-resourced, like continuous development of user skills, benefits identification and delivery, resources and career management. This comprehensive view takes into account necessary activities beyond the IT-development itself and could therewith serve as a model for other eHealth projects on a national or regional level. In a recent re-organisation of the Directorate, the Change and Benefits group was merged with the Programmes group to reflect the conviction that “local commissions for projects have commitments to address change and benefits.”



Source: http://www.ehealth.scot.nhs.uk/?page_id=51

²⁸ Note that both the organisational structure and the Programme itself are undergoing revisions.

3.2 Involving stakeholders

In the meantime, as part of their eHealth governance²⁹ structures, many countries have advisory bodies involving professional associations, patient representatives, third party payers or care providers. Careful planning, organisational setup and stakeholder involvement are key success factors for eHealth (infrastructure) projects.³⁰ A flawed institutional structure or ill-conceived processes can jeopardise an entire project because of deficient conflict-resolution procedures or competing centres of power whose rivalry jeopardises progress. In Austria, a success eHealth initiative was established in 2005 already. It represents an interesting example of early involvement of stakeholders in strategic shaping of a national eHealth project. Stakeholders were motivated to become involved in defining the goals and objectives to be achieved by the overall eHealth programme.

Case 4: The Austrian eHealth Initiative

In April of 2005, the Austrian Ministry of Health, together with the national working group on data processing³¹ established a high level coordination committee for developing the national eHealth strategy: This Initiative was comprised of about 100 members from IT-companies, hospital organisations, social and private insurance companies, the chambers of doctors and of pharmacists, universities, Ministry of Health, and eGovernment experts. The aim was to shape and accompany the design and introduction of eServices in the healthcare system. These include electronic health record systems, for which a separate task force was set up³², the establishment of telemedicine services and of online health portals. Seven work groups (Arbeitskreise - AKs) were established:

AK1: National eHealth strategy

AK2: Interoperability – standardisation

AK3: Patient identification and archiving

AK4: Network of the health care and social system, infrastructure

AK5: Customer related information systems

AK6: Health care system related information systems

AK7: Telemedicine

The results of AK2 – AK7 were to be synthesised by AK1 into a coherent national eHealth strategy. This approach was complemented by so called “accompanying measures” which included active efforts for promoting acceptance of eServices, evaluation of the eHealth strategy, and analysing good practice examples from other EU countries. Following a reorganisation in 2009, the AK1 on eHealth Strategy is now focussing more on the provision of position papers regarding different eHealth relevant issues. In addition, as of December 2010, two new working groups on emergency care medicine and ambient assisted living (AAL) were added to the existing structure.³³

²⁹ Governance denotes principles of cohesive policies, goal-oriented institutional structures, consistent management, balanced processes and decision-rights for a given area of responsibility. The European Commission has defined as “European governance” principles “openness, participation, accountability, effectiveness and coherence”. Cf. White Paper on European Governance, see: http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf

³⁰ See, e.g., Stroetmann, Karl A. et al. (2006). eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites (eHealth IMPACT study report). Luxembourg: Office for Official Publications of the European Communities, 2006.

³¹ Arbeitsgemeinschaft für Datenverarbeitung („ADV“ - [Data Processing Working Group]).

³² The Federal Health Commission of Austria decided to establish the task force electronic health record “Arge ELGA” in July 2006 as a national coordinating body for design and implementation of a national electronic health record system. The decisions so far have covered the institutional setup, the legal framework, the financing of the first project phase and the technical standards to be used.

³³ See <http://ehi.adv.at/>

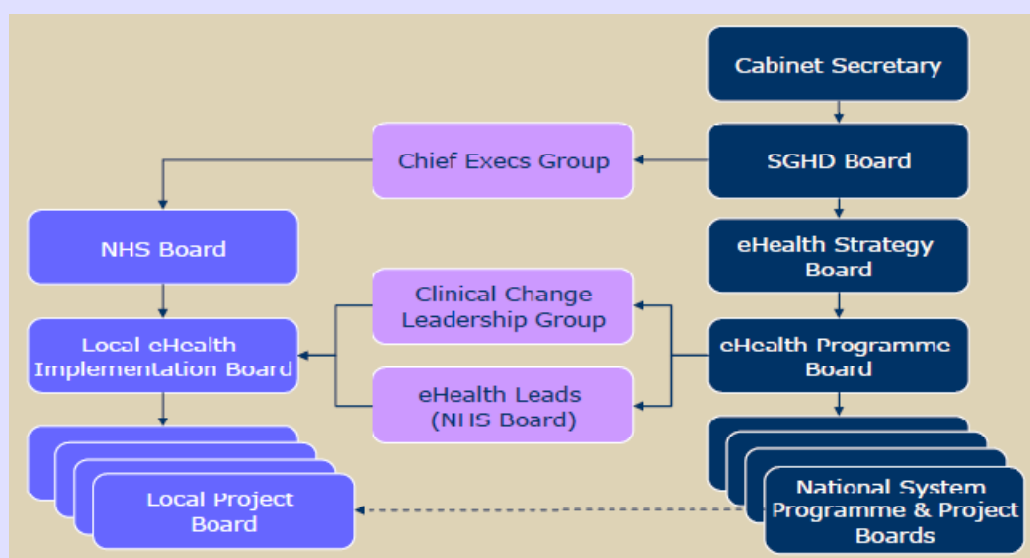
Such bodies in part resolve the challenge of potentially ambiguous or distributed responsibilities for eHealth. They are also a sign of strong political commitment. Irrespective of the health system type, they seem to follow the insight that without such a coordinating and sometimes also directing initiative national or regional implementations will not succeed. Although they are not a sufficient condition for success, it seems they are a necessary ingredient.

Case 5: eHealth Programme governance in Scotland

Directed by the Scottish Government Health Directorates (SGHD), the eHealth Strategy Board provides overall strategic guidance and investment approval for the national eHealth Programme: Key groups of this structure are

- a) The Clinical Change Leadership Group (CCLG) which has been established to ensure clinical input into the Programme and has a key role in presenting and consulting on the Programme with relevant clinical groups
- b) The eHealth Leads Group which provides a link between NHS Boards and the eHealth Programme at a management level and is key to the successful implementation of projects at NHS Board level.

The elaborate national programme governance flow structure is illustrated below:



Source: <http://www.ehealth.scot.nhs.uk/wp-content/documents/ehealth-programme-governance-flow-chart1.pdf> (currently under revision)

A strangely neglected field in the overall governance domain seems to be the continuous development of user skills, be they professionals like nurses and doctors, be they citizens as patients and informal carers. The EC funded study on needs and opportunities to "Supporting and boosting investment in eHealth" had already concluded that "The most important part of eHealth investment that needs expanding is the eHealth skills and knowledge of healthcare staff and ICT suppliers' staff. An expanded capability is essential to achieve more success and so help to boost eHealth investment."³⁴

³⁴ Dobrev, Alexander, Jones, Tom, Stroetmann, Veli N. et al. (2008) Sources of financing and policy recommendations to Member States and the European Commission on boosting eHealth investment. Final report of the Financing eHealth study. Bonn/Brussels, empirica Dec. 2008. http://www.financing-ehealth.eu/downloads/documents/FeH_D5_3_final_study_report.pdf

3.3 Legal and regulatory facilitators

Legal and regulatory issues are among the most challenging aspects of eHealth: privacy, confidentiality, liability and data protection all need to be addressed in order to enable a sustainable implementation and use of eHealth applications. Rarely does a country report on a coherent set of laws specifically designed to address these diverse aspects of eHealth. Rather, in most countries the use of eHealth is currently regulated only by the general legal framework, in particular by laws on patient rights and data protection and by regulations on professional conduct. New legislation is often still in the process of being drafted and enacted. In 2006, legal activities with a specific regard to handling eHealth issues were reported in 14 countries. Today, 22 countries are dealing with eHealth related legal regulations, showing that this topic is now widely recognised as an important enabler for progress in this sector.

Amongst the forerunners in designing a legal framework adapted to the use of eHealth are Denmark, England, Estonia, Finland, France, Norway, Scotland, Slovak Republic and Sweden. Almost all countries which do not (yet) have specific regulations with regards to one or more fields of eHealth, such as Austria, Cyprus, Latvia, Malta or Portugal, do have some regulation on health data, if only through the transposition of article 8 of the EU Data Protection Directive.³⁵

With regard to the regulation of electronic health records it can be noted that nearly all European countries legally enforce a duty to keep a carefully updated and safely stored health record, but most keep the option open of storing the health record on paper or electronically. If they have an electronic form, additional requirements concerning content, access and security often apply. It is however expected that the obligation to store the records electronically will arise in more and more countries, if only because many are currently planning to roll out electronic health record-like systems that will become mandatory unless patients opt-out.

The extent of regulations concerning *telehealth* service delivery is presently considerably smaller than that of electronic health record systems. This is mainly because the usefulness of legal provisions dealing with telehealth specifically is being questioned. If regulated at all, the measures usually focus on whether to uphold the requirement to treat a patient initially in person and allow for teleservices only after a first direct contact, the fact that specific accreditation for such services is not available, and liability issues, particularly in cross-border situations.

Regulatory instruments specifically on *ePrescribing* focus primarily on requirements with regard to the use of authentication techniques, electronic signatures and the need for patient consent, a complementary paper copy and to uphold the obligation of prior clinical examination. Apart from ePrescriptions itself, the introduction of electronic pharmaceutical care records is also on the rise. Also in the context of future applications of clinical decision support and other patient safety tools medication profiles need to be kept and accessible. In the majority of countries the legal framework is however not yet adapted to the specific needs arising from electronic prescription services.

³⁵ Article 8 deals with the processing of special categories of data, see Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, Official Journal L 281, 23/11/1995 P. 0031 – 0050. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML>

3.4 Financing and reimbursement issues

When looking at financing sources for the development and implementation of eHealth infrastructures and applications, a mixed picture emerges. Across Europe, the primary sources of funding are government or quasi-public sources, e.g. the general budget for health, as well as dedicated ICT budgets or special levies on statutory health insurances. Considering that individual service providers usually do not have an incentive to establish such infrastructures for all, this result is not surprising. To compensate for market failure and allow a network effect³⁶ to kick in, adopting a 'public good' perspective of eHealth infrastructure seems warranted.

Recurring public budgets dedicated specifically to eHealth are the exception (Austria, England, Spain), whereas there is widespread use of projects-based sourcing. Sometimes private and public insurance companies or public technology or innovation agencies (for example Tekes, the Finnish Agency for Technology Development and Innovation) are involved in financing. Among the international sources of funding mentioned, EC RTD project co-financing as well as funding from European Structural and Regional Funds and the European Investment Bank are mentioned.

Case 6: Financing eHealth infrastructure through the ERDF

The European Regional Development Fund (ERDF)³⁷ is one of the three European Union Structural Funds (ESF) which allow the European Commission to grant financial assistance to resolve structural economic and social problems in defined regions of the Union. ESF support Member State policies that promote full employment, improved quality and productivity at work, or reduced social exclusion and disparities at work.

The main focus of EU regional development funding for healthcare has been on health system infrastructures. For the period 2007-2013, the scope and eligibility of health-related projects co-funded from Structural Funds also includes technical assistance, ICT systems for medical services, productive investment including medical equipment, and exchange of good practice. These topical fields also cover eHealth investments with specific goals, such as facilitating easier access to healthcare for minorities in border regions, and cooperation between health service providers across borders. Support to research and innovation, promotion of small and medium-sized enterprises, information society (i.e. eHealth services for citizens) and human capital (i.e. active ageing and prolonging working lives) is also included.³⁸

The ERDF can support healthcare related projects in the context of its Convergence Objective (formerly Objective 1), which is to promote the development and structural adjustment of regions whose development is lagging behind. Projects are supported that help less-favoured regions to raise their level of use of technology, including information and communication technologies (ICT). The ERDF finances up to 85% of a project's total cost in the Convergence Objective regions.³⁹ It is managed through national and regional authorities. The European Structural Funds played a major role for financing

³⁶ A network effect is present when the value of a product or service increases as more people use it. Cf. Blind, Knut (2004). *The Economics of Standards: Theory, Evidence, Policy*. Cheltenham Glos: Edward Elgar Publishing.

³⁷ See: http://ec.europa.eu/regional_policy/funds/feder/index_en.htm; cf. also Dobrev, Alexander et al. (2008). *Sources of financing*, op. cit., Available at: <http://www.financing-ehealth.eu/>

³⁸ See: http://ec.europa.eu/regional_policy/themes/health/index_en.htm

³⁹ See: http://ec.europa.eu/regional_policy/sources/docoffic/official/regulation/pdf/2007/publications/guide2007_en.pdf

eHealth related infrastructure and services in Hungary, such as hospital information systems, telemedicine infrastructure, further development of a central electronic registry of health insurance funds, etc.⁴⁰ Lithuania also made use of the ESF, among other financing sources, for its eHealth system development.⁴¹

The telemedicine decree in France (*décret télémedecine*) is a recent example of how to tackle the challenge of reimbursement for a concrete application. This decree specifies the kind of telemedicine services to be made available and how they may be reimbursed. One option is to integrate such services into multi-annual contracts ("*contrat pluriannuel d'objectifs et de moyens*") which regional health agencies in France sign with healthcare providers. Alternatively, telemedicine services can become funded through a separate fund set up by the social health insurance in order to improve quality and coordination of healthcare, the so called "*fonds d'intervention pour la qualité et la coordination des soins*."⁴² These funds are also disbursed through the regional health agencies.

In the Netherlands, the reimbursement rules of integrated care for chronically ill patients allow for eHealth services to become an element in such care plans. Here, instead of reimbursement by fee for service, a fixed budget is allocated for the complete treatment cycle, based on performance standards and output quality criteria. The Ministry of Health, Welfare and Sport has already introduced integrated care reimbursement for patients suffering from diabetes, cardiovascular diseases, and COPD (chronic obstructive pulmonary disease). The impact will be evaluated after three years.

A number of countries explicitly mention the pressures exerted by the current financial crisis and the resulting need to cut public spending as obstacles with regard to sustained eHealth financing. However, justifying significant spending on eHealth projects and infrastructures out of public sources seems to be a shared challenge, especially when combined with changes in national government as for example recently in the United Kingdom and Germany. Furthermore, still pending legislation on eHealth seems to have repercussions on financing as well. This problem is mentioned in reports on Estonia, Slovenia, Greece and Italy, but it is likely to be also a challenge in other countries. Where alternatives for public funding, for example through public private partnerships (PPP) are sought,⁴³ these meet with healthy scepticism as is the case for Slovenia.

3.5 Evaluation activities

The topic of ex-ante impact assessment as well as formative and ex-post summative evaluations has gained considerable momentum across Europe. Whereas in 2006 only 5 countries reported related activities, in 2010 already a considerable majority of 21 countries mentions such undertakings - this is the largest increase in interest of all topics surveyed. The scope and procedures used are very diverse, however, and a systematic

⁴⁰ eHealth Strategies Country Brief Hungary, October 2010 (study funded by the European Commission). Available at: http://ehealth-strategies.eu/database/documents/Hungary_CountryBrief_eHStrategies.pdf

⁴¹ See Good eHealth case studies at: <http://kb.good-ehealth.org/search.do> (search for Lithuania).

⁴² See the Décret n° 2010-1229 du 19 octobre 2010 relatif à la télémedecine, available at: <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022932449&dateTexte=&categorieLien=id>, and its various references to the social security code and the public health code.

⁴³ For details on such schemas see chapter 3.10 Public-private partnerships (PPP) in Dobrev, Alexander et al. (2008) Sources of financing, op. cit., pp. 46-50.

comparison of approaches, techniques/tools applied and specific applications or processes evaluated was not possible.

Not surprisingly, countries with more advanced eHealth infrastructures and services have a higher propensity to carry out assessments of the benefits of their eHealth investments and the challenges encountered. Around one-half of the 34 countries surveyed (including the four home countries of the UK) mention a specific body of one form or another as being responsible for evaluation activities. These include: national eHealth-platform (Belgium), Estonia State Audit Office, Centro Nazionale per Informatica nella Pubblica Amministrazione (CNIPA, Italy), Department of IT of Ministry of Health (Lithuania), Centre for Health Economics (Latvia), National Institute for Health and Welfare - THL/Ministry of Health (Finland). Some mention a diversity of entities/agencies, two the involvement of research institutes. Some of these bodies have only recently taken up responsibility for the evaluation role and – from the evidence offered – have not yet finalised any particular evaluation.

In decentralised healthcare systems such as Italy and Spain, regional evaluations prevail over systematic national level assessments.

Six countries (under way in Ireland, England, Switzerland; planned in France, Slovenia, Slovak Republic) report on actual assessments of the impact of investments in the eHealth domain. As such analyses are expected to lead to an optimisation of resource allocations not only with respect to planned investments, but also for already running activities, one can expect more attention to be paid to such socio-economic and change management aspects in future.⁴⁴

In Switzerland, the federal government commissioned a Regulatory Impact Assessment (RIA) of potential specific eHealth legislation, which is under discussion at the parliamentary level right now. RIA is a systemic approach to critically assessing the positive and negative effects, including benefits, costs, incentives and risks, of proposed or existing regulations and their non-regulatory alternatives. As employed in OECD countries since 1974, it encompasses a range of methods based on benefit-cost analysis;⁴⁵ at its core, this is an important element of an evidence-based approach to policy making.

Case 7: Regulatory impact assessment of proposed eHealth legislation in Switzerland

An electronic medical record for every citizen is a central component and pillar of the "eHealth Strategy Switzerland". It should lead to better quality health care by supporting clinical processes and improving economic efficiency of the overall system. The potential to realize these benefits was examined by a regulatory impact assessment (RIA), commissioned by the Swiss Government. Based on modeling the impact of the introduction of patient record systems and networks, estimates of benefits and costs for each major stakeholder group were derived. Also different incentives to optimize the overall impact as well as various implementation risks were considered.

The RIA analysed three scenarios: a reference scenario without regulation, the implementation of regulatory measures as proposed by an eHealth expert group, and an alternative with high up-front investment incentives for healthcare provider organizations. The assessment was limited primarily to the use of patient clinical data in an environ-

⁴⁴ eHealth priorities and strategies in European countries - eHealth ERA report (2007). Available at: <http://www.ehealth-era.org/documents/2007ehealth-era-countries.pdf>

⁴⁵ OECD Reviews of Regulatory Reform (2009). Regulatory Impact Analysis: A Tool for Policy Coherence. Paris: OECD.

ment of connected GPs, hospitals and pharmacies. Future secondary uses such as for public health or medical research purposes were not considered.

For a time horizon of around 20 years, the estimated socio-economic net benefit of the proposed regulatory interventions, when compared with the reference scenario, is positive for society as well as for the various stakeholder groups. However, quite significant investments will be necessary in the short- and medium term.⁴⁶

The United Kingdom is another example of regular evaluations of the National Programme for Information Technology (NPfIT) of the National Health Service in England by a wide variety of actors.

Case 8: Evaluating the National Programme for IT in England

The National Programme for IT (NPfIT) in England is an example of almost continuous evaluation by independent third parties. Since 2006, two evaluations of elements of this programme were completed and six further ones are ongoing. All of these evaluations were or are undertaken by researchers from one or more UK universities. The research is commissioned based on responses to public requests for proposals (RFP).

The NHS Connecting for Health Evaluation Programme was commissioned by NHS Connecting for Health (CfH) through the Research and Development Directorate of the Department of Health. It was set up in April 2006 to evaluate certain elements of the NPfIT delivery. It aims to inform subsequent deployments of technologies and to provide high quality, objective, third-party insights into the lessons learned as a result of such large-scale projects.

Furthermore, the National Audit Office (NAO) conducted two reviews of the National Programme. It published a document entitled "Department of Health: The National Programme for IT in the NHS" in June 2006. This was an initial assessment of the programme's progress two years after its inception. The conclusions and recommendations in the report addressed challenges in three key areas:

- Ensuring that the IT suppliers continue to deliver systems that meet the needs of the NHS, and to agreed timescales without further slippage.
- Ensuring that NHS organisations can and do fully play their part in implementing the Programme's systems.
- Winning the support of NHS staff and the public in making the best use of the systems to improve services.

Two years later, the NAO published another document entitled "The National Programme for IT in the NHS: Progress since 2006" (May 2008). Although this was largely a value-for-money review, it did consider technical issues, and it examined how the implementation of new technology affected organisations, staff and patients.⁴⁷

⁴⁶ Bundesamt für Gesundheit BAG, Staatssekretariat für Wirtschaft SECO (2010). Regulierungsfolgenabschätzung zur Umsetzung der «Strategie eHealth Schweiz». Studie zu den von der Expertengruppe eHealth des EDI vorgeschlagenen rechtlichen Rahmenbedingungen für die Einführung eines elektronischen Patientendossiers. November 2010, <http://bit.ly/eW0u4O>

⁴⁷ See in particular: List of the evaluation projects on this website: University of Birmingham, <http://www.haps.bham.ac.uk/publichealth/cfh/research.shtml> and also National Audit Office (2008) The National Programme for IT in the NHS: Progress since 2006. http://www.nao.org.uk/publications/0708/the_national_programme_for_it.aspx

Next to NHS England, evaluation activities are also going on in other countries of the UK, notably in Wales, where the NHS established an independent international advisory board to evaluate its “Informing Healthcare Programme.”

Case 9: Wales - Evaluation through an independent International Advisory Board

In 2006, the Informing Healthcare Programme (IHC) of Wales invited top health informatics and eHealth experts from around the world to serve as an International Advisory Group (IAG). It is an independent review board composed of specialists from all over the world. Each year its members are brought together at an International Advisory Group conference, where they put *Informing Healthcare* under the microscope and publicly peer review the programme's progress and achievements.

E.g., in 2007 the members spent three days visiting NHS trusts around Wales and examined the progress of the IHC programme. Then, at a public conference, they delivered their appraisal to 120 delegates from within NHS Wales, other care organisations, government and commercial partners. This type of open exchange and dialogue is considered “*unprecedented in national IT / healthcare improvement programmes*”.⁴⁸ After the conference, the IAG submitted to the IHC programme a written report detailing the expert panel's findings and putting forward recommendations for future actions.⁴⁹ It recommended a stronger focus on overall system architecture for the future deployment of pan-Wales software solutions, and the development of technical and clinical standards for system interoperability: “In combination with *defining a core set of standards*, IHC should develop a *conformance and compliance testing service* to accredit both commercial systems and those developed in-house... It is essential that IHC begin to define and publish a *set of common standards for data interoperability of core clinical data items*.”

Learning from others was strongly recommended: “Wales might consider looking into what happened in Finland. They leveraged the VA [USA Veterans Administration] experience to push through legislative changes in the Finnish Parliament; they used the VA numbers and experiences to create the vision. In their opinion, imitation is great. Furthermore, Wales should consider the approach being used by the National Patient Safety Agency and Connecting for Health in England in terms of integrating information technology into the patient safety agenda.”

In 2009, the international experts confirmed that “Informing Healthcare is on the right track”.

A few Member States also mention EC co-financed studies which have provided them with insights into the socio-economic impacts of their eHealth solutions (Denmark, Malta, Sweden). The two reports cited were the Institute for Prospective Technological Studies (IPTS) commissioned study of state-of-play vis-à-vis eGovernment and eHealth in ten New Member States (2005-2008)⁵⁰, and the EC-commissioned eHealth Impact study⁵¹ analysing 10 routine applications across Europe (Denmark, Sweden) (2005-2006).

⁴⁸ http://www.wales.nhs.uk/IHC/documents/IHCachievements_en.pdf

⁴⁹ Protti, Denis J. et al. (2007). International Advisory Group Assessment of Informing Healthcare in Wales, Wales NHS. Available at: <http://www.wales.nhs.uk/IHC/documents/IAG%20Report%202007.pdf>

⁵⁰ Various reports (2005-2008). The Development of eServices in an Enlarged EU: eGovernment and eHealth. Institute for Prospective Technological Studies. Available at: <http://ipts.jrc.ec.europa.eu/publications/search.cfm>

⁵¹ Stroetmann, Karl A. et al. (2006). eHealth is Worth it, op. cit.

4 Deployment of eHealth applications

Strategic eHealth applications as mentioned in the 2004 eHealth Action Plan are patient summaries and EHR systems, ePrescription services as well as telehealth solutions. For each of these applications, also key legal challenges will be reviewed.

4.1 Patient summaries and electronic health records

Touted for 20 or more years as the 'holy grail' of eHealth, electronic health records (EHR), or more precisely EHR systems, are a consistent element of almost all national strategies and roadmaps. However, whereas EHR-like systems have been implemented or are under development in many healthcare provider organisations, covering patient data from within their own organisational boundaries, and also in various regional health-care systems, there exist hardly any at the national level. The urgent clinical need for large-scale *national* systems⁵² is being questioned more and more, as a recent English evaluation noted: "Clinicians' enthusiasm for electronic health records often related to perceived benefits on their immediate surroundings and did not necessarily relate to the NHS Care Records Service goal of geographically widespread sharing of patient data."⁵³

⁵⁴

4.1.1 What is meant by patient summary and EHR?

In the framework of this study, and using the epSOS⁵⁵ project's definition, a *patient summary* is defined as a minimum set of a patient's data which would provide a health professional with the essential information needed in case of unexpected or unscheduled care (e.g. emergency, accident), but also in case of planned care (e.g. after a relocation, inter-organisational care path).⁵⁶ Patient summaries, also referred to as core minimum data sets, are usually generated and maintained by GPs. Such a summary was referred to as the "Emergency EHR" in England's 1998 Information for Health strategy and is the foundation of the Emergency Care Summary (ECS) in Scotland.

When it comes to the term *EHR*, it is much less clear what is meant. To develop a more consistent use of the term, the following distinctions can be made:

- Electronic Medical Record (EMR) – the electronic record of an individual in a physician's office or clinic, which is typically *in one setting* and is provider-centric
- Electronic Patient Record (EPR) – the electronic record of an individual in a hospital or health care facility, which is typically *in one 'organisation' and is facility-centric*

⁵² Covering large populations; within smaller countries and regions the situation may be quite different.

⁵³ Robertson, Ann et al. (2010). Implementation and adoption of nationwide electronic health records in secondary care in England: qualitative analysis of interim results from a prospective national evaluation. *BMJ* 2010;341:c4564 doi:10.1136/bmj.c4564

⁵⁴ A different perspective is the usage of such systems for public health or knowledge generation purposes.

⁵⁵ epSOS: Smart Open Services for European Patients – Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription. See at www.epsos.eu

⁵⁶ epSOS Deliverable D3.2.2 "Final Definition of Functional Service Requirements – Patient Summary", section 4.1., p. 13. Available at: http://www.epsos.eu/fileadmin/content/pdf/deliverables/D3.2.2_Final_definition_functional_service_requirements_-_Patient_Summary.pdf

- Electronic Health Record (EHR) – the *longitudinal* electronic record of an individual that contains or virtually interlinks data in multiple EMRs and EPRs, which is to be shared and/or interoperable *across healthcare settings* (inter-institutional) and is patient-centric.⁵⁷

Recognising that there is, as yet, no universally accepted standard definition, for purposes of this study, a patient's electronic health record (EHR) is understood to be a shared, integrated or interlinked (virtual) record of *all* his/her clinically relevant health and medical data independent of when, where and by whom the data were recorded. In other words, it is an account of his/her diverse encounters with the health system as recorded in a variety of medical records maintained by various providers such as GPs, specialists, hospitals, laboratories, pharmacies etc. In many cases, an EHR is understood to contain a patient summary as one of its core elements or artefacts.

Across most countries, policy documents mentioning EHRs usually do not contain specific definitions, i.e. it remains unclear what is really meant. It seems that, for implementation purposes, mainly patient summaries or extended versions thereof are envisaged. Such patient summaries (usually including medication records) as well as ePrescription services are key applications for many Member States and other European countries. Supported by the EC, initially 12 and now 23 of them are currently involved in a large scale pilot, epSOS,⁵⁸ for defining, testing and piloting these two services in the cross-border context. These epSOS services will be based on sound elements of legal, security, semantic and technical interoperability. They also need various building blocks like citizen identification and provider identification. All of these issues are being tackled within the pilot. This generates a considerable momentum to move from high-level policy statements to the resolution of concrete challenges in the participating countries and regions.

Case 10: The epSOS patient summary definition

The epSOS project defines a patient summary as “a reduced set of patient’s data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (emergency, accident...) and in case of planned care (citizen movement, cross-organisational care path ..). [I]ts main purpose [is] unscheduled care.”⁵⁹

4.1.2 Deployment of patient summary and EHR solutions

Although all countries surveyed in the ERA Study in 2006 already reported activities aimed at enabling EHR or patient summary systems, so far only a few countries have operational patient summary or limited, EHR-like services deployed at the national level. In Denmark, e.g., which launched its first eHealth/EPR strategy in 1996, the use of electronic patient records is well established and GPs and specialists now have access to pa-

⁵⁷ For a concise overview of such definitions see Protti, Denis J. (2007). Comparison of Information Technology in General Practice in 10 Countries. *Healthcare Quarterly* 10(2), pp. 107-116.

⁵⁸ See epSOS project, op. cit.

⁵⁹ epSOS Deliverable D3.2.2 “Final Definition of Functional Service Requirements – Patient Summary”, section 4.1, p. 13. Available at: http://www.epsos.eu/fileadmin/content/pdf/deliverables/D3.2.2_Final_definition_functional_service_requirements_-_Patient_Summary.pdf

tient data regardless of where it was created.⁶⁰ Almost all GPs' offices are computerised.⁶¹ In Scotland, a central Emergency Care Record (ECR) for virtually all 5m citizens exists since 2007, being updated twice daily automatically from the respective GP systems.⁶² Its usability is underlined by more than 200,000 accesses per month. Recently, a palliative care summary (PCS) has been added, and a key information summary (KIS) will soon be ready for the 5% of GP patients who have long term conditions and need to be case managed in their homes to avoid emergency hospital admissions.

In the Czech Republic, the IZIP⁶³ system provides a nation-wide web-based EHR containing information on lab results, radiology reports, emergency care and other data where information for more than 20% of the population are recorded and available to connected care providers if the patient agrees. In Sweden, a National Patient Summary (NPÖ) has been piloted since April 2008. It is based on experience from an earlier national patient summary pilot. The implementation is ongoing. The NPÖ contains current care contacts, personal information, chronic disease diagnoses, and medical alert information such as allergies, current examination results, and a list of dispensed drugs.

In Bulgaria, a personal health record (eLAK) system has been integrated into the national health portal. eLAK is a patient's web-based health data storage facility, where an emergency care data set and copies of prescriptions, immunizations, physicians' letters, X-rays, ECGs (electrocardiograms) etc. can be uploaded. Only the owner decides what information should be accessible to whom. Implementation of these pilot applications depends on a comprehensive assessment of their effectiveness and a detailed scale up strategy. It is foreseen to link eLAK to hospital and GP information systems.

In Turkey, a basic electronic health record service has been implemented as an element of the national family medicine application, the data of which are synchronised with health records stored in the central servers of the Ministry of Health.

Case 11: Condition-specific summaries in Finland

To support coordinated or integrated care of chronic disease patients, a number of national strategies foresee the inclusion of condition-specific patient summaries in their EHR-like systems. An interesting example is Finland:

The Finnish **minimum data set** contains the following core data elements: information for patient identification, clinical data (such as diagnoses, investigations, procedures, medications, nursing data, physiological measurements etc), health risk data and other information like a treatment will or an organ donor will. Until the fall of 2010, extensions of the core data set for specific clinical domains had been developed for

- Emergency care
- Occupational health

⁶⁰ Cf. Stroetmann, Karl A. et al. (2006). eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites. Luxembourg: Office for Official Publications of the European Communities, 2006.

⁶¹ Cf. Dobrev, Alexander et al. (2008). Benchmarking ICT use among General Practitioners in Europe. Bonn: empirica, April 2008. Study commissioned by the EC, available at: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm

⁶² Cf. Dobrev, Alexander et al. (2010). Interoperable eHealth is Worth it - Securing Benefits from Electronic Health Records and ePrescribing. Luxembourg: Office for Official Publications of the European Communities.

⁶³ Cf. Stroetmann, Karl A. et al. (2006). eHealth is Worth it, op. cit.

- Dental health
- Respiratory diseases
- Psychiatry
- Diabetes and vascular disease treatment and prevention
- Maternity and child care

In contrast to the national level, fully-fledged *regional* EHR systems exist or are in advanced stages of realisation in some regions like Kronoberg or Norrbotten in Sweden, Lombardy in Italy and in a few Finish regions. The DIRAYA system in Andalusia represents a truly global benchmark, being well on its way to becoming the first true regional EHR system for a significant sized population (over 8 million) fully integrating all patient information from primary to tertiary care including emergency and in-patient care, also connecting all pharmacies, their logistics and billing.

Case 12: The Diraya EHR system in Andalucía, Spain

Diraya supports integrated healthcare in a region of over 8 million inhabitants. It involves a single regional electronic health record system shared by all health care providers, including pharmacies and hospitals. This critical initiative, which began in 1999, has been centralising more than 1,000 databases, specifying homogenous data and organising their structures. Each individual's health information from primary health care, pharmacies, specialised outpatient health care and hospital emergency care is integrated within this health record system. It can be accessed by authorised health professionals, as appropriate, at any time and in any location in Andalucía where the individual in question needs health care. It is used by about 95% of all primary health care professionals, while 75% of accident and emergency episodes rely on it. The initiative has been associated with a 15% reduction in visits to primary care practitioners by those patients receiving an electronic prescription for an episode of care or chronic condition that can be filled out several times within a twelve month period. Non-attendance at outpatient appointments was also decreased by 10% with a similar reduction in costs resulting from the use of a single centralised database replacing a range of local databases.⁶⁴

In the below table, the state of patient summary and EHR-like systems is summarised.⁶⁵ An attempt was made to group countries according to the stage of planning, pilots, implementation or routine operation. Implementation was here understood to be with reference to the declared national goal, meaning that the phase of piloting and testing of concepts has largely passed and the system is being rolled-out. This is the case for example in France where national roll-out is beginning in December 2010 or in the Netherlands, where the GP record is already in use regionally, but a national federation of data is still pending.

⁶⁴ Dobrev, Alexander et al. (2010). Interoperable eHealth is Worth it, op. cit.

⁶⁵ The numbers in the table regroup the EU-27 incl. England, Scotland, Wales and Northern Ireland, as well as Switzerland, Iceland and Norway.

Table 2: Deployment stage of patient summary and EHR-like projects in European countries, 2010

Planning	Implementation	Pilots	Routine	Sum
20	5	2	7	34

Source: eHealth Strategies study, 2010

4.1.3 Legal aspects of patient summary and EHR efforts

Obligation to keep patient health records

Nearly all European countries legally enforce a duty to keep a carefully updated and safely stored health record. This enforcement is often incorporated in patient rights regulation. In a large majority of the countries that recognise the right to a health record, the choice to keep the health record either electronically or on paper is still open. Belgium, Greece, Lithuania, Slovak Republic and Slovenia for example explicitly enable the maintenance of health records in either paper-based or electronic form. If in electronic form, additional requirements are sometimes set, such as requiring the use of electronic signatures and the adoption of other security related measures. The use of an electronic form is obligatory in very few countries at this time. As an example, the Finnish Client Data Act requires all public healthcare units to keep all health records in electronic form by 2011. A similar obligation is expected to be introduced in other countries as many are currently planning for electronic health record systems, and an electronic record will be created unless a citizen explicitly objects.

Opt-in or opt-out based electronic healthcare records

In all countries *trust* in eHealth systems by both citizens and professionals has been identified as one of, if not *the* key challenge; privacy is recognized as the most sensitive aspect of electronic health record systems. The question, whether the creation of a (shareable/national) electronic record for a specific patient should be opt-in based (the citizen has to explicitly agree to its creation) or opt-out based (the record will be established unless the patient explicitly refuses) is the most controversial one being addressed around the world and not only in Europe. Many countries are still debating what type of option to introduce.

Countries like Belgium, France, Italy, Spain, Iceland and Switzerland do require the patient to consent explicitly orally or in writing before an electronic health record may be created for her/him. In Spain, the requirement for explicit consent follows from the Health Law enacted in conjunction with the Data Protection Legislation. In Iceland, the Health Sector Database Act, enacted in 2002,⁶⁶ was heavily criticized for the fact that citizens were identifiable in the national opt-out database; the recently enacted Patient Rights Act⁶⁷ now requires the prior consent of the patient before information can be stored in any database. In France, an electronic health record can only be created after the consent of the patient, but once created the reimbursement rates are linked to the use of the record; the CNIL (Commission nationale de l'informatique et des libertés) did however point out

⁶⁶ Act on a Health Sector Database (No. 139/1998).

⁶⁷ Patients' Rights Act No 74/1997 (with amendments according to Acts 77/2000, 40/2007, 112/2008 and 55/2009), see: <http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20100>

that by linking reimbursement rates to the use of the DMP (Dossier Medical Personnel) the right to consent is at risk of being compromised.

Other countries have chosen to install an opt-out based system. Examples thereof are: Estonia, Poland Scotland, Slovak Republic and Sweden. In Estonia, the Amendment Act (Amending the Health Services Organisation Act)⁶⁸ lays down the general principles for the management of health information and sets ground for the automatic creation of electronic health records in the central Health Information System unless the patient objects to it. In Scotland, there is no explicit provision for the consent of the patient with regard to the creation of a health record. The dominant view in Scotland is that although the UK Data Protection Act⁶⁹ (which is in force in Scotland) does require explicit consent, this does not preclude obtaining consent on an opt-out basis. In the Slovak Republic, the Act on Health Care⁷⁰ states that maintaining medical records is an integral part of the health-care provision and therefore, consent from the patient is not necessary in order to create a medical record, whether written or electronic.

Three storage types of electronic healthcare record systems

Many countries' legislation furthermore reflects the storage type of electronic health record systems they opt for: centralised, decentralised or host-based.

In Belgium and The Netherlands – two countries that chose a decentralised system - specific laws are created to install a national “traffic control” platform. Spain also has gone with decentralised storage, and enforces it through its data protection legislation.

In countries which have decided on a centralized system, legislative changes often proved necessary in order to install the central/national repository; this was for instance the case in Czech Republic and Finland. In Finland, the Act on Experiments with Seamless Service Chains in Social Welfare and Care Services was enacted in 2000 with the aim to gain experience of arranging seamless service chains and of ways to optimise the use of information technology. This Act was followed by the Client Data Act covering archive services, encryption and certification services in 2007, and the Act on the Use of Electronic Prescription in 2008.

France is the best example of a country that went with a third option: a host-based electronic health record system. French users are free to choose a data-host for their health record. As prescribed by the French Decrees on Data Hosts⁷¹ and Confidentiality⁷², data hosts can only deal with health data after having obtained certification.

4.2 ePrescription

4.2.1 What is meant by ePrescription?

In the framework of the eHealth strategies study, ePrescription is understood as the process of the electronic transfer of a prescription by a healthcare provider in a primary care or community health centre setting to a pharmacy for retrieval of the drug by the patient. A necessary condition for this to occur is the recording of medications in the prescriber's office Electronic Medical Record (EMR) or other system in order to generate an

⁶⁸ As ratified by the Parliament on 20 December 2007.

⁶⁹ Data Protection Act (1998). Scottish Parliament.

⁷⁰ Act on Healthcare, No. 576/2004.

⁷¹ Decree on Data-hosts dealing with health related data, 4 January 2006.

⁷² Decree on Confidentiality, 15 May 2007.

electronic document, the medication prescription, to be transferred via communications connections to a specific pharmacy or a regional or national ePrescription repository. More advanced capabilities include the use of computer decision support to assist in the medication ordering process before the electronic transmission of the prescription.

Case 13: The epSOS ePrescription definition

The epSOS project defines ePrescription as a service “made up of electronic prescribing and electronic dispensing:

- ePrescribing is defined as prescribing of medicines in software by the healthcare professional legally authorized to do so, for dispensing, once it has been electronically transmitted, at the pharmacy.
- eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information of the dispensed medicine(s).⁷³

The ePrescription process in primary care needs to be distinguished from the use of computer technology in hospitals to facilitate the medication prescription and administration process. In those types of settings, the gold standard is a closed loop medication administration system which may include medication reconciliation and adverse drug event monitoring. Closed loop medication systems usually include an electronic medication administration record (eMAR) as well as the use of Computerized Provider/Physician Order Entry (CPOE) by physicians and/or other clinicians and support staff.

4.2.2 Current state of ePrescription in Europe

Only a few European countries have implemented a fully operational national primary care ePrescription service. But the majority of Member States (16) reported it as an element of their national eHealth strategy and/or implementation plan already for 2006, a number which has increased to 22 by 2010. At the national level, a full ePrescription process is used routinely only in Denmark, Estonia, Iceland, and Sweden. The Netherlands has established routine use of ePrescription in some regions, at different levels of penetration depending on the GP or hospital environment. Examples of pilots on ePrescription that are intended for eventual regional or national implementation can be found in the Czech Republic, Finland, Italy and Poland. At a national level, only in Denmark do patients have access to their medication profiles and are able to re-order certain repeat medications themselves, e.g. via a web service.

⁷³ epSOS Deliverable D3.1.2 Final definition of functional service requirements: ePrescription. Available at: http://www.epsos.eu/fileadmin/content/pdf/deliverables/D3.1.2_Final_Definition_of_Functional_Service_Requirements_ePrescription.pdf

Case 14: eRecept in Sweden

Currently already more than 85% of all prescriptions in Sweden are transferred from a doctor to a pharmacy electronically. There are two ways for an eRecept (electronic prescription) to be transmitted. The first is from a primary care electronic medical record system, which has been supplemented by a software module to permit sending an eRecept. The other route is by using secure web-based prescribing, which means that the doctor only needs a computer with Internet access although this is not used often. The electronic prescription form is available only to registered clinicians and, when completed, is securely dispatched through the healthcare digital network, a national eGovernment infrastructure. The 'e' part of the service is that prescriptions are being transmitted directly to any pharmacy from the GP's surgery as well as from all hospital facilities for outpatient and ambulatory care. When the eRecept has been produced, it can either be sent to a specific pharmacy or to the national ePrescription database. The database allows all pharmacies in Sweden to pick up an eRecept so that patients do not have to specify the pharmacy they use for their medicine - they simply choose the most convenient at the time. The database was introduced in 2004 and has been a success with all users, especially patients who enjoy greater flexibility and a wider range of services, such as a 24 hour call centre offering advice and home delivery.

Presently, efforts are ongoing to further develop an immediate online drug utilisation review of eRecepts issued by any professional. These checks are currently done in 10% of pharmacies upon dispensing the drug. Interaction control at the point of prescribing (e.g. in the GP office) is being tested; it immediately notifies the GP of potential mistakes, missed alerts, or drug-drug interactions such as:

- Early refill
- Duplicate therapy
- Drug-drug interaction
- Drug-disease interference
- Inappropriate dose (e.g. for children)

It is expected that this will considerably improve patient safety in this sensitive field.

The de-regulation of the Swedish pharmacy market has resulted in the establishment of a new, state-owned, company, Apotekens Service AB, owning and operating the national ePrescription infrastructure for all – now privately owned - 1,000 pharmacies. The same company also operates the interaction-control system mentioned.

In Spain, where healthcare is the responsibility of the regions, Andalusia has an advanced solution implemented across the entire region, which is connected to the patient record as well as a logistic and billing system for pharmacies. Currently, the Spanish government plans an extension of these kinds of services to the entire National Health System. As of July 2009, an ePrescription service was also implemented on the Balearic Islands and in Extremadura. Other countries such as Portugal have local implementations of ePrescription software in hospitals or pharmacies, but currently no electronic transfer of prescriptions from GPs to pharmacies is implemented.

A further example of ePrescription implementation can be found in Estonia. It is one of the few countries in Europe which has managed the entire ePrescription sequence from electronic capture of the prescription in the GP office to the electronic transfer and dispensation. Here, the ePrescription project is part of a large scale Digital Health Record effort.

Case 15: Digital prescription in Estonia

After a pilot phase, the Estonian Ministry of Social Affairs launched the central digital prescription service in January 2010. It enables medical personnel and pharmacies to monitor and manage all prescriptions. The system stores incoming prescriptions (messages) on a server of the Estonian Health Insurance Fund and sends patients' prescriptions on demand to a pharmacy's information system. The pharmacist identifies the patient using his/her ID card. If not specified otherwise, all prescriptions are public, i.e. another person can collect the prescribed drugs on behalf of the patient with the patient's personal identification code. A patient can also restrict the group of people who are allowed to receive her/his prescribed drugs, in which case an authorised prescription is issued; or a private one, restricted only the patient her/himself.

Even though healthcare budget cuts and technical difficulties with implementing the system had to be overcome in the beginning, the number of digital prescriptions has been growing steadily, reaching already over 750,000 ePrescriptions in March 2010.⁷⁴

The following table illustrates the state of ePrescribing ranging from the electronic capture to electronic transmission and electronic dispensation recording.

Table 3: State of ePrescribing in European countries, 2010

	eCapture	eTransfer	eDispensation
Currently available	15	9	7
Planned for near future	5	8	6
Unavailable	12	15	19

Source: eHealth Strategies study, 2010

4.2.3 Legal issues in ePrescription

In some countries, ePrescription in primary care is not being used in part due to national legislation forbidding or not addressing the electronic transmission of prescriptions and the use of electronic signatures. The legal requirements concerning ePrescription mostly deal with authentication and electronic signatures, patient consent, the possibility to obtain a paper copy, and in some countries the obligation to prior clinical examination.

In Wales, e.g., the new National Health Service (Pharmaceutical Service) Amendment Regulation of April 2010⁷⁵ requires that advanced electronic signature procedures must be applied for ePrescription purposes. The ePrescribing process must be based on mo-

⁷⁴ Estonian Health Insurance Fund. "FAQ – digital prescription." Retrieved 17/11/2010, from http://www.haigekassa.ee/eng/digital_prescription/faq. Cf. also: <http://eng.e-tervis.ee/lithuania-will-use-estonia-experience.html>: "Since January 2010 ... around 85 % of the medical prescriptions have gone digital."

⁷⁵ National Assembly for Wales (2010): The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010. 868. Available at: <http://www.legislation.gov.uk/wsi/2010/868/contents/made>

dalities that the signatory can maintain under its sole control. Any subsequent change of data must be detectable.

In Finland, the Act on the Use of Electronic Prescriptions⁷⁶ and a Decree of the Ministry of Social Affairs and Health concerning electronic prescriptions state that the patient's consent is not required for issuing an electronic prescription, but the patient will have the right to receive the prescription on paper. When the prescription is electronic, the patient furthermore needs to be informed about the national database service so that s/he is aware of the data exchange and archiving operations that will take place. In France, the Healthcare Insurance Act⁷⁷ allows prescription by email only after the healthcare professional has performed a prior clinical examination.

The introduction of electronic pharmaceutical services usually requires that specific legislation be passed. In France the law no. 2007-127⁷⁸ introduced a pharmaceutical record for every beneficiary of social health insurance. Contrary to the nation-wide electronic health record, which is opt-out based; the pharmaceutical record is optional and is thus opt-in based. The patient has the right to refuse the update of the record with specific drug information, refuse access to it, and close it. In Belgium, the Royal Decree containing instructions for the pharmacist was amended in 2009⁷⁹, introducing an obligation by law for the pharmacist to register certain data related to prescribed medication. It also introduced a more elaborate opt-in based pharmaceutical record. .

4.3 Telehealth

Telehealth applications may concern service delivery from a healthcare provider or wellness service to a citizen, among health professionals, or among citizens and family members. European Commission services defined telemedicine as “the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location”. In its 2009 *Communication on telemedicine for the benefit of patients, healthcare systems and society*, the Commission emphasised the value of this technology for health system efficiency and the improvement of healthcare delivery.⁸⁰ It was mentioned as a key application domain already in the 2004 eHealth Action Plan.⁸¹

⁷⁶ Ministry of Social Affairs and Health [Finland] (2007). Laki sähköisestä lääkemääräyksestä [Law on ePrescription]. Available at: <http://www.finlex.fi/fi/laki/alkup/2007/20070061>

⁷⁷ LegiFrance (2010). Loi n°2004/810 sur l'Assurance Maladie [Healthcare Insurance Act]. Available at: <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000625158>

⁷⁸ LegiFrance (2007). Loi n°2007-127 à l'organisation de certaines professions de santé et à la répression de l'usurpation de titres et de l'exercice illégal de ces professions et modifiant le code de la santé publique. Available at: <http://bit.ly/h0VzS9>

⁷⁹ Ordre royal portant instructions pour les pharmaciens (2009). Publié le 30 janvier 2009. Available at: <http://www.ordredespharmaciens.be/fr-BE/news/AR%2021%20janvier%202009%20+%20annexes.pdf>; See also: Arrêté royal du 7 juin 2009 réglementant le document électronique remplaçant, dans les hôpitaux, des prescriptions du médecin compétent et du praticien de l'art dentaire compétent, en exécution de l'article 21, alinéa 2, de l'arrêté royal n° 78 du 10 novembre 1967 relatif à l'exercice des professions des soins de santé (2009). M.B. 1er juillet 2009. Available at: <http://www.belgiquelex.be/V2/belgiumlex/website/fr/>

⁸⁰ European Commission (2008). COM/2008/0689: Communication on telemedicine for the benefit of patients, healthcare systems and society. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0689:EN:NOT>

⁸¹ European Commission (2004). eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area. Brussels: COM(2004)356 final.

4.3.1 The telehealth landscape in Europe

The analysis of the country reports reveals that all countries surveyed report at least small local telehealth or telemedicine pilots, a minor increase (+4) from the already high level of such experimental implementations reported in 2006. This concerns mostly telemonitoring applications for chronically ill patients, access to care from a distance in scarcely populated areas, sharing of patient data and coordination of services between health and social care providers, and telecare provision as an element of case management for particularly expensive patients.

Perhaps the largest, still experimental implementation is reported for England. Its "Whole System Demonstrator (WSD) programme is a two year research project funded by the Department of Health to find out how technology can help people manage their own health while maintaining their independence. The WSD programme is believed to be the largest randomised control trial of telecare and telehealth in the world to date."⁸² It covers various aspects of support for independent living at home as well as health and social care.

At the European level, the RENEWING HEALTH (REgioNs of Europe WorkINg toGether for HEALTH) project will start to implement in 2011 "large-scale real-life test beds for the validation and subsequent evaluation of innovative telemedicine services using a patient-centred approach and a common rigorous assessment methodology. It involves 9 of the most advanced regions in the implementation of health-related ICT services, where service solutions are already operational at local level for the telemonitoring and the treatment of chronic patients suffering from diabetes, chronic obstructive pulmonary or cardiovascular diseases."⁸³ It is a so-called Large Scale Pilot partially supported from the European Community's Competitiveness and Innovation Framework Programme.

However, the wider use of such services at the national level is still the exception and is reported for Nordic countries only: Denmark, Sweden, Norway, and Finland. In Poland, a move from local pilots to large scale regional pilots is planned for 2011.

A number of countries, outside of the Nordic ones already mentioned, have explicit national strategy documents for telehealth implementation. Examples can be found in Slovak Republic, Romania and Spain, and regional activities in Spain and Italy.

First signs are emerging that some countries begin to tackle the issue of reimbursement rules for telehealth services. Examples are legal changes in France in the framework of the healthcare reform law HPST⁸⁴ and the UK National framework agreement for telecare, which defines a list of telemedicine items cleared for purchase within NHS England.⁸⁵

⁸² Department of Health [UK] (2009). Whole Systems Demonstrators - An Overview of Telecare and Telehealth. London: Leaflet, 16 June 2009. Available at www.dh.gov.uk/en/healthcare/longtermconditions/wholesystemdemonstrators

⁸³ For details, see <http://www.renewinghealth.eu/>

⁸⁴ Ferraud-Ciandet, Nathalie (2010). French eHealth Policy, Global Telemedicine and eHealth Updates: Knowledge Resources, Volume 3, Proceedings of Med-e-Tel 2010.

⁸⁵ NHS Purchasing and Supply Agency (2006). National framework agreement for telecare - part A (including equipment, installation, maintenance, monitoring and response services). Reading, June 2006. Available at: http://www.eastmidlandsiep.gov.uk/documents/news_info/Telecare%20Contract%20Info.pdf

Case 16: Telehealth services in Hull, United Kingdom

The Hull telehealth service model is an exemplar of integrated care for chronic patients, delivered by a variety of health service providers working collaboratively in the community. Services are delivered in partnership between National Health Services (NHS) Hull and a number of other providers: the University of Hull, NHS City Health Care Partnership, Hull and East Yorkshire Hospitals NHS Trust, and Hull Churches Home from Hospital. They deploy technology and complementary services provided by various industrial partners and the national NHS Direct service.

Currently, a key priority is to extend the telehealth offer from one focused only on monitoring to one that encourages self-care. For example, non-adherence to a medication regime is a major cause of suboptimal clinical benefits, so decision support software that motivates patients to adhere to their treatment plan has been developed. To support self-management by those patients who are capable and motivated to do so, a closed-loop disease management solution feeds back the short- and long-term effects of their treatment, based on the physiological and statistical modelling of medication and lifestyle effects.

Telehealth services are currently offered to patients with heart failure (HF) or chronic obstructive pulmonary disease (COPD). These services use technology as the enabler for better services, providing practitioners with the information necessary to deliver evidence-based, individualised care. Over 240 patients have benefited from the HF telehealth service, and this number is continuing to rise at around 12 per month.

The COPD telehealth service is delivered via the community-based long term conditions team of City Health Care Partnership, and approximately 40 patients are currently receiving the service. It has been very successful and popular with patients and staff alike. As a result, NHS Hull has an agreed commissioning strategy in place to increase local capacity by 100 patients per year to reach full capacity of 400 patients per year by 2014.

The HF telehealth service is delivered by secondary care nurses based within Hull and East Yorkshire NHS Trust. Patients are predominantly referred into the service from secondary care, following an acute admission with new or decompensated heart failure. As discharge from hospital nears, a liaison nurse makes the referral to the telehealth team, who arrange for equipment to be installed by the industry supplier. Patients are consented, and receive a home visit by a charity worker and nurse to assess the environment and explain how the equipment is operated. Once the equipment is installed in their home, patients record their weight, blood pressure and pulse on a daily basis. They also answer questions regarding their well-being, including any signs or symptoms that they are experiencing. These data are sent via a secure server to a telehealth nurse, who is automatically alerted to any unexpected findings (for example, an increase in weight or report of breathlessness). In response to these alerts, the telehealth nurse may contact the patient directly via the telephone to offer advice, or may refer the patient onto a community practitioner for a face-to-face visit. The heart failure telehealth service offers both improved outcomes for patients and reduced costs for healthcare providers. It is extremely popular with patients and carers, and saves around £1,000 per patient per year in avoided hospital admissions.

4.3.2 Legal issues in telehealth

The amount of legal and regulatory documents available on telehealth is considerably smaller than on electronic health record implementations. Two causes for this can be identified: first of all telehealth applications are less advanced than electronic health record systems, and secondly there is a tendency to regard the use of telehealth services to be less problematic under current legal frameworks, so that the usefulness of legal provisions dealing with telehealth specifically is questioned. In Belgium, the Czech Republic, Greece, Italy and the Netherlands there do not seem to be any major legal obsta-

cles for the use of telehealth applications, even though no specific regulations were passed. On the other hand, a number of countries report that legal issues are still an obstacle towards wider deployment (e.g. Austria, Cyprus, Hungary).

The three most common regulatory issues with respect to telehealth are: a) the requirement to treat a patient in person, i.e. in direct face-to-face contact; b) accreditation is not available for professionals, and c) the liability of the provider of telehealth services is uncertain.

Treatment in person

The requirement to render medical services face-to-face means that telehealth services from professionals to patients are not allowed (e.g., Austria⁸⁶). The Polish Act on the Professions of Physician and Dentist⁸⁷, too, requires that a diagnosis is made only after personally examining the patient. However, the Austrian guideline on 'Physician and Public'⁸⁸ specifies that the use of telemedicine can be accepted in case of an emergency. In Malta, on the other hand, online interaction or telephone-based consultations by the family doctor are not accepted as professional practice. In some countries these rigid requirements are now under discussion, and revisions may be expected. In England, the question whether a doctor is obliged to physically attend a patient arose in another than telemedicine context, but it was concluded that there is no general principle requiring the physician to do so.

Accreditation

The issue of accreditation and relevant training arose in particular in England. The British Medical Association therefore issued in 2007 its own recommendations with regard to the need for training in supporting self and home-care by ICT facilitated means. Their recommendations state that education in rendering telehealth services should be included in the medical curriculum and that healthcare professionals should be rewarded for undertaking learning and skills development.

Liability

Sometimes, liability issues are complicating the delivery of telehealth and telemedicine services. However, when telemedicine is used at the national level, most countries seem to apply their general regulatory framework by analogy. This is for example the case in Denmark. The Danish Board of Health concluded in its legal guidelines⁸⁹ regarding the liability and other legal matters in connection with the provision of telehealth services by practitioners that the usual legal rules apply as well. In Belgium jurisprudence ruled that the laws applied to the liability of physicians who provide medical advice to patients by phone are the same as those for traditional liability for negligence.⁹⁰

Both in England and Scotland, NHS Direct services make heavy use of nurse telephone advisers for consulting patients. The Scottish NHS service came under scrutiny in 2008

⁸⁶ Physician Act (Ärztegesetz) 169/1998. Austria.

⁸⁷ Act on the Professions of Physician and Dentist. Poland. 5th December 1996.

⁸⁸ Richtlinie "Arzt und Öffentlichkeit". Austria. Available at: <http://www.aerztekammer.at/service/Werberichtlinie2004.pdf>

⁸⁹ Guideline nr. 9719, 9th November 2005. Denmark.

⁹⁰ Court of Appeal Liège 3 October 1995; Jurisprudence de Liège et Mons 1996, page 742: a physician was held liable for the death of a child who had eaten poisonous mushroom; the court considered that the physician committed a serious professional fault by giving merely medical advice by telephone.

when a patient died who had been wrongly diagnosed after a telephone consultation. In legal terms, however, the fact that the advice was given by telephone rather than in a face to face situation would not per se impact upon the existence or extent of liability.⁹¹ The misdiagnosis was not only made by the NHS 24 advisor, but also by the GP visited at the Primary Care Emergency Centre.

Whereas at the national level few barriers seem to exist, the lack of clarity concerning liability rules when practicing telemedicine in a cross-border context seems to cause some restraints to offering cross-border telemedicine services. Although EU private international rules such as the Rome I⁹², Rome II⁹³ and Brussels I⁹⁴ regulations are in place to determine the national applicable laws and competent courts under normal circumstances, the virtual cooperation of several actors in the field of medicine and social security, under several liability rules, causes confusion. As a consequence social security services were excluded from the scope of Brussels I.⁹⁵ The numerous guiding factors in these regulations, which patients can use to determine where and what type of complaint they want to issue, complicate the delineation of liabilities by healthcare practitioners or companies.⁹⁶ The confusion is furthermore enhanced by the often complicated controller – co-controller – processor relationships. It is therefore not surprising that no examples of such cross-border services were recorded in the country reports.

⁹¹ Cases 200502301 & 200600457: NHS24 and Lanarkshire NHS Board, available at: http://www.spsso.org.uk/webfm_send/780

⁹² Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations. (Rome I). Official Journal of the European Union L 177 (4.7.2008), pp. 6-16.

⁹³ Regulation 864/2007 on the law applicable to non-contractual obligations.

⁹⁴ Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

⁹⁵ Article 1, c) Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

⁹⁶ See for example S. Callens and J. Ter Heert, "Juridische beschouwingen bij telegeneeskunde", *T. Gez.* 1999-2000, 313.

5 Infrastructure implementation aspects

To allow for the ubiquitous, but secure access to health data across jurisdictional boundaries, an all-embracing eHealth infrastructure is indispensable. Elements concern items like governance rules and processes, competence centres and supporting organisational structures, secure, unique identification of patients, health professionals and service provider entities, security and data privacy, regulation of technical and semantic standards,.

Such an environment will allow for a network effect to kick in, also known as user externality. The more people use a network, the greater is the value to each of them. When such a network effect is present, the value of a product or service increases as more people use it. Unless it is a regional or national health institution, individual service providers usually do not have an incentive to establish such an infrastructure, i.e. we have a market failure situation where this 'public good' problem can only be solved by a policy intervention, e.g., at government level, a union of health service providers or a group of Third Party Payers.

In this context, the following sections will briefly summarise the status achieved with respect to electronic identifiers, eCards, standards, and semantic issues – which remain for Europe the grand challenge.

5.1 Electronic identifiers

A key component of any national or regional eHealth infrastructure is the ability to uniquely identify electronically citizens/patients, healthcare professionals, healthcare providers, and pharmacies.⁹⁷ This is a central requirement to assure patient safety and an unambiguous relation between a patient and his data. Whereas patient identifier (ID) was an element of eHealth strategies in most countries (24) in 2006 and increased by only two in 2010, the challenge of professional IDs was neglected till recently (mentioned by 13 only in 2006), but is now an acknowledged topic in 22 countries. The study shows that there are quite different approaches across Europe to addressing these challenges.

Patient IDs

In Scandinavian countries, a long tradition of various citizen registers using the same identifier facilitates the creation of healthcare IDs for patients and doctors. On the other hand, the diverse administrative identification systems which are in use in most other countries cannot and will not automatically be used for healthcare purposes. These ID systems often do not meet the country's strict health system privacy criteria, because they contain information that is traceable to a particular person, such as the date of birth or gender. Examples of patient IDs that are specifically created for the purpose of electronic health service provision (as opposed to social security or citizen IDs) can be found in France, Germany, and Greece. In most of the Central and Eastern European Member States of the EU, a tradition of a single national citizen ID prevails from socialist times, even though the identifier sometimes contains information such as the date of birth. This will probably lead to a review of these identifier systems, once eHealth systems become ready for roll-out.

⁹⁷ Depending on security and liability regulations, also the unique identification of locations and devices/hardware may be required.

Case 17: Trust Centre for unique patient identifiers in Germany

A Trust Centre for the Health Insured Number (Vertrauensstelle Krankenversichertennummer) was founded in 2007 to develop a safe system to determine a unique number for each German citizen. This number is based on a mathematical algorithm deriving the new number from the social security number which is now assigned at birth to every citizen. This complex procedure meets all data protection requirements as specified by law (§ 290 Health Insured Number of the Social Law book V on Health Insurances) and cannot be traced back to the original social security number.⁹⁸

The national associations of the different types of German compulsory health insurance providers mandated the establishment of the Trust Centre and sustain it. The Trust Centre operates under the legal control of the Ministry of Health, and works together with the Federal Office for Information Security.

The identification number will be valid lifelong, across all German states (Bundesländer), and will be retained also when changing the insurance company. The personal, unchangeable part of the number consists of ten digits (numeric and alphanumeric), and is combined with a part identifying the insurance provider and another part indicating whether the person is covered by the insurance of a family member instead of being insured individually.

Professional IDs

With regard to healthcare professionals, the situation of identifiers is complex and defies a clear quantitative measurement. This is due to a wide variety of approaches towards assigning responsibility for issuance and management of electronic IDs (professional chambers, central government, insurance companies, special agencies). Another confounding factor are the quite disparate definitions of which professions are indeed to be regarded as health professions *and* in need of an electronic ID in the context of national eHealth infrastructures (e.g., nurses and midwives are excluded from official electronic healthcare professional registers in some countries).

5.2 eCards

In the context of patient and professional ID management, eCards are widely used across European countries as a token for basic ID and insurance verification purposes as well as for access to eHealth infrastructure applications. But the concrete realisations are of such a great variety that any quantitative assessment remains very vague and imprecise. This concerns the type of card - simple plastic cards, cards with a magnetic strip to carry basic data, various types of smart chips imbedded in the card -, the data stored on the card - usually only basic administrative data, sometimes also more detailed data on the insurance status, but up to now rarely any clinical data - as well as the sophistication of the security features. In addition, some cards are multi-purpose cards, i.e. they have not necessarily been introduced for eHealth purposes, but can, like general purpose electronic ID cards, be used in eHealth environments. Or, alternatively, eHealth Insurance Cards can be used for accessing eGovernment services as well.

Patient eCards

Citizen cards to be used in the health system environment are a topic in most European countries' eHealth documents. Already in 2006, 22 mentioned their planned use as an ID

⁹⁸ See: <https://kvnnummer.gkvnet.de>

token, and this number has slightly increased to 25. Virtually all cards issued so far by European countries are only electronic health *insurance* cards, not eHealth cards in the proper sense of carrying medical information.

Patient eCards are often based on or equivalent to multipurpose eCards for eGovernment services - including healthcare. In Finland for example, when providing citizens with a personal identity code, the Population Register Centre creates also an electronic identity for them (FINEID). The electronic client identifier is used for electronic user identification in secure online transactions. It is a dataset consisting of a series of numbers and a check character that helps identify Finnish citizens. In Portugal, an eCard for patients was deployed, that integrates previously issued cards in the field of personal identity card, taxpayer's card, social security card, voter's card and health system card. Their eID is a smartcard that provides visual identity authentication, with increased security, and electronic identity authentication based on biometrics (photo and finger print) and electronic signature features.⁹⁹ Similarly, in Austria the Patient ID is the social insurance number in combination with a cryptographic process which makes the ID unique. The token is an eCard with the extension to a citizen card for eGovernment services. In September 2007, Bulgaria started issuing its first electronic health cards as part of a small pilot project launched by the Ministry of Health and the National Health Insurance Fund (NHIF). Each eHealth card is equipped with a microchip that stores data about the patient and the issuer, including the card number and a security certificate. With this information, the patient's insurance status and his/her assignment to a General Practitioner can be automatically checked. In addition, it is planned to later also record electronic prescriptions for medications covered by the Bulgarian health insurance fund on the chip.

Case 18: Using the citizen eID card for health services in Belgium

To uniquely identify a patient, two types of eCards are in use in Belgium. So far, the insurance status of a person has been documented by a social security (or "SIS") card issued since 1998 by the national sick funds at a person's birth. It will be phased out as the new national eID Card becomes available more broadly. Social security and health insurance status verification will take place using this card bearing a unique identification number.

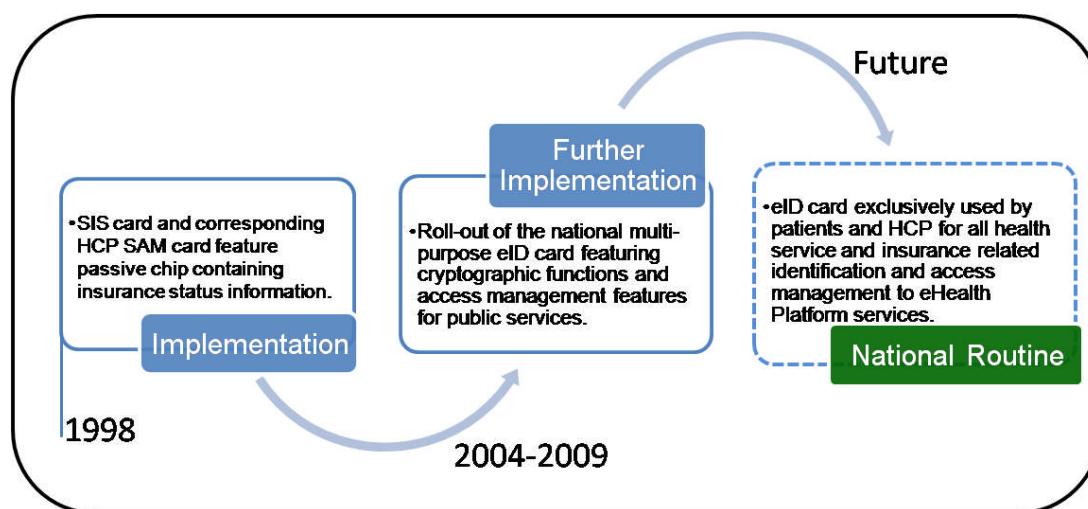
Assigning an identification number (National Unique Identifier) to citizens started in 1968 and was legally endorsed in 1983, resulting in a centralised national register of physical persons. The register is maintained by the Ministry of Internal Affairs. The national eID card with the national eID number was introduced in 2004, and rollout to nearly all inhabitants has been finalised in 2009. The national eID cards are issued by the Federal Government in three different versions: The standard eID card for each Belgian citizen over the age of 12, one for children, and one for non-Belgian inhabitants of the country.

The multi-purpose eID card has a pin-protected chip with cryptographic functions and is used for enabling access to public eServices (libraries, museum, etc.), for tax purposes and for signing eDocuments. It will not carry any other than administrative information. Rather, specific patient data, e.g. emergency data, clinical information or the insurance status, will be made accessible on secured central servers via the Belgian eHealth Platform, with the eID card serving as key.

⁹⁹ See "New electronic identity card enables patients to look after their records" at <http://www.ehealthurope.net/Features/item.cfm?docId=238>

The development and implementation stages of eCards in Belgium are illustrated in the following figure:

Figure 2: eCards in Belgium



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Professional eCards

The interest to use eCards as a token for professional ID and as access means to eHealth systems has increased considerably in recent times, from only 7 countries reporting such activities in 2006 to 18 in 2010. In nine European countries, smartcard systems for healthcare professional identification are already in place.¹⁰⁰ An essential prerequisite for a functioning healthcare professional identifier is a functioning system of healthcare professional registration, which may not always be located at the national, but rather at the regional level such as in Italy.

In Lombardy, Italy, professionals can no longer work in the healthcare system without their electronic ID card at hand. In Estonia, ID cards are used for visual identification of persons, to access different services, for electronic identification and for digital signatures. They can be verified against the Population Registry. Health care professionals use this eID card, like other citizens. Through the assignment of IDs to every professional, status confirmation can be requested through the MISP server (Mini Info System Portal). This portal is part of the "X-road project"¹⁰¹ and enables professionals to be identified as a registered professional as well as having access to a specific patient's data and medical information. In Finland, a dedicated healthcare professional eCard was introduced. The card is validated against the VALVIRA Central Register of Health Care Professionals TERHIKKI (established in 2009), which offers an authentication database service describing the capacity and competences of the medical professional. The healthcare professional card in France is currently shifting from being based on an older numéro ADELI (Automatisation DEs LIstes), a 9 digit identifier for all healthcare professionals including

¹⁰⁰ HPRO Card Project, WP2, Deliverable 3: Mapping of smart cards, identifiers and frames of reference of health professionals in the Member States, p. 25-26. Available at: <http://www.hprocard.eu/images/20091012-hpc-wp2-deliverable3.pdf>

¹⁰¹ The X-Road project was preliminarily initiated for interconnecting Estonian governmental databases to a common data resource accessible over the Internet. After the successful start of sending database queries and answers, the X-Road environment was expanded to send all kinds of XML-format electronic documents securely over the Internet.

social workers and psychologists - which is composed from administrative data and stored currently on the healthcare professional card (CPS) - towards a system where the ID is provided through a recently installed "Distributed repository of healthcare professional data" (RPPS). The distribution of the new eCard for healthcare professionals, which provides higher ID security through electronic access to the RPPS, has already begun for certain groups of healthcare professionals such as hospital doctors.

5.3 Standards

Establishing and managing the life cycle of technical and semantic standards are core elements of any national infrastructure. Here also a remarkable boost in activities can be observed. Nevertheless, semantic interoperability still remains a grand challenge.

5.3.1 A boost in standards related activities

There is now a wide recognition across European countries of the relevance of standardisation efforts for realising the benefits of eHealth. The encouraging increase in reported standards-related activities from 19 in 2006 to 27, i.e. for all Union countries, is witness to this stark change in assessing the pivotal role of standardisation. Indeed, such issues and related interoperability challenges are not just mentioned as policy elements, but are key topics in the agendas of national (and regional) eHealth strategies, roadmaps and implementations. Everywhere Member States are working with stakeholders to develop strategies for standards development, interoperability and wider implementation actions, certification, conformance testing, maintenance of standards and management of their life cycle, and deployment support.

The instrumental stimulus of the *EC Recommendation on EHR interoperability*¹⁰² is widely acknowledged and its recommendations are carefully studied. Similarly, countries participating in the above mentioned European-wide epSOS project explicitly underlined the impact of epSOS decisions and choices of standards on national activities and the importance of participating in these processes.

5.3.2 Authorities in charge of eHealth standardisation

Almost all countries have some kind of national body directly responsible for eHealth standards development or for overseeing standards development and implementation. Ministries of Health and their respective units play a key role in some countries, e.g., the Directorate of Health in Iceland, the Ministry of Health in Italy, the National Board of Health and Welfare in Sweden, the Department of Health Informatics Directorate (DHID) in England. In others, they complement partially the activities of other actors, like in Belgium, where the Ministry of Health is dealing with content-related standards for several medical professions, and the National Health Insurance Institute with coding schemes related to billing.

In other countries, national competence authorities or similar agencies have been charged with responsibilities for assuring technical interoperability and harmonised national standards, like ELGA GmbH in Austria, the eHealth Foundation and the Centre for Standardisation in Estonia, ELOT S.A. in Greece, the Quality Agency of the National Health Service of the Ministry of Health in Spain, the Hungarian Standards Institute in Budapest, the Centre for Health Economics in Latvia, the Centre for Information Systems

¹⁰² European Commission (2008). "Commission Recommendation on cross-border interoperability of electronic health record systems" COM 2008(3282) final, 02.07.2008.

in Healthcare (CSIOZ) in Poland, or the Health Informatics Standards Board in Slovenia. In some countries, a national panel or institutional body is authorised explicitly by law to take decisions about eHealth standards, like the eHealth-Platform in Belgium or the Health Information and Quality Authority (HIQA) in Ireland.

Case 19: Localisation of European and international eHealth standards in Greece

ELOT S.A., the “Hellenic Body for Standardisation”, is the national standardisation organisation in Greece mandated by law. ELOT establishes sectoral technical committees (STCs) to deal with standardisation in specific domains, one such sector being health-care. In order to support national priorities in eHealth, ELOT set up a Technical Committee subordinate to the sectoral technical committee on health to closely follow up and report on European and international standardisation in eHealth as well as localise and adopt European technical specifications that emerge from the epSOS large scale European pilot. Activities include for instance the localisation and maintenance of the epSOS technical semantic sets. Currently, members of the sectoral technical committee on eHealth are:

- Ministry of Health; General Secretariat of Social Security; General Secretariat of Public Administration and eGovernment; Foundation of National Insurance
- Hellenic Medical Association; Hellenic Nursing Association; National Organization for Medicines; Hellenic Pharmacists Association
- Institute of Communications and Computer Systems (ICCS); Informatics Laboratory, Aristotelian University of Thessaloniki
- HL7 Hellas

Where no national institution has the competence to take binding decisions on standards, a workgroup may be coordinating such activities. E.g., in Switzerland a sub-group on standards and architecture of the “eHealth Suisse” Initiative is dealing with interoperability issues.

5.3.3 Standards in use

The majority of countries require the application of European and international standards. Standards currently in use include: HL7 V2 and V3 (Health Level 7, version 2 and 3) - fifteen countries, CDA R2 (clinical document architecture, release 2, an HL7 V3-based standard) - eight countries, ISO 13606 for electronic health record communication - eight countries, DICOM (Digital Imaging and Communications in Medicine standards) - eight countries, LOINC (Logical Observation Identifiers Names and Codes) - four countries. Various other standards are mentioned, including implementation standards for specific applications like KMEHR (Kind Messages for EHR) and SUMEHR for patient summaries in Belgium.

However, such standards are often not specific enough to assure interoperability, they may not be complementary, or even contradictory. Therefore, to indeed allow for interoperability at various levels, they need further agreement on more detailed specifications. Here organisations like IHE - Integrating the Healthcare Enterprise¹⁰³ -, or the Continua

¹⁰³ www.ihe-europe.net

Health Alliance¹⁰⁴ work on such detailed specifications. Their activities are closely followed by several countries, in spite of these organisations not being registered as official Standards Development Organisations (SDOs).

Mandate 403 issued by the European Commission to three European standards development organisations (ESOs) - CEN, CENELEC, and ETSI - to develop a coordinated work programme for standardisation in health informatics, and the eHealth-INTEROP activity in response to this mandate have been closely monitored by most countries as well.

Furthermore, some countries report participation or at least great interest in standards related activities by EC funded projects such as eHR-QTN: Thematic Network on Quality and Certification of EHR systems. Overall, certification of eHealth systems as well as conformance testing are becoming increasingly common for many countries. Education and training in the use of standards is mentioned as another key challenge. Other issues include the wide diversity of incompatible standards, the need for long term, sustained standardisation policies, or the need for an elaborated (European-wide) interoperability framework. Improved health professional involvement, IPR (intellectual property rights) issues and costs are also mentioned.

5.3.4 Semantic issues remain the grand challenge

It is widely recognised that semantic interoperability is *the* key factor for realising a wide range of expected benefits from the implementation of eHealth infrastructures and applications. This holds not only for the regional or national level, where in many countries multiple languages may be involved (e.g., 2 in Finland, 3 in Belgium, 4 in Switzerland), but even more so in trans-border and pan-European situations, where potentially more than 20 languages and three alphabets are concerned. For improving health services quality and patient safety it is mandatory that the electronic exchange and analysis of health and clinical data allows the involved professionals to fully understand and act on the information received.

A key driver of developments in this field is the global International Health Terminology Standards Development Organisation, IHTSDO (SNOMED CT - systematic nomenclature of medicine, clinical terms) in Denmark, where by now also ten European countries are members: Cyprus, Denmark, Estonia, Lithuania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and the United Kingdom (i.e., England, Northern Ireland, Scotland, Wales). Discussions about the use of SNOMED CT are underway in many other countries, e.g., Belgium, Luxembourg and Poland. Bulgaria is contemplating translation of (sets of) SNOMED CT in 2012. A few countries have translations of older versions of SNOMED (Hungary, France, Germany) and are discussing possibilities for transition to present SNOMED CT.

The WHO-developed and maintained International Classification of Diseases (ICD-10) is in use in eighteen countries,¹⁰⁵ whereas its older version ICD-9 is still being used in seven countries; some of the latter apply both versions in different implementations. Official implementation of ATC (The Anatomical Therapeutic Chemical [ATC] Classification System), used for the classification of drugs, has been reported by four countries.

¹⁰⁴ www.continuaalliance.org/

¹⁰⁵ As WHO maintains the ICD only at a relatively high level (up to level 3), national implementations exposing a finer granularity (up to level 5) are not necessarily compatible or interoperable at the more detailed level.

In some countries, health institutions or communities tend to choose and/or develop semantic standards according to their specific idiosyncratic cultural contexts and needs. An interesting initiative to coordinate such developments was launched in Belgium with the aim to analyse the feasibility of a federal “terminology service” to deal with all terminologies and classifications used in the country through a federally compiled so-called Controlled Medical Vocabulary (CMV) service.

The epSOS project has also made considerable advances in the area of semantic services, defining a commonly agreed medical terminology which is based on value sets extracted from existing, internationally approved code systems, namely the epSOS Master Value Sets Catalogue (epSOS MVC).¹⁰⁶ The content of the epSOS MVC will also be provided in an ontology (coded in OWL¹⁰⁷) to foster semantic interoperability across Europe.

¹⁰⁶ See Deliverable D3.5.2 of the epSOS project, available at: <http://www.epsos.eu/work-plan.html>

¹⁰⁷ More information available at: <http://www.w3.org/TR/owl2-overview/>

6 Summary and recommendations

In virtually all the European countries surveyed, the political as well as stakeholder interest in eHealth policies and *the planning and implementation of national or regional infrastructures has gained considerable momentum*. This concerns not so much the number of new priority goals identified, infrastructure components tackled or pilots run, but rather the overall level of awareness, activities, and concrete undertakings.

EC as well as Member State initiated activities and co-operations like the large-scale, pan-European epSOS project or the Member States driven European eHealth Governance Initiative have both significantly contributed to this state of affairs and are witness thereof.

6.1 eHealth Action Plan progress

Significant progress on several key dimensions of the eHealth Action Plan of 2004 was achieved. The most noteworthy one has been the strongly increased commitment of national and regional health authorities to provide leadership to eHealth implementation efforts, underlined also by the remarkable growth in assessment and evaluation activities. Whereas in 2006 only 5 Member States reported related intentions, in 2010 already a considerable majority of 21 states mentions such undertakings - this is the largest increase in attention of all topics surveyed. The scope and procedures used are very diverse, however. Furthermore, by now all countries surveyed have either established specific competence centres or/and have dedicated departments in ministries.

Some kind of national patient summary or electronic health record-type system is a consistent element in all strategies and roadmaps. Some progress can be registered, but the vast majority (20 of 34) of European countries surveyed are still at the planning stage. This is not a surprising result because their full implementation presupposes the availability of various infrastructure components.

ePrescription is another key application which the majority of countries mention as a part of their national eHealth strategy. It is used here to mean the electronic capture and transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the medicine by the patient. The majority of Member States (16) reported it as an element of their national eHealth strategy and/or implementation plan already in 2006, a number which has further increased to 22 by 2010. However, up till now, only a few countries have indeed implemented a fully operational national system.

With respect to telehealth applications delivering services for patients, all countries surveyed report at least small local pilots, a minor increase (+4) from the already high level of such experimental implementations reported in 2006. But the wider use of such services at the national level is still the exception.

Progress towards establishing a common national eHealth infrastructure as a mandatory basis for the further diffusion of eHealth applications is also significant. The ability to uniquely identify electronically citizens/patients is a central requirement to assure an unambiguous relation between a patient and her/his data. Whereas a patient identifier (ID) was an element of eHealth strategies in most Member States (24) in 2006 and increased by two in 2010, the challenge of professional IDs was somewhat neglected till recently (mentioned by 13 countries only in 2006), but is now an acknowledged topic in 22 states.

A noteworthy increase in standards-related activities from in 19 Member States in 2006 to

27 in 2010 was reported, i.e. for all Union States. This is witness to the by now wide recognition of the pivotal role of standardisation for the wider diffusion of eHealth. Indeed, such issues and related interoperability challenges are not just mentioned or under scrutiny, rather they are key topics in the agendas of national (and regional) eHealth roadmaps and implementation plans.

Legal and regulatory issues remain a very diverse and complex field, but here, too, considerable progress can be noted; an increase of focused attention from in 14 to 22 countries was recorded. With regard to health record systems, a key application, nearly all European countries legally enforce a duty to keep a carefully updated and safely stored patient health record, but most keep the option of storing it on paper or electronically open. If opted for an electronic form, additional requirements on content, access, and security often apply. It is expected that the obligation to store the records electronically will arise in more and more countries, if only because many are currently rolling out national patient summary or electronic health record systems that will be opt-out based.

6.2 Synthesising European experience

The impetus of the eHealth Action Plan of 2004 and the clear identification of common challenges there has initiated and massively contributed to a heightened degree of activities in Member States. Across Europe eHealth has matured from a policy debate to a very tangible, implementation oriented endeavour. From this experience, seven key success factors can be identified.

Leadership: Politicians must assure a comprehensive health policy dialogue leading to clearly defined goals specifying where eHealth solutions should substantially contribute to better quality and safety of health services, access for all, and long-term sustainability. Reaching agreement about eHealth strategies and, even much more so, implementing them has almost everywhere proven to be considerably more complex and time-consuming than initially anticipated. The complexity of eHealth as a management challenge has been vastly underestimated.

Health professional and stakeholder engagement and needs: As part of their eHealth governance structures, many countries have established advisory bodies involving professional associations, patient representatives, third party payers, care providers, data protection officers, and others. Full stakeholder engagement already at the early planning stage, supported by efficient organisational structures and processes, is a key success factor for any eHealth project. Such bodies in part resolve the challenge of potentially ambiguous or distributed responsibilities for eHealth.

Establishment of strong trust: Closely related and complementary is the need to assure strong trust by all into eHealth infrastructures and applications. This requires legal and regulatory certainty, challenges which are among the most demanding aspects of eHealth. Privacy, confidentiality, data protection, and liability issues are involved.

Regional rather than national focus: It seems that the complexity of national EHR systems cannot be managed in larger countries. European experience so far suggests that countries with more than around 10m inhabitants tend to fail with their endeavours, particularly if they do not feature a top-down healthcare system. It is also increasingly evident that clinicians' enthusiasm for comprehensive electronic health records, which may connect patient data in diverse record systems, relates primarily to perceived benefits in their immediate surroundings. This would suggest a middle-out approach, opting for local and regional systems building on a national infrastructure. Seamless national exchange of core patient data like summaries could be assured via common data models.

Reliable infrastructure: Infrastructure elements concern items like governance rules and processes, competence centres, unique electronic identifiers for patients, health professionals, and service provider entities, legal provisions for security, data privacy and liability, regulation of technical and semantic standards, and payment/reimbursement issues. They allow for a network effect to kick in, also known as user externality. Unless a single (public) regional or national health institution exists, service providers usually do not have an incentive to establish bottom-up such an infrastructure, i.e. we have a market failure situation which needs to be solved by national/federal government intervention. The implementation and diffusion of distinct eHealth solutions will become easier to be accomplished once such an infrastructure is available.

Training: Qualified human resources are another key ingredient for success. Education, training and continuous professional development for all, including for those citizens and patients which are capable and motivated to become engaged in their own care, must be strongly promoted. "The most important part of eHealth investment that needs expanding is the eHealth skills and knowledge of healthcare staff and ICT suppliers' staff. An expanded capability is essential to achieve more success and so help to boost eHealth investment."¹⁰⁸

Impact assessment and evaluation: European experience shows that the chance of success will be greater the more precise the foreseen implementation measures and applications indeed meet a concrete health policy objective and benefit the needs of key actors. Socio-economic and financial assessments allow to select optimal policy measures, help to develop rational business cases, guide implementation processes, and allow to continuously monitor and validate outcomes.

6.3 Recommendations

The results of the eHealth Strategies Study summarised in this report were presented, discussed, and validated at a workshop in the fall of 2010 in Brussels. Participants underlined that, to become even more successful, it will be mandatory to better mainstream and align eHealth implementations with strategic health policy goals. eHealth should not be the objective of a standalone strategy, but be fully integrated into overall health policies. i.e. *health and societal policy priorities must guide the further development of the eHealth domain both at national levels and across the Union.*

The ten key recommendations to follow are mainly addressed to the European Commission, the Member States, or both. However, depending on the domain of concern, also stakeholders, experts, and researchers need to become involved:

1. Cross sector cooperation, integrated care

In the context of health system development, Member States should improve ICT-facilitated cooperation *beyond core healthcare service providers* towards an *integrated well-being and care* approach which includes social care providers, ambient assisted living (AAL) initiatives, prevention and wellbeing services.

Furthermore, the EC and Member States together should explore cooperation opportunities in the *wider eGovernment* field on topics like ID management, secure infrastructures, data protection, access rights, thereby also avoiding the duplication of efforts. The high

¹⁰⁸ Dobrev, Alexander, Jones, Tom, Stroetmann, Veli N. et al. (2008). Sources of financing and policy recommendations to Member States and the European Commission on boosting eHealth investment. Final report of the Financing eHealth study. Bonn/Brussels, empirica Dec. 2008. http://www.financing-ehealth.eu/downloads/documents/FeH_D5_3_final_study_report.pdf

relevance of reliable infrastructure components as a mandatory base for innovative ICT applications needs to be acknowledged.

As a corollary, it follows that together creating *trust* across different regions, languages, authorities, as well as regulatory and professional cultures is a key requirement for European success.

2. Learning together, trans-European exchange of experience

In spite of the structural differences across regional and national health service systems, *diffusion* of eHealth solutions should be accelerated through further improved cooperation between the EC and Member States, among Member States and between their national competent centres.¹⁰⁹ Areas should be, e.g., knowledge transfer between eHealth front-runner countries and newcomers. It also needs to be analysed where and how organisational models used are scalable and exportable to other regions.

Creating still wider awareness and ‘teaching’ policy makers and stakeholders is important for all in order to reach a lasting consensus beyond the electoral cycle. Key topics to be promoted should be related to health reform and policy priorities, including urgently needed efficiency gains of workflow processes and related resource savings. There are great opportunities to learn from in-depth studies of national or regional experience. It is also suggested to further explore issues such as ‘Compared to centralised systems, what are the benefits of federated or distributed approaches to electronic health record systems?’

A plan for how to organise and create structures and processes for such a collaborative learning and knowledge transfer needs to be designed by all actors together, e.g. in the context of the high level *eHealth Governance Initiative*.

Efforts at the country or regional level must also include strategy formation and implementation as an iterative process, and *improving change management processes*. A critical observation is that political, technical, legal and other disruptions of such processes mean that actuality does rarely follow the detailed path of a well-designed roadmap.

3. eHealth governance

The EC-facilitated *eHealth Governance Initiative* of Member States is a good opportunity to associate eHealth policy with the mainstream of health policy objectives. Relevant health system priorities include the safety and quality of healthcare/social care; provision of appropriate information to patients; patient empowerment; patient choice; and cross-border relations that support continuity of care.

The *Governance Initiative* also provides a powerful opportunity for all Member States to collaboratively design the future European eHealth strategy and infrastructure. Countries are experiencing similar challenges and the same pressure on health system and societal resources; they can cooperatively build on exemplary, successful eHealth practice.

4. Industrial and stakeholder involvement

Representatives of the eHealth industry and other stakeholder groups would be keen to see an approach which assures co-shaping in developing and implementing eHealth

¹⁰⁹ Exchange of experience across the Atlantic should also prove beneficial, such as foreseen by the “Memorandum of Understanding between the United States Department of Health and Human Services and the European Commission on Cooperation Surrounding Health Related Information and Communication Technologies.” Comm C 2010 8451, Dec. 17, 2010, and already under way in EC supported projects ARGOS and epSOS.

strategies. A governance process should be initiated where, e.g., companies and patients are encouraged to examine the availability and analysis of personal data for the common good and not purely out of self-interest.

5. Invest in training and education

There is a strong felt need to improve eHealth training and education for professionals, but also to focus on reducing the asymmetry in capabilities, information and knowledge between health professionals and motivated patients, and thereby strengthen stakeholder engagement.

All of this should contribute to a continuous improvement of professional expertise as medical knowledge advances, to more effective patient information, empowerment, choice, and growth in responsibility and self-management through eHealth solutions.

6. Standardisation

The strong felt requirement for further standardisation and, in particular, specification and certification efforts is evident. Such common initiatives should focus on well defined and bounded applications and data models, like in epSOS, and they need to closely engage health professionals and nurses to assure that their needs are met.

Member States should be encouraged to enact legislation that will help to produce such standards and require their testing, certification and application.

Incorporating eHealth-related standards in eHealth procurement procedures and tender specifications is another request made. Here EC guidelines may prove helpful.

7. Evaluation and impact assessment

The issues involved in the evaluation, monitoring/benchmarking and socio-economic impact assessment of eHealth investments and services are another increasingly important topic. While the 2004 eHealth Action Plan underlined the importance of monitoring progress by Member States, this is also a crucial time to look ahead over a 5 to 10 year time-horizon and to explore approaches helping to prioritise actions to be considered in forthcoming national or European action plans. Extracting lessons learned that would facilitate prioritisation and selecting successful implementation pathways should be pursued.

The EC may also support Member States in further exploring the need for more structured, comparative eHealth diffusion and usage data to allow to benchmark developments based on an agreed upon template. - Finally, the need for quality benefit-cost analyses is underlined. In prospective forecasts, eHealth usually shows significant savings, but often empirical studies do not (yet) validate these.

8. Re-use of individual patient health data

A largely neglected domain in national eHealth roadmaps is the re-use of patient data in anonymised form. To reap further benefits from eHealth solutions for public health, clinical research, and patient safety, this topic needs heightened attention. There is a distinct opportunity to leverage upon eHealth systems and applications for such purposes. This requires good quality, semantically coded data so that they can indeed be merged and analysed by health analytics tools. Here a strong need is felt for expanding present EC-supported initiatives as well as Member State and healthcare provider involvement.

9. Financing challenges

There is no agreement on how relevant financial challenges indeed are. Perhaps financing issues are less important than sometimes considered; on the other hand, a number of

newcomer countries to eHealth do see the dominant challenge as a financial one. One approach could be for the EC to better inform about how to co-finance eHealth infrastructures through EU Regional and Structural Funds.

10. Improve support for citizens and patients

Finally, with the support of the EC and Member States, health system actors should explore together how to deliver innovative eHealth solutions to better respond to the changing and diverse needs of Europe's citizens and patients, depending on their individual health and social situation, capabilities, and motivation to become actively involved in their own treatment. The *Digital Agenda*, a European Flagship Initiative in the context of the Europe 2020 Strategy, may provide the appropriate base for such activities.

6.4 Outlook

In the overall context of pro-actively addressing the challenges of European healthcare systems and assuring their sustainability, increased political commitment across all European countries towards development and implementation of eHealth strategies has been observed. This is also exemplified by the engagement of 23 countries in the epSOS (Smart Open Services for European Patients) Large Scale Pilot project; it will deliver a substantial contribution towards the co-ordinated realisation of European eHealth Action Plan objectives for the benefits of all European citizens.

Realising the European eHealth vision also supports sustaining the European Social Model and the common values and principles in European Union health systems,¹¹⁰ which are *universality, access to good quality care, equity, and solidarity*. Together they constitute a set of overarching values that are shared across Europe. Universality refers to the universal, i.e. for everyone, access to healthcare; solidarity relates to the financial dimension of ensuring accessibility to all; equity emphasises that access should be according to needs, regardless of ethnicity, gender, age, social status or ability to pay.

Despite following different approaches, all EU health systems aim at ensuring healthcare provision, which is "patient-centred and responsive to individual need."¹¹¹ In spite of all the issues, challenges and barriers identified, the results of this study are proof that European countries are not only well on their way towards implementing eHealth solutions to uphold their social values, but that Europe is indeed leading the rest of the world in advancing towards modern eHealth infrastructures and implementations at a level not seen anywhere else in such a concentration.

¹¹⁰ Council Conclusions on Common Values and Principles in European Union Health Systems. Document (2006/C 146/01). Official Journal of the European Union, 22 June 2006, pp. 1 – 5.

¹¹¹ Ibidem.

European countries on their journey towards national eHealth infrastructures

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