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connected Health

Quality and safety for European Citizens



Report of the Unit ICT for Health in collaboration with the i2010 sub-group on eHealth (formerly known as the eHealth working group) and the eHealth stakeholders' group



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**“Connected Health:
Quality and Safety for European Citizens”**

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the eHealth stakeholders' group

Special acknowledgements to the Members of the former eHealth working group, eHealth stakeholders group, the EU projects eHealth ERA, RIDE, Semantic Health, Q-REC, SHARE.



Gérard Comyn
Head of unit - ICT for Health

Foreword

Among this decade's major challenges are many that affect the provision, continuity and safety of health care. Europe's peoples are ageing. At the same time, Europeans are increasingly moving around the Union for purposes of travel, study, work and retirement. Citizens and patients are demanding healthier lifestyles in combination with the provision of better, higher quality, and economic healthcare. Not only do these demands place considerable pressures on our nations' health authorities and policy-makers, but they also offer unparalleled opportunities to European industry to help in the creation of a prosperous, professional, Europe-wide market for health applications and health technologies.

Such substantial social and economic developments – and the need to provide good, effective, and sustainable health care – mean that we are moving rapidly to a need to consider the requirements of eHealth interoperability. By interoperability, we mean systems and services that are connected and can work together easily and effectively, while maintaining patient and professional confidentiality, privacy, and security. As a result, we would hope to see enhancements to the quality, safety, access and economy of care for the benefit of Europe's patients, health professionals from all the myriad health occupations and levels, Europe's health authorities, but also – following in the steps of the Lisbon strategy – Europe's industrial and commercial partners.

The very beginnings of the eHealth interoperability map have now been drawn and the journey towards this exciting destination has been started. The roots of this initiative are grounded in the eHealth action plan of 2004. The Commission services outlined a work plan – among other initiatives – for a commitment to targets for eHealth interoperability, expanded use of electronic health records, online services, ePrescribing, standardisation efforts, and all the relevant supporting best practices. This work has been taken forward in collaboration with both the Member States and various Europe's eHealth stakeholders. While this relationship of active collaboration started two years ago, the effort has particularly strengthened over the previous six months. It was encapsulated in the bringing together of both health authorities and industry at the eHealth 2006 conference in Malaga, Spain.

This collaborative relationship with Member States and stakeholders has successfully brought forward this final report on 'Connected Health'. The combined and fruitful working of the former eHealth working group – now known as the i2010 subgroup on eHealth – and an eHealth stakeholders' group, composed of many different industrial and user-oriented constituencies, together with a number of co-financed eHealth projects, has led to these thought-out ideas.

The report focuses its emphasis on providing optimal health services within the European Union, independent of their location. It portrays a vision of health, social care, and other service providers collaborating as a team, if necessary beyond their own country and language boundaries. These will support safe and effective health care to European citizens who in turn move around the social, economic and linguistic landscape of the European Union.

The important way forward is through a commitment to an evermore integrated eHealth network that brings together patients, professionals, providers, regions, and nations. Future next steps mean engaging over the next five-year period to a staged and structured approach, first advocated by the 2005 eHealth Ministers at their Round Table in Trømsø, Norway.

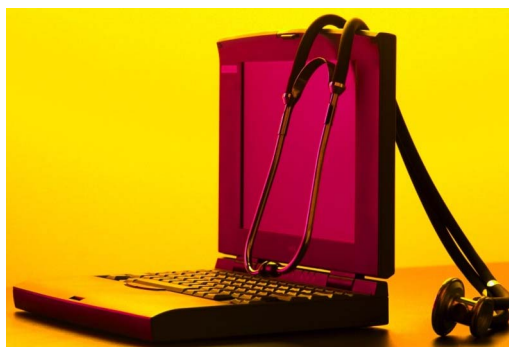
The necessary steps concentrate on the political, social, legal, organisational, administrative and financial aspects of support to eHealth interoperability. However, the aim will also be to focus on technical and semantic aspects of eHealth interoperability, security, privacy, and certification issues.

Crucial in the short and middle-term future will be the development of a proposed set of guidelines on eHealth interoperability. However, more than this, the Member States and the Union together will need to work together on an agreed process to implement these guidelines. This is our next and most immediate challenge!

Executive Summary

Member States are directing their health policies to subscribe increasingly to the paradigm of citizen-centred and patient-centred services. This implies several activities that are: to gather, analyse and disseminate relevant quality information for policy-making; support the need to improve patient safety along the full continuum of care; support healthcare professionals in their daily work and provide citizens with tools that enable them to become both well-informed and self-assured patients. All this will be aided by the provision of optimal medical services independent of their location within the European Union.

To achieve this vision, health, social care and other providers must no longer work in isolation, but need to collaborate as a team, if necessary beyond their national and linguistic borders – information and communication technologies can facilitate this co-operation. It is vital that these parties can have access to and share securely up-to-date information on a citizen's health status, data which they can understand and act on. Without an appropriate information and communication technologies-based infrastructure this goal cannot be reached. It is full interoperability that is the key to success.



The main reasons for accelerating the introduction of interoperable eHealth solutions in a collaborative and coordinated way in Europe are the increasing mobility of European citizens, the aging population and the empowerment of citizens, the continuity of care and the creation of a bigger, European-wide market for many health applications and technologies. This will lead to the increased opportunity for provision of new services, new jobs, and new technologies.

Developed with input from both the i2010 sub-group on eHealth¹ and the eHealth stakeholders' group, this paper contributes to enhancing the continuum of care and ensuring that the flow of information between primary care (local health centres, general practitioners' offices), secondary care (hospital), and tertiary care (specialised consultative care) is promoted, on behalf of better patient care, safety and quality of life as well as better or new citizen-oriented services. A systemic approach, that establishes a collaborative network among all health professionals and organisations, will be extremely beneficial for achieving the proposed goals.

Health technologies should also be used to reinforce the information tools available to citizens, helping them for example to inform themselves better about health issues, particularly preventative health measures.

The *European eHealth Action Plan* of April 2004² provides a mid-term roadmap for the development of these interoperable eHealth solutions in and across Member States. To progress towards interconnected and collaborative eHealth services at the regional, national and pan-European level, further concrete and structured steps are needed.

This paper outlines priority issues which must be pursued vigorously in order to reach all of these health systems goals – improve patient safety, encourage well-informed citizens and patients on health matters, and create **high-quality health systems and services** – and, at the same time, face **international competition in the eHealth sector**. It focuses on the overriding theme of comprehensive eHealth interoperability: eHealth solutions must be *interoperable* to facilitate and foster the *collaboration* of health professionals and health care organisations, and

¹ This sub-group was formerly known as the eHealth working group.

² eHealth action plan part of COM(2004) 356(final): e-Health – making healthcare better for European citizens: An action plan for a European e-health area.

the various stakeholders must *cooperate* and involve themselves to resolve legal, organisational and policy barriers.

Member States have realised that implementing eHealth interoperability is a long-term process requiring a sustained commitment with respect to political involvement and resources. Achieving interoperability is seen as a goal that can be achieved only gradually – application by application – and is often envisioned in a ten-year, if not longer, framework.

The paper recommends the necessary steps to reach these goals for the benefit of Europe, its citizens and its societies, thereby supporting the long-term objectives of the *Lisbon Strategy*.³ These cover the domains of political, social, and regulatory issues; appropriate processes and structures to achieve eHealth interoperability; technical standardisation; semantic interoperability; and certification and authentication processes.

The result of this process will be a set of guidelines on eHealth interoperability, as well as an agreed process to implement these guidelines in the various Member States and at the Union level.

³ eHealth plays a clear role in the European Union's eEurope strategy, and is key to achieving stronger growth and creating highly qualified jobs in a dynamic, knowledge-based economy – the vision set out by the Lisbon European Council in March 2000.

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1. GOALS AND CONTEXT

1.1. Objectives

A healthy living and working environment for all European citizens in an inclusive society is the overriding goal of the Union. To further improve individual health and well-being, access to high quality and safe services, quality assurance and benchmarking, public health measures and surveillance, and knowledge generation and decision support, connected health systems – that is, fully interoperable technical solutions and intensive collaboration of health and care providers – are fundamental prerequisites. It is these connected health systems that will underpin better health services organisation and delivery, and improve citizens' awareness of how to prevent disease and preserve good health.



The European eHealth Action Plan, adopted in April 2004⁴, provides a mid-term roadmap for the development of interoperable healthcare systems in and across Member States. To make further progress towards health systems and services that are connected at the local, regional, national and pan-European level further concrete steps are *urgently* needed. This is necessary in order to avoid implementation of costly stand-alone

solutions which will necessitate large investments in order to render them interoperable.

Priority topics must be pursued vigorously in order to reach the goals of the eHealth Action Plan, and to ensure the competitiveness of the European healthcare industry in a global market by moving towards a single eHealth market in Europe, while respecting Member States' responsibilities in relation to the delivering and organisation of healthcare systems.

This report focuses on the overriding theme of eHealth interoperability – eHealth systems must be interoperable in order to facilitate and foster the collaboration of health professionals and organisations as well as between health professionals and their patients. To achieve this, national/regional representatives and stakeholders must cooperate in order to resolve the various associated legal, organisational and policy issues.

Interoperability is not just a technical matter. It has legal, ethical, economic, social, medical, organisational, and cultural aspects. To approach eHealth interoperability, all these aspects need to be addressed. It could be argued that, under certain conditions, the technical requisites for eHealth interoperability may be the ones that can be more easily fulfilled in this complex equation.

Steps are set out to reach these goals for the benefit of Europe, its citizens and its societies, thus supporting the longer-term objectives of the Lisbon strategy⁵. **In the short term**, the result of

⁴ COM(2004) 356(final): e-Health – making healthcare better for European citizens: An action plan for a European e-health area.

⁵ European Council (2000): *Presidency Conclusions*, Lisbon European Council, 23-24 March, 2000.

this process will be a **set of guidelines on European eHealth Interoperability. In the medium term, implementation sites (large scale pilots)** will be designed. **In the long term, an agreed process for implementation** of interoperable solutions in Member States and throughout the Union will be set up.

A coordinated effort by Member States representatives and all stakeholders – citizens, health professionals, and relevant organisations – accompanied by a wide consultation of interested parties, is necessary in order to agree on such a set of guidelines. This initiative will enable easy and fast access to a citizen's electronic health record or a targeted extract from it (like a patient summary or emergency data), from any place, and at any necessary time, in Europe.

This paper is therefore addressed to all those who are involved in this far-reaching process:

- health professionals and health service providers
- policy decision-makers at various levels of political activity
- industry
- implementation authorities/bodies in eHealth, and
- citizens.

1.2. Policy and institutional context

At the June 7, 2005 launch meeting of the then called **eHealth working group**⁶, the Member States representatives emphasised the importance that they place on eHealth interoperability, and raised a crucial number of issues that they wished to see clarified and covered in further discussions. eHealth interoperability was perceived as a key challenge both for the implementation of national eHealth roadmaps and the implementation of the European eHealth action plan. The group favoured strategic discussions on priorities surrounding eHealth interoperability both within and among Member States and on the process to be established to achieve interoperability.

These priorities were also reflected in the 2005 report on its work of the High Level Group on Health Services and Medical Care, working group Information and eHealth⁷, where Member States underlined that “the long-term aim of information and eHealth should be to ensure full access to all necessary health-related data on a comparable and comprehensible basis by appropriate and authorised people whenever and wherever it is needed throughout the Union.” As a first step, it was proposed to focus “on defining a ‘minimum data set’ for patients and ensuring that these data are available throughout the Union. This would provide immediate benefits in terms of patient care and patient safety.”

The Member States themselves and the various Commission services, working through an informal inter-service mechanism, are developing this programme of activities. Use is also made of the development of the applications and infrastructures for a so-called ‘Electronic European health insurance card’, by encouraging harmonisation of core data processes and profiles through the standard development organisations and formal standardisation bodies, so as to ensure concrete progress on eHealth interoperability.

Following the discussion of the eHealth working group during its meeting of September 27, 2005, an **eHealth stakeholders’ group** was created to support and advise the eHealth working group on its tasks in general and its particular priorities.

⁶ This group was founded as a sub-group to the eEurope advisory group. Its role was to focus over a nine-month period on the key elements of the eHealth action plan and to propose means of accelerating the implementation of these. As from April 20, 2006, the group is now referred to as the i2010 sub-group on eHealth. Its mandate is located at: http://europa.eu.int/information_society/activities/health/policy_action_plan/working_group/index_en.htm.

⁷ European Commission, Health & Consumer Protection Directorate-General: Work of the High Level Group on health services and medical care during 2005. Brussels, 18 November 2005, HLG/2005/16, p. 11.

The eHealth stakeholders' group involves key decision-makers and leaders at the European level from industry associations, health care provider associations, health professional organisations, user groups involving patients and citizens, European standardisation bodies (such as the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI)), European branches of international interoperability initiatives (such as Integrating the Healthcare Enterprise), and representatives of current Sixth Framework Programme support actions, projects and studies.

Specific topics which have been identified as a priority by the eHealth working group were explored by the eHealth stakeholders' group. The activities were particularly related to a proposal of requirements of interoperability of **patient summaries**⁸, **patient and health practitioner identifiers** needed in the context of patient summaries, **and an emergency data set** as an important part of a patient summary. These elements were seen as a concrete step towards achieving interoperability of electronic health records across Europe. Special attention has been paid to data security and privacy aspects as a transversal theme for all three of these areas of work.

2. POLICY BACKGROUND AND EXPECTED BENEFITS

2.1. The European Union eHealth policy framework

eHealth interoperability within and among regional, national and European health systems and health care providers became a major area of concern and policy attention in the eEurope 2005 action plan framework during the period 2002-2005.

A central document during this period has been the 2003 Final Report of the Health Telematics Working Group of the High Level Committee on Health (set up by the Directorate General Health and Consumer Protection of the European Commission) which extensively addressed the problem of sharing data.⁹ A variety of other European Commission documents also concentrate on this priority issue.¹⁰ Among them are the Ministerial Declaration on eHealth of Brussels, May 22, 2003¹¹, and the conclusions of the June 2, 2004 health risk management workshop.¹² Of prime importance is the previously mentioned *Action Plan for a European e-Health Area* of April 30, 2004, adopted by the European Council, and which defines European Union policy in the area. A long history of research and deployment in the information and communication technologies for health area (comprised of almost two decades of European research programmes and more than €550 million of funding) formed the basis for this action plan.



The eHealth action plan was in fact one of a trio of Communications launched in 2004 which provide

⁸ A patient summary is defined as a clinical document that is stored in repositories with cumulative indexing systems and secure access by authorised people. In order to achieve maximum benefit from this instrument, the structured content of patient summaries should be agreed at an international level, starting from a few generic summaries and gradually developing a series of summaries specific for each clinical context. (Citation from an eHealth ERA coordination action deliverable.)

⁹ European Commission (2003): *Health Telematics Working Group of the High Level Committee on Health - Final Report*. Luxembourg, 04/2003, HLCH/2003/1/7.

¹⁰ eHealth 2003 Ministerial Declaration, Brussels, May 22, 2003:
http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf

¹⁰ see http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf

¹¹ see http://europa.eu.int/information_society/activities/health/events/2004events.htm

substance for these new, proposed initiatives on eHealth interoperability in so far as they were based on both the challenges of patient mobility in Europe¹³ and methods of solution-building created around the open method of coordination¹⁴.

The eHealth action plan should therefore allow the European Union to achieve the full potential of eHealth systems and services within a **European eHealth Area**. This concept is further pursued by the 2005-launched strategic framework *2010 – European Information Society 2010* which sets as priorities the completion of a Single European Information Space, the promotion of innovation, and strong support for the inclusion of all European citizens – topics which are at the heart of eHealth interoperability.

At the **eHealth 2005 conference** in Trómsø, Norway, the Ministers and political representatives of the twenty-two Member States in attendance concluded: 'In a Europe in which our citizens are increasingly mobile – whether within the borders of their own Member State or among different countries – we need to raise awareness of the pressing need for a more **integrated and interoperable** European health information space. The Ministers commit to taking up this challenge in a staged and structured approach over the next five-year period'. These crucial issues are also ones which have been picked up in a major way at the eHealth 2006 conference in Malaga, Spain in May 2006 and will be further explored at the World of Health IT conference in Geneva, Switzerland in October 2006.

Similar sentiments have been expressed by the Committee of the Regions in its comments on the eHealth action plan,¹⁵ and in reports by the European Parliament.¹⁶

Preliminary results of the eHealth ERA project also confirm the observation that interoperability issues are high on the agenda of most eHealth strategies and roadmaps of Member States.¹⁷

The main reasons for accelerating the introduction of interoperable eHealth solutions in a collaborative and coordinated way in Europe are that:

- The increasing mobility of European citizens, their expectations and needs together with the trend towards more global health markets require improved interoperability.
- eHealth interoperability and integration of data can improve the care provided to patients, the reduction of medical error, and the human and economic cost savings that can be achieved.
- As a result of an aging population and the empowerment of citizens, demands on health and social care are continuously rising. The advantages obtained from eHealth include accessibility and timely availability of medical data, improved workflow and seamless disease management, new clinical applications. Better information flow across healthcare organisation boundaries leads to better decision-making, containment of costs, improved quality and efficiency of care, provision of home care, and enabling the continuum of care. The transformation of the delivery of health care through information and communication technologies can of course provide better care based on better informed actors.

¹³ COM (2004) 301 entitled *Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union*.

¹⁴ The open method of coordination in relation to health care is addressed in the Communication from the Commission COM(2004) 304 *Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the 'open method of coordination'*.

¹⁵ CdR 256/2004 final *OPINION of the Committee of the Regions of 17 November 2004 on the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area COM(2004) 356 final*.

¹⁶ European Parliament, Committee on the Environment, Public Health and Food Safety. *Draft report on patient mobility and healthcare developments in the European Union* (2004/2148(INI)). Rapporteur: John Bowis. See also EU European Parliament, Committee on the Environment, Public Health and Food Safety. *Draft report on modernising social protection and developing good quality healthcare* 2004/2189(INI). Rapporteur: Milan Cabrnoch.

¹⁷ See www.ehealth-era.org

- While data are recorded only once, they become available for secondary uses such as quality assurance and benchmarking, reimbursement, better management and control, disease surveillance and emergency preparedness, decision support, public health monitoring, knowledge generation and research.
- Building on economies of scale, market size, and creating a critical mass is absolutely essential for the European eHealth industry to grow further and retain its global competitiveness. The European healthcare information technology industry will not become a world player if the market continues to be fragmented due to the lack of coordination of its interoperability and component compatibility developments.

2.2. Providing evidence and expected benefits from eHealth interoperability – focus on patient safety

A major benefit of eHealth is improving patient safety. In this section, the focus of the search for evidence and expected benefits from eHealth interoperability is on this particular topic.

Patient safety matters: it is a challenge of crucial, contemporary importance in terms of providing high-quality, reliable health care. The need to manage health risks both within and outside clinical settings and to improve patient safety along the full continuum of care is now a priority issue on the international health policy agenda. These are goals which cannot be reached without more comprehensive information and knowledge-sharing among all providers, including citizens and family carers. Clearly it is important to implement a safety-oriented work-culture and to encourage health professionals to report failures so as to improve the healthcare system.

The interoperability of eHealth solutions can bring important gains in terms of access (facilitating information for patients and health professionals, improving contacts with health professionals, and avoiding unnecessary transportation), quality (making pertinent medical information available for prevention and diagnosis, avoiding treatment error due to lack of information) and cost (avoiding duplication of laboratory and radiology examinations, and so on).

Experts working on safety issues, including patient safety have taken the aviation industry as a role model, as it has achieved dramatic safety improvements by introducing systematic procedures and control mechanisms into the system. While there is a considerable difference between a passenger in a large commercial aircraft and a patient in an intensive care unit, we can learn from safety procedures in high risk industries such as aviation or railway transport. In healthcare, there is an urgent need to reduce the incidence of avoidable deaths due to medical interventions, adverse drug effects and preventable injuries. Recent evidence¹⁸ suggests that in Europe hundreds of thousands of citizens may be affected every year. Addressing these risks is essential for European citizens' well-being. Because of the acknowledged severity of the issue, once resolved, this is a field where considerable benefits for European health systems and citizens are to be expected.

Much of today's evidence about the quality of care and the impact of unavoidable accidents in the medical field comes from the United States of America. Researchers have found that:

(1) More than one million patients suffer injuries each year as a result of broken healthcare processes and system failures (Institute of Medicine, 2000¹⁹; Starfield, 2000²⁰);

(2) Little more than half of United States' patients receive known 'best practice' treatments for their illnesses and less than half of physicians' practices use recommended processes for care (Casalino *et al*, 2003²¹);

¹⁸ National Audit Office (NAO) (2005) *A Safer Place for Patients: Learning to improve patient safety*, November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1.

¹⁹ Institute of Medicine (IOM) Report (2000). *To err is human: Building a safer health system*. Available at: <http://books.nap.edu/books/0309068371/html/index.html>.

²⁰ *Journal Of The American Medical Association (JAMA)* Vol 284, No 4, July 26th 2000 article written by Dr Barbara Starfield, MD, MPH, of the Johns Hopkins School of Hygiene and Public Health.

²¹ *External Incentives, Information Technology, and Organized Processes to Improve Health Care Quality for Patients With Chronic Diseases* - Casalino *et al*. *JAMA* 2003;289: 434-441.

(3) An estimated thirty to forty cents of every United States' dollar spent on healthcare, or more than a half-trillion dollars per year, is spent on costs associated with 'overuse, underuse, misuse, duplication, system failures, unnecessary repetition, poor communication, and inefficiency'²².

(4) The United States Commission on Systemic Interoperability in its recent report, *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*²³ pointed out that medical errors are killing more people each year than breast cancer, AIDS, or motor vehicle accidents together.²⁴

(5) At least 1.5 million preventable adverse drug events occur in the United States each year (Institute of Medicine, 2006²⁵); and, finally,

(6) According to the United States Institute of Medicine, over a half million people are injured each year because of adverse drug events, many of which could be avoided if healthcare providers had complete information about which drugs their patients were taking and why.²⁶

Although the above observations hold only for the United States of America, it is widely believed that findings developed there can be readily extrapolated to the European context and that the situation in many, if not all, European health delivery contexts is characterised by similar deficiencies.

For example, the Department of Health in England estimates that one in ten patients admitted to National Health Service hospitals will be unintentionally harmed²⁷, a rate similar to other developed countries. Around 50 per cent of these patient safety incidents could have been avoided, if only lessons from previous incidents had been heeded.

Moreover, in the Netherlands, research²⁸ carried out by TNS-NIPO, a market research organisation, shows that around 800,000 Dutch people over the age of 18 have been subject, in their own perception, to errors based on the inadequate transfer of medical information. Of the respondents interviewed, 86 percent expected that this type of error would be reduced once an electronic patient record has been introduced.

Finally, from an economic perspective, the potential value of the interoperable exchange of health related data between healthcare institutions is expected to be substantial. Recent studies²⁹ in the United States of America estimated that net savings from the national implementation of fully standardised interoperability between healthcare providers and five other types of organisations (such as specialists, laboratories, and insurance funds) may yield up to around **\$US 75 billion annually** of savings, or about 5 percent of the projected \$US 1.7 trillion spent on United States' healthcare in 2003. Interoperability of eHealth systems could have an impact on eradicating

²² Proctor P. Reid, W. Dale Compton, Jerome H. Grossman, and Gary Fanjiang, Editors (2005) *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Committee on Engineering and the Health Care System, National Academies Press, 276 p., <http://www.nap.edu/catalog/11378.html>.

²³ Commission on Systemic Interoperability (2005) *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*, U.S. Government Printing Office, Washington, October 2005, 249 p., <http://endingthedocumentgame.gov/PDFs/entireReport.pdf>

²⁴ Institute of Medicine, Centers for Disease Control and Prevention; National Center for Health Statistics: Preliminary Data for 1998 and 1999, 2000.

²⁵ IOM Report (2006). Preventing Medication Errors. Report available at <http://www.nap.edu/catalog/11623.html>. Report brief available at: <http://www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf>.

²⁶ Agency for Healthcare Research and Quality, Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs. Research in Action: Issue 1. March 2001.

²⁷ National Audit Office (NAO) (2005) *A Safer Place for Patients: Learning to improve patient safety*, November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1.

²⁸ For relevant information, see <http://www.npcf.nl/>. Similar information is also available from WINAP and from the Dutch Association of Pharmacists.

²⁹ *The Value Of Health Care Information Exchange And Interoperability: There is a business case to be made for spending money on a fully standardized nationwide system*, by Jan Walker, Eric Pan, Douglas Johnston, Julia Adler-Milstein, David W. Bates, and Blackford Middleton – Health Affairs: Web Exclusive, January 19, 2005 (<http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.i0v1>).

treatments that do not improve health status, are redundant, or are not appropriate for patients' conditions which are estimated, by other studies, at costing between 20–30% of American health care spending, or up to \$US300 billion each year.³⁰

All these examples – with their focus on the high importance of patient safety – plead for the need for a more efficient exchange and sharing of information among health care providers and other actors. There are many other reasons why eHealth interoperability and integration of data must be enhanced; nevertheless, a focus on improving the care provided to patients, the reduction of medical error, and the human and economic cost savings that can be achieved, is fundamental to a European ethos of high-quality health care provision.

As a realistic first step that is able to move the eHealth community forward, improved and enhanced information-sharing can be facilitated by the European common specification of a patient summary. This specification for a patient summary could include the implementation of cross-jurisdictional patient, professional and provider organisation identification policies and the elaboration of a minimum, or emergency, data set for use in acute care cases.

3. PATIENT SUMMARIES IN THE CONTEXT OF NATIONAL EHEALTH STRATEGIES - EUROPEAN EXPERIENCE TO DATE

The representatives of the Member States³¹ considered the concept of a patient summary as the most appropriate way to initiate the process of establishing cross-border eHealth interoperability. The eHealth working group requested, in 2005, that the eHealth stakeholders' group focus its attention on the appropriateness and utility of the concept of the patient summary, the opportunities that such an instrument can provide to re-design effectively eHealth systems and services, and especially the role of patient summaries in achieving the Member States' objectives.

3.1. Empirical evidence on patient summaries

At the request of the eHealth working group, and in order to further an understanding of these possibilities in Europe, the eHealth stakeholders' group – with assistance of the eHealth ERA coordination action – undertook a brief survey during the early months of 2006 in order to collect preliminary evidence on so-called electronic patient summaries.

As a partial base for future policy recommendations, the survey was designed to find out basic information about the state of development and implementation of patient summaries, and also to gather information about why certain organisational and design choices were made by Member States.

A questionnaire was sent to selected experts in Europe and abroad, and 18³² positive answers were received from the countries which have an implementation plan in the area of patient summaries. Half of these responses came from official bodies such as a country's Ministry of Health or its so-called implementation authority/body³³.

³⁰ Wennberg, *et al*/Geography and the Debate over Medicare Reform, *Health Affairs*. 02/13/02. W96-W114; Wennberg *et al*/ Use of hospital, physician visits and hospice case during the last six months of life among cohorts loyal to highly respected hospitals in the United States. *BMJ*, March 13, 2004; Fisher *et al*/ The implications of regional variations in Medicare spending, Part 1: The content, quality and accessibility of care. *Annals of Internal Medicine*. 2003; 138:273-287; Fisher *et al*, The implications of regional variations in Medicare spending, Part 2: The content, quality and accessibility of care. *Annals of Internal Medicine*. 2003; 138:288-298.

³¹ The Member States' representatives made their wishes known to the eHealth working group, sub-group to the 2010 Advisory Group and through the working group on Information and eHealth, sub-group to the High Level Group on Health Services and Medical Care.

³² Of those 18, the fifteen Member States, Candidate or European Economic Area countries which replied to this survey were Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Norway, Sweden, The Netherlands, Turkey, and the United Kingdom.

³³ Implementation authorities/bodies are defined as official bodies that coordinate or support at national or regional level the implementation of eHealth infrastructures and applications.

The analysis of the questionnaires showed that the sharing of clinical information across healthcare organisations is typically achieved through a document-based approach, with documents securely stored in repositories and accessed by authorised persons³⁴.

A patient summary may be used for several purposes, either to make basic information available to a care provider in the event of unexpected contact with an unknown patient, or to counter the potential fragmentation of care provision within shared clinical pathways.

In two-thirds of the respondents' cases, the patient summary is part of a more comprehensive national eHealth programme which also includes other kinds of clinical documents, such as prescriptions of medications, diagnostic orders and reports (laboratory and images), or hospital discharge summaries.

In addition to identification data about the patient (such as patient name, address and date of birth) and the patient's next-of-kin, the patient summary often includes data on the clinician (family doctor) and on the patient's insurance system or scheme, where appropriate.

Typically, a summary includes all of the following sections: patient history, allergies, active problems, test results, and medications. Depending on the intended purpose of the summary and the anticipated context of use, further information can be included.

Further investigation is needed to compare the amount of structured data within each section of the patient summary described, and to relate the data to potential scenarios in which the patient summary and other kinds of clinical documents are intended to be deployed.

Similar preoccupations are described for the United States of America, Canada, and Australia, where national plans have been set up that relate to the deployment of national eHealth infrastructures, a patient summary, a patient and professional identification architecture, and other health-related services.

An important initiative which started in the United States of America and has been further developed in Europe is the Integrating the Healthcare Enterprise initiative which involves both industry and users. *Inter alia*, the initiative describes practical ways of moving towards achieving an interoperable patient summary³⁵.

3.2. The context of national or regional eHealth strategies

Member States or regions often apply multilevel and multimodal approaches to defining and implementing patient summaries that involve to various degrees:

- Users and other stakeholders, including in some instances not only associations but also private companies;
- Central, regional and local governments and healthcare providers;
- Activities at different layers and levels, which can be broadly grouped into political, organisational, and technical categories.

The patient summary survey undertaken indicates that most Member States have already or are establishing specialised bodies that are tasked with eHealth implementation in general, and with eHealth interoperability in particular. However, the structure, composition, remit, and organisation of these bodies vary considerably.

³⁴ In some cases (for example, in the Netherlands) the exchange of information will be done through a central service (National ICT Exchange Hub) that will provide the facilities necessary for the electronic exchange between healthcare providers. The Hub links the healthcare information systems used by the various healthcare practitioners; the information itself remains at its source location.

³⁵ This is referred to as a Cross-Enterprise [clinical Document] Sharing of Medical Summaries (or XDS-MS). XDS is an implementation profile that enables the search for the location where any document is held, and how to publish this location. This solution was initiated by Integrating the Healthcare Enterprise.

Member States have realised that implementing eHealth interoperability is a long-term process requiring a sustained commitment with respect to political involvement and resources. Achieving interoperability is seen as a goal that can be achieved only gradually – application by application – and is often envisioned using a ten-year framework, if not longer. Additionally, it is observed that most national efforts are in a pilot stage or pre-deployment stage.

Member States have focused on different aspects of eHealth interoperability and have thus developed different forms of specialised expertise. This provides a useful base for the exchange of experiences and the identification of good practices and mutual learning. Areas of focus have been, for instance: patient summary, ePrescribing, standardisation management, market and industry involvement, the development of public-private partnerships, and the development of Open Source software.

The overarching reasons for implementing eHealth infrastructures and applications, while ensuring interoperability, vary considerably. In some Member States, reducing medical errors and improving overall patient safety are placed at the forefront, while other countries implement eHealth in the context of overall healthcare reform, decentralisation of health services, or efforts to contain the growth of health system costs. In the context of this report, however, the importance of patient safety is viewed as the crucial and overriding rationale that underpins eHealth interoperability.

4. EXAMINING THE UTILITY OF AN ELECTRONIC PATIENT SUMMARY: VARIOUS SCENARIOS

Given the importance of patient safety, it is important to examine the patient-related context in some detail.

Use cases are scenarios which are developed to describe and explore some ways in which new applications and techniques can be used. The eHealth stakeholders' group has developed several use cases which explore more concretely how electronic health information systems in general, and electronic patient summaries in particular, may be used in practice.

Such concrete application situations will make it easier both to relate the abstract priorities agreed on by the eHealth working group to the reality of patient, citizen and healthcare systems needs, and to derive recommendations on which practical next steps will be needed to achieve this vision.

Three such scenarios have been developed. The three cases are detailed in Annex 1.

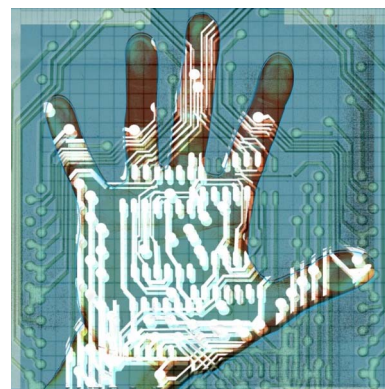
They relate to:

- a single acute case (unpredicted access to clinical information),
- a so-called 'normal' patient case (*ad hoc* interactions among professionals), and
- a chronic case (sharing information according to a predefined, agreed care plan).

During each of these scenarios, information is transferred among different partners within the healthcare system to ensure correct follow-up treatment and to improve the overall governance procedure. In each case, the notion of an electronic patient summary is explored.

It should be emphasised that these scenarios were not developed for the purpose of defining the information for the patient summary itself, but to uncover and explore other conditions and requirements that need to be met in order to use the summary. The following five requirements were found:

1. Identification and authentication of actors and organisations: all health professionals involved in the various types of care process as well their institutions and local facilities must be uniquely identified and authenticated across all Member States. The mutual recognition of identification and the processes for authentication must be clearly specified and based on a legal framework applicable across all Member States. Similarly, citizens and patients must be uniquely identifiable and authenticated. The



initiative involves what is called 'meta-data': examples of such meta-data are the author of the document, how to contact him/her, the date of the document creation, logging information, who has access to and who has accessed the content, and so on.

2. Emergency data set: An emergency data set may be derived from the patient summary in the event of some unspecified acute care. Both emergency and acute medical systems have to be 'self-contained' and have to work independently from centralised devices, services or even power supplies.

3. Infrastructure: Communication of summaries beyond healthcare institute borders will also require interoperability of the underlying information and communication technology infrastructure in Member States.

4. Authorisation: relates to access guarantee (responsibility and logging), patient consent (privacy), and signature. For many medical and legal reasons, data should be well managed. Responsibility for granting access to patient data should be directed to that person or institution which is able to store the identification data securely and make the data available securely.

5. Sustainability of the financial model: Often the organisation that has to make an investment in eHealth is not the same organisation that benefits from these investments. This sometimes delays the introduction of eHealth solutions. Even though pilot projects often show benefits, there is no sustainable financial model for eHealth interoperability unless new methods of financing are introduced such as public-private partnerships.

Resolving these issues in individual jurisdictions, regions, and across and between regions and Member States is a considerable challenge for European health care systems and services. The complexity of achieving eHealth interoperability at its various levels of analysis is therefore outlined in the following section, covering such issues as technical standardisation, organisational interoperability, semantic interoperability, certification, and authentication. The case for legal and policy support to eHealth interoperability issues is, in addition, made strongly. It should be noted that at present there is no lack of technology or standards, but rather of the operational context in which to introduce interoperability.

In section 6 of this document, practical ways to achieve eHealth interoperability are explored, and concrete proposals are put forward for the period, 2007-2013.

5. ACHIEVING INTEROPERABILITY IN EUROPE – THE NEXT STEPS

Interoperability is a means to contribute to the goal, of seamless transfer of information between healthcare systems in order to satisfy a clinical purpose. Any level of interoperability cannot be defined without first specifying the clinical context, analysing the workflow, defining the information that needs to be managed and transferred and, finally, defining the technical solutions to transfer this information. Therefore, the co-operation of health professionals in this process, that is in defining the clinical context, is crucial to any effective solution.

Co-operative care involving different health professionals in multiple care settings, whether it is for an emergency situation, provision of specialised services, or provision of remote care to patients – in, for example, a rural environment – requires extensive communication.

Communication and co-operation among healthcare establishments, and between the organisations and their patients, demand different frameworks. These operate at various levels within the context of a clinical application:

- a legal or regulatory level;
- an ethical-cultural-social-medical level;
- an administrative (including financial) and an organisational level; and, finally,
- a technical interoperability framework.

Any obstacles at any of these levels may cause the whole communication to falter. Each level needs to be addressed in order to achieve effective communication.

Here, all four of the levels listed above are not explored in detail. Rather, in order are outlined the need for legal and policy support; the need for authentication services; the need for semantic interoperability; and the need for certification.

5.1. The Need for Legal and Policy Support

The concept of eHealth interoperability and its reality in daily and regular medical practice, as well as in emergency situations, can fundamentally challenge understanding of the practice and regulation of healthcare in terms of the relationship between practitioner and patient, practitioner and institution, and among institutions.

In the traditional model of health care provision, patient access to the healthcare delivery system has sometimes been limited to predetermined points of entry, such as through a primary care physician. From such an entry point, the patient's progress through the system has been relatively linear and has often been dictated by the particular health system's reimbursement system, which differs from country to country. Similarly, processes such as diagnosis, treatment and care have involved physical presence and personal interaction between providers and patients. Of course, in such conventional health delivery, consumers have paid directly or indirectly for all aspects of their healthcare information, treatment and care, either directly through taxation or social security systems, or indirectly through more complex reimbursement systems.

eHealth, however, is premised on a fundamentally new patient experience that may be unconstrained by familiar points of entry and structures or by traditional channels for delivering information or care. Anonymity or pseudo-anonymity can, potentially, be preserved much more easily. Not surprisingly, therefore, the eHealth revolution has as many serious implications for healthcare regulators, policy-makers, lawyers as for health professionals and patients.

Policy-makers have noted at both European and national/regional levels that a lack of legal certainty about the use of eHealth tools and applications exists. Yet little has been done to study the issue in detail. Certain research and study projects³⁶ funded under the European Commission's various Framework Programmes have looked at general legal issues concerning the use of information and communication technologies. Others have included work packages that examine the legal aspects of a particular technology or application³⁷. Yet others have explored a single particular issue, such as confidentiality, in greater detail³⁸. However, it would seem that very little work has been undertaken to date to look across the whole range of legal issues relevant to the use of information and communication technology tools and services in healthcare and to draw conclusions about the regulatory needs which may exist in a European-wide or cross-border environment.

As long ago as 1999, the European Commission first launched the eEurope 2002 initiative with the adoption of the Communication *eEurope – An Information Society for All*³⁹. Although the market for technological applications in the medical domain was developing rapidly in Europe and the increase of health-related information and education material available on the internet was of growing significance, five years ago, the full exploitation of both sectors of eHealth was hindered by a lack of legal clarity and certainty. This 2002 Communication specifically observed that in the clinical (including commercial) eHealth applications domain 'uncertainty persists in the health telematics-related industry about responsibility and data protection, the legality of providing on-line medical opinions as well as on-line pharmaceutical information and product supply.'

The issue was raised again in the 2004 Action Plan for a European eHealth Area⁴⁰. This second Communication identified that, despite adoption of European Union legislation on issues such as Data Protection (95/46/EC), Electronic Signatures (99/93/EC), eCommerce (2000/31/EC), Distance

³⁶ see for example Legal IST – FP6-IST.

³⁷ see for example NEXTGRID – FP6-IST or EUROAGENTEST – FP6-LIFESCIHEALTH.

³⁸ see for example FP5-EUROSOCAP – Quality of Life Programme.

³⁹ COM (1999) 687 final, of 8.12.1999.

⁴⁰ [COM\(2004\) 356\(final\): e-Health – making healthcare better for European citizens: An action plan for a European e-health area](#)

Contracting (97/7/EC) and the existing legislation on General Product Liability (92/59/EEC) and on Medical Devices (93/42/EEC), considerable uncertainty on the legal aspects of the use of eHealth applications, tools and services continued. Accordingly, the eHealth Action Plan proposed that, by 2009, the European Commission shall 'provide a framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation.' In particular, the 2005 Opinion on the Action Plan by the Committee of Regions, as just one commentator on the content of the eHealth action plan, encouraged even more rapid treatment of this particular challenge.

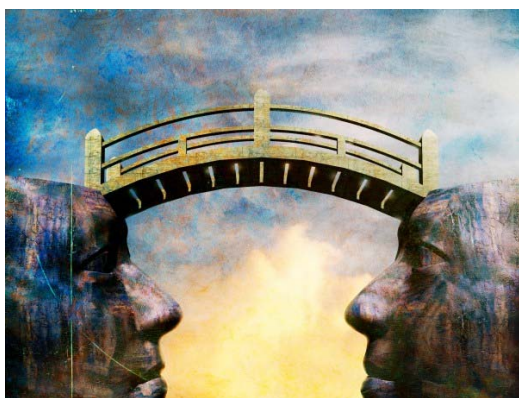
In this context, later in 2005, the Commission called for a study to establish a baseline report on existing European Union-level legislation, its impact on the delivery of eHealth and an analysis of the legal *lacunae* which may exist. The results of this study will form a concrete regulatory basis for the legal aspects of the proposed set of guidelines focused on the eHealth interoperability.

5.2. The Need for Authentication Services

As a basis for the prioritised applications that support shared care, infrastructural services are needed. These include the identification and authentication of all the principles involved such as persons (patients as well as health professionals), organisations, systems, devices, applications, and components. Identification requires identifiers, identification *schemae*, and appropriate algorithms and services for creating and maintaining identifiers, as well as directory services for distributing them. To provide trustworthiness in open environments, identification is usually bound to authentication processes, authorities and technical services. This is generally done by creating and managing identification certificates.

Authentication processes provide the assurance that the claimed identity is the actual identity of the claimant. Such authentication processes are also needed for properties bound to principles such as specific roles, specialties, and qualities which are summarised as attributes to be managed by attribute authorities which have issued and maintained attribute certificates. Relationships between principles have to be established, certified and communicated by extending these directory services towards the sharing of additional personal information. Special attention has to be paid to the trustworthiness of infrastructure and processes. For this purpose, standardised services related to identification and authentication such as privilege management, access control, tracking of information and processes, accountability, integrity and confidentiality services, policy management, and audits are highly valued.

5.3. The Need for Semantic Interoperability



Semantic interoperability addresses the application context in which interoperability needs to be achieved. First the clinical context and workflow is defined. Then information from different parts of the care process must be defined in such a way that it can be used and understood by others. This procedure assumes a common understanding of the process entity, the underlying concepts and the special steps needed. As a prerequisite, understanding and tolerance of the care components, harmonisation of procedures, avoidance of misinterpretation, combined with trustworthiness, shared between all the parties involved – including

the patient – must be guaranteed. For this reason, process description, underlying models and concepts, terminology and ontology of knowledge representation have to be shared unambiguously. This also requires harmonisation of technical means including the supporting health information and communication systems.

More recently, automatic language processing and intelligent information retrieval have emphasised a need for genuine semantic interoperability, that is, the guarantee that any particular language in a data set is unambiguous and has the same meaning for any subsequent user of the system. In addition, the precise meaning must be captured in such a manner that it can be both formally described – in order to be processed by machines – and transformed based on

pre-established rules – so as to be easily understood by the system’s users or used by other applications.

5.4. The Need for Standardisation

Voluntary use of open and formal standards by the industrial actors already contributes tremendously to eHealth interoperability. Standardisation is an integral part of the European Union’s policies to increase the competitiveness of enterprises and to remove barriers to trade. This was confirmed by the European Parliament in 1999 and by the Council both in its Resolution of October 28, 1999 and its Conclusions of March 1, 2002⁴¹ on the role of standardisation in Europe. At the same time, the Council invited the Commission to review the objectives, scope and needs of European standardisation policy.

The results of this analysis of standardisation policy were presented in the 2004 Communication on *The Role of European standardisation in the Framework of European policies and legislation*⁴² which sets out the Commission’s priorities in this area. The Communication analyses the current situation and identifies the key areas where the European standardisation system and the instruments available to European standardisation policy can and should be improved further.

The Council endorsed this Communication in December 2004. It called for a more extensive use of European standardisation in European policies and legislation, as well as further improvements in the efficiency, coherence and visibility of European standardisation and its institutional framework.

In the eHealth area, the 2005 Report from the European Committee for Standardization /Information Society Standardisation System eHealth Standardisation Focus Group (March 14, 2005), emphasises that health information standards are essential to achieving the goals of eHealth in Europe. These recommendations of the eHealth Standardisation Focus Group formed part of the starting point for the activities in the standards area of the eHealth stakeholders’ group. The report recommends the creation of an interoperability platform. Among other tasks, this platform should establish a Europe-wide view on the requirements for eHealth standardisation and its implementation, in collaboration with standardisation organisations, and this should be based on input from relevant stakeholders’ communities.

The report proposes that semantic aspects and technical means to eHealth interoperability also have to be harmonised through setting and enforcing voluntary standards. Standards have to be defined at European or – even better – at an international level with the participation of relevant stakeholders. To guarantee semantic interoperability, systems and solutions have to be designed properly based on a defined architecture. This is especially important for shared applications such as electronic health record systems. Furthermore, content and its representation have to be agreed. Semantic and technical interoperability can be enabled among others by standardising technical interfaces, protocols, messages and documents; so too the business processes involved in such context as clinical procedures and pathways.

To summarise, many forms of standards could be appropriate: such as standards for devices, protocols, messages, documents, processes, architecture, design and modelling, as well as standards for infrastructure and infrastructural services with specific emphases on safety, security and privacy services. Furthermore, it can be considered that standards for specifications, knowledge representation, terminologies and ontologies can be deployed for shared care through a voluntary, collaborative process that involves all the relevant stakeholders.

⁴¹ The Council Resolution of October 28, 1999 on *The Role of Standardisation in Europe* emphasises that standards should be fit for purpose, have a high degree of acceptability as a result of the full involvement of all relevant interested parties in the standardisation process, be coherent with each other and allow for technological innovation and competition. Therefore, they should be based on sound scientific research, be updated regularly and, be performance-based, where possible.

⁴² COM(2004)674 final - *Communication on the Role of European standardisation in the Framework of European policies and legislation*.

5.5. The need for Certification

eHealth interoperability requires a common process for analysis, specification, implementation and deployment of conceptual models, common concepts, a framework architecture and its prioritised solutions and for infrastructure elements and services. In this context, legal and other regulatory policies, collaborative business views, a common understanding of process, information and concepts based on reference models and terminologies or ontologies, have to be brought together. The process for benchmarking, evaluating, and labelling the conformance to these requirements performed by a body that is duly authorised and recognised is called certification.

Specifications and protocols used should preferably be standardised at an international level or at least be mutually agreed among the various parties involved.

Certification services can be implemented in a centralised or – even better – in a hierarchically decentralised way.

The claim of presumed conformance to the law must either be verified by an independent third party or clear rules must be established under which self-certification can be undertaken.

Whether third party certification improves the quality of implementation remains to be seen. There is little or no experience with certification at the high (semantic) levels that are needed in the eHealth field. Current practical experience (for example, with DICOM⁴³ or with Integrating the Healthcare Enterprise) shows that conformance claims by industry, together with voluntary testing sessions and testing tools in the public domain, are very effective and efficient.

6. TOWARDS A EUROPEAN ROADMAP FOR ACHIEVING eHEALTH INTEROPERABILITY

Considering the wide diversity of eHealth systems that are emerging or are already in place in the Member States, and the complexity of legislation throughout Europe, further exploration is needed in order to issue a set of guidelines on eHealth interoperability. It is recognised that a single architecture for the wide variety of health information systems and the different purposes that many of them, or their components, address will not be possible.

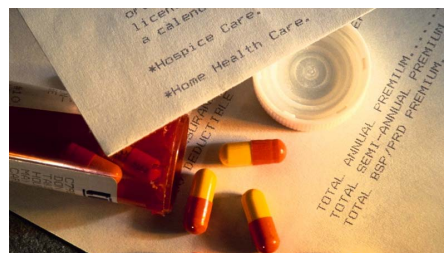
Indeed, for a particular eHealth application to be interoperable with another eHealth application, the relevant parties will have to agree on very different issues belonging to very diverse domains. Addressing these issues and domains is to be done in an organised manner through what can be called an **Interoperability Framework**.

Experience from other initiatives of this kind shows that it is practical to structure this work into four layers for which an interoperability agreement is sought between all the relevant parties concerned:

- The political/social/legal layer
- The organisational/administrative/financial layer
- The application and semantic layer
- The technical layer.

Issues, such as security, privacy, and certification eHealth applications, must be also taken into account.

Five of these aspects are outlined below. Primarily, the political, social, legal, organisational, and administrative aspects are all discussed together immediately below in section 6.1. Following this, the semantic layer, technical layer, security and privacy issues, as well as certification, are all treated separately in section 6.2 through to section 6.5.



⁴³ DICOM stands for the Digital Imaging and Communications in Medicine (DICOM) standard - see <http://medical.nema.org/>.

6.1. At the level of feasibility of eHealth interoperability involving political, social, legal, organisational, administrative, financial aspects

Making progress towards interoperable solutions in eHealth needs to take place in the Member States through their implementation authorities/bodies. It is proposed that it occurs through an *ad hoc* group which will focus on the definition of **patient summary, patient and practitioner identifiers, and the emergency data set**. According to the priorities outlined in the eHealth action plan⁴⁴, the *ad hoc* group will also address the area of **ePrescribing**.

This eHealth interoperability *ad hoc* group will be set up within the framework of the Common Interest Preparatory Activities funded by the eTEN programme⁴⁵. These activities are related to the proposal of the Commission to Council and Parliament to continue support for the deployment of electronic services in the public interest in the context of the Information and Communication Technologies Policy Support Programme within the proposed Competitiveness and Innovation Framework Programme 2007-2013⁴⁶.

The members of the *ad hoc* group will be proposed by the former eHealth working group; they will be considered as the designated representatives of the different Member States' implementation authorities/bodies. External, independent experts may be needed to provide additional advice.

Proposed activities of the eHealth interoperability *ad hoc* group

The eHealth interoperability *ad hoc* group will undertake three major activities which are largely advisory in character:

1. Contribute to advising on the necessary requirements at European level for achieving interoperability in the medium-term (3 years) in the field of patient summaries and in the long-term (6-7 years) in the field of the electronic health records.

This activity will start in September 2006 and finish in September 2007. It will form the basis for a set of guidelines for implementation of interoperable patient summaries.

This activity will take into account:

- The priorities set up in the national and regional roadmaps of the Member States regarding patient and professional identity management, patient summary (or equivalent) and emergency data set.
- The outcomes of the legal study (a study on *Legal and regulatory aspects of eHealth* is made on behalf of the European Commission during the course of 2006) as well as the patient and professional mobility issues as outlined by the relevant jurisprudence⁴⁷ and other legal documents.
- The use of the European *health insurance card* as a method for promoting a common approach to patient identifiers and developing new functions such as the storage of medical emergency data, in accordance with the eEurope 2005 plan, approved by the Seville European Council and as suggested by the Parliament report on patient mobility and healthcare developments in the European Union (2004/2148(INI)).
- The *open method of coordination*⁴⁸.

⁴⁴ eHealth action plan part of COM(2004) 356(final): *e-Health – making healthcare better for European citizens: An action plan for a European e-health area*.

⁴⁵ See http://europa.eu.int/information_society/activities/eten/library/index_en.htm#calls_documentation.

⁴⁶ COM(2005) 121: *Proposal for a Decision of the European Parliament and of the Council establishing a Competitiveness and Innovation Framework Programme (2007-2013)*.

⁴⁷ The judgements of the Court of Justice of the European Communities in Decker (C-120/95, 28 April 1998), Kohll (C-158/96, 28 April 1998), Geraets-Smits & Peerbooms (C-157/99, 12 July 2001), IKA (C-326/00, 25 February 2003) and Müller- Fauré & van Riet (C-385/99, 13 May 2003).

⁴⁸ Communication from the Commission to the Council, the European Parliament, the European and Social Committee and the Committee of the Regions on Modernising social protection for the development of high-quality, accessible and

- Aspects of patient safety, as underpinned by the European Commission study launched in 2006 called *Impact of ICT on patient safety and risk management*.

Changes in health systems organisation could make possible the full impact of interoperable health information and communication systems. Mechanisms of information, training, exchange of experience and all other necessary mechanisms to implement eHealth solutions must be designed by Member States so as to make possible this transformation of health systems. These tasks could be approached systematically in the *ad hoc* group as well as the identification of financial barriers and underlying business models that make possible to implement interoperable patient summaries.

2. Advise the Commission on the conception of a Call for proposals for large scale pilots in the area of interoperability of patient summaries and emergency data set as well as on ePrescribing. In this context, the *ad hoc* group will give its opinion on the process of priorities, requirements, pilots, testing, implementations and deployment of interoperability solutions.

This work is part of the different instruments foreseen in the area of Competitiveness and Innovation Framework Programme 2007-2013⁴⁹.

This activity could start in September 2006 and finish at the end of 2008.

During 2007-2008, two large-scale pilots could be set up with the support of the *ad hoc* group: the first, a large-scale deployment pilot in emergency data as a subset of a patient summary exchange and the second on ePrescribing. Several *New Services Deployment Pilots*⁵⁰ could test innovative services in the interoperability area.

3. Contribute to the implementation of interoperable eHealth solutions according to the priorities defined by the Member States and following a set of evolving guidelines on eHealth interoperability. This is a long term activity and would accompany the implementation of interoperable electronic health records, after 2008, until 2013.

Co-ordination efforts need to be undertaken with other areas domains of activity within the European Commission such as eGovernment, eBusiness, eInclusion, and with the European Interoperability Programme (IDABC)⁵¹. A collaboration scheme must be strengthened with the Directorate-General Enterprise and Industry and the Directorate-General Regional Policy. This initiative should take place in order to implement the technical aspects of the further coming set of guidelines on eHealth interoperability and to assure the sustainability at both the regional and national levels of the eHealth systems to be implemented. An inter-service group on eHealth interoperability will be set up in light of this proposal.

6.2. At the level of semantic interoperability

In the area of semantic interoperability process description, underlying models and concepts, terminology and ontology of knowledge representation have to be unambiguously shared. The *ad hoc* group, with the collaboration of European Commission co-financed research projects, European and international standards organisations, industry representatives, World Health Organisation and health professionals will explore this particular area of interoperability together with those Member States' organisations that are responsible for the uses made of medical language.

sustainable health care and long-term care: support for the national strategies using the 'open method of coordination' (COM(2004)304 final).

⁴⁹ COM(2005) 121 *Proposal for a Decision of the European Parliament and of the Council establishing a Competitiveness and Innovation Framework Programme (2007-2013)*.

⁵⁰ New Services Deployment Pilots- explore market feasibility of new service paradigms based on the innovative use of ICT in the area of Competitiveness and Innovation Framework Programme 2007-2013.

⁵¹ The European Interoperability Programme (EIF) available on the website of IDA programme at <http://europa.eu.int/idabc/en/document/3761/5583>.

6.3. At the level of technical interoperability

The Commission services will invite European standards development organisations, through a mandate, to identify the existing standards to be used in the area of both patient summary and emergency data sets.

European standards development organisations are strongly encouraged to collaborate with international standards development organisations such as Health Level 7⁵² (HL7), SNOMED International⁵³ and DICOM⁵⁴ as well as international standards organisations and the International Telecommunication Union. In addition, it is recommended that information and communication technologies companies, including large corporations and small and medium-sized enterprises create a forum to develop interoperability guidelines. This will be based on best-known methods and practices that focus on framework architecture, interoperable patient/physician identifiers, and patient summary records to create an emergency data set.

Based on the input of standards development organisations that include the participation of industrial experts and particularly from the information and communication technologies sector, the future set of guidelines will focus on **framework architecture, possible technical solutions for patient summary, identifiers and an emergency data set**. Industrial representatives will include both large corporations and – presumably – small- and medium-sized enterprises. Scalability and technological neutrality issues will be taken into consideration so as to transparently contribute to the development of industry. Co-operation is also required with Integrating the Healthcare Enterprise-Europe. Although this entity is not strictly a standards organisation, Integrating the Healthcare Enterprise has established profiles for standards to enable seamless communication.

6.4. Security and privacy issues

One of the tasks of the *ad hoc* group will be a definition of concepts, framework architecture elements, infrastructure components and services that facilitate the implementation of safety, security and privacy mechanisms (such as security and data clearinghouses that simplify integration of all of a patient's health information at the point of care).

6.5. Certification issues

Based on work in the Member States and on the outcomes of the European project Q-REC⁵⁵, as well on a validation process initiated with the implementation authorities or bodies, guidelines for certification of eHealth applications will be prepared. The goal will be to create conformance-testing methods and processes (an example is the Integrating the Healthcare Enterprise Connect-a-thons) where components, applications, and tools can be evaluated for their adherence to standard profiles. Software and hardware testing processes that identify incorporation of and compliance with these profiles should assist vendors and purchasers of software to direct their resources toward those systems that offer interoperability.



7. CONCLUDING REMARKS

In conclusion, this report has outlined the key priority issues which must be pursued to achieve the goals of collaborative and continuous care provided with high-quality and appropriate cost in Europe, while ensuring both the safety of Europe's citizens, and improving the European eHealth industry, thereby enabling it to face international competition. It concentrates on the overarching theme of comprehensive eHealth interoperability. It covers content, process, and roadmapping

⁵² www.hl7.org/ehr/.

⁵³ www.snomed.org/.

⁵⁴ <http://medical.nema.org/>.

⁵⁵ http://www.prorec-france.org/Q-REC_LESSIS/Q-REC.html .

activities. Hence, it looks towards a vision of eHealth systems that must be *interoperable* in order to facilitate and foster the *collaboration* of health professionals and organisations, and in which the relevant key stakeholders must *cooperate* to resolve the associated legal, organisational and policy barriers. High on the agenda for final results are the reduction in medical errors and the improvement in the standard of patient safety offered.

The paper recommends the necessary steps to reach these goals for the benefit of Europe, its citizens and its societies: the initiative is very much in support of the policy objectives of the Member States and of the Lisbon Strategy.

Interim steps and procedures are made within the framework of this roadmap, so as to achieve eHealth interoperability. Fundamentally, they lie around the facilitation of an *ad hoc* group on three specific areas of work – **patient summary, patient and professional identifiers, and emergency data set** – that will advocate, develop, and make constructive progress on the activities necessary to move towards eHealth interoperability in these areas among collaborative, willing, and voluntary Member States. According to the priorities outlined in the eHealth action plan⁵⁶, the *ad hoc* group will also address the area of **ePrescribing**.

The result of this entire process will be a set of guidelines on eHealth Interoperability. Accompanying this set of guidelines, there will also be an agreed process to implement them in the various Member States and at the level of the European Union.

⁵⁶ eHealth action plan part of COM(2004) 356(final): *e-Health – making healthcare better for European citizens: An action plan for a European e-health area.*

ANNEX 1: EXAMPLES OF SCENARIOS

This annex provides non-exhaustive examples of several use cases (referred to as scenarios) which are developed to describe and explore the way in which new information and communication technologies applications and techniques can be used. These scenarios have been developed with the contribution of the eHealth stakeholders' group. They explore concretely how electronic health information systems in general, and electronic patient summaries in particular, may be used in practice.

Acute care scenario – secure access to clinical information:

Mrs X is on summer holidays in a foreign European country. She has a hormonal treated adrenal insufficiency which, in hot weather, can lead to confusion and intense abdominal pain. Suddenly, in a main railway station bookstore, she feels ill. She experiences intensive abdominal pain and vomiting. She calls for help. The healthcare professionals ('paramedics' in this case) arrive and start to give Mrs X the appropriate first aid. Using the basic medical information from Mrs X's electronic patient summary, available securely online, the paramedics detect her hormonal insufficiency and – in agreement with the emergency practitioner – treat her with the required substitution drug. Once she has arrived at the hospital, Mrs X recovers quickly and, after some hours, she is discharged with an electronic prescription for more adequate hormonal treatment which she can get both from a local pharmacy, an Internet pharmacy and eventually from a pharmacy in her own home town. The intervention is registered in her patient summary, which is organised according to a common structure or template agreed among different European Union Member states.

In the absence of the information available from her personal patient summary, which was accessed remotely in her country of origin, on this occasion the patient would have been at serious risk of undergoing an emergency abdominal surgery intervention.

Normal care scenario – efficient communication:

Mr P suddenly experiences severe back pain. He consults his family doctor, whom he has not seen for several years. She consults the patient's electronic patient record which is synchronised with his national electronic health record registry that provides pointers to records entertained by other health care providers on the same person, and where a summary of this complex overall file is maintained and updated as required. However, no new information relevant for the present examination is found.

The doctor decides to give the patient an anaesthetic injection and to refer him to an orthopaedist. She obtains an appointment for her patient using the remote appointment system which, in agreement with Mr P, is set for the very next morning. The orthopaedist examines the patient, fills in the data in his electronic patient record system which, at the same time, also automatically updates the central patient summary record, and requests a computerised tomography of the lumbar spine to exclude disk herniation for the very same afternoon. The results are made available to the orthopedist ten minutes after being signed off electronically by the radiologist, together with the images. Disk herniation was indeed discovered. The orthopedist applies a conventional therapy for this condition. Both the electronic patient record and the central patient summary are updated accordingly, and the family doctor receives a notification about the updated record. Happily, Mr P can now be followed up by the family doctor who has all the necessary information available to her electronically. Data relevant to public health monitoring is transmitted to the health authorities and to the statistical office in respect of patient confidentiality.

Chronic care scenario – effective sharing:

Mrs K is elderly and overweight, and has a number of chronic conditions. In particular, she has severe diabetes. She has to be regularly monitored and supervised, with data that identify two types of indicators: process indicators and outcome indicators. These identify, respectively, the quality of the care process (process indicators), and the progress or remission of the disease (outcome indicators). The disease management requires a shared care plan that involves Mrs K's general practitioner, a specialist and, as the need arises, a secondary care facility. Periodic tests and visits to the general practitioner are registered, and a yearly consultation (or, in an acute situation) with a diabetes specialist has been integrated. Her situation also necessitates occasional stays in a hospital, and the need for paramedical specialist care such as medical pedicure. The care plan is complemented with periodic visits to her pharmacy for medication refills, information, and management.

With each health-related intervention, the patient can permit access to her lifelong electronic health record, which contains a focused selection of clinical information extracted from local electronic patient record systems used by her various care providers and linked to the central summary record. Timely clinical information is thus available at the point of care to adjust treatment immediately or to referral to a specialist as required. The data is also used to support administrative and organisational activities, for quality assurance and public health statistical purposes, and may be used later also for clinical research based on informed consent already provided by the patient.

A regularly updated emergency data set, that includes the details about the current treatment, is specified as a subset of the patient summary. It is centrally available to any authorised emergency care provider and could help avoid errors in treatment of this particular patient.

ANNEX 2: DESCRIPTIVE ELEMENTS OF PATIENT SUMMARY PROGRAMME

This annex provides a list of elements as a basis for future discussion in order to describe a programme on patient summary. This starts from the structured content of the summary, and considers some features related to the context. It also raises some issues concerning the purpose of the patient summary and its use.

The patient summary is necessary in situations of normal care, acute care and chronic care. A minimum data set has to be derived from it in the event of acute care that is immediately understood by emergency paramedics and physicians.

Parts of the summary document can be generated automatically from the local electronic patient record. Additionally the recipient of the summary may wish to import structured clinical data from the summary into the local electronic patient record.

Basic information

- Patient demographics and contact information about relatives
- Treating physicians and web services to access the sources of clinical information
- Allergies, risks, chronic conditions
- Ongoing/last medications
- Meta-data (document owner, date of document creation, how to contact him/her, log information, and so on).

Problem-oriented registration profile

- Registration of patients for administrative and organisational purposes (e.g. for checking the rights to exemptions of co-payments and to grant permission to access specific services, e.g., home care programmes)
- Main and minor diagnoses
- Reference clinical pathways and customised (shared) care plan
- Process indicators (is the patient following the care plan?) and outcome indicators (are the clinical parameters within the planned range?).

Lifelong electronic health information in general

- History of the patient and development of the disease (reports from the healthcare contacts)
- Referrals among clinicians, based on predefined referral forms, which specify the context-specific clinical data sets needed in the different circumstance
- Notes by the physician/paramedics
- Notes by the patient
- Reasoning notes for general purpose of the time course of the disease
- Statistically relevant data for the healthcare authorities

Expected usage of data received from external sources

- presentation only (no data processing)
- presentation and storage/retrieval locally (e.g. as electronic documents, separate from the local record)
- presentation and semi-automatic import of clinical data into the local electronic patient record (with appropriate measures).

Format of data (structure of the content)

- Numeric/itemised *versus* narrative
- Non-Structured *versus* structured (e.g. as a complex data type for medications, with separate fields for generic ingredient, its code, package, dosage, route, etc)
- Context-dependent clinical datasets
- Semantic tables and terms of understanding.

Clinical knowledge

- Library of reference clinical pathways that are easy to use and to be customised into a patient-specific care plan
- Context-specific clinical data sets needed for effective cooperation among clinicians (international, national, local agreements)
- Medication databases (interactions, adverse reactions, costs)
- Evidence based medicine
- Multi-channel, multi-cultural authoritative clinical knowledge for patients and their families, to modify lifestyles and to induce the most appropriate use of services / facilities.

ANNEX 3: LEGAL AND REGULATORY BACKGROUND

The following list identifies a range of instruments that provide a possible legal and regulatory background for any work at the European level on eHealth interoperability. The items laid out in the list are outlined in diminishing order of the relative importance or impact of the instruments or documents. That is, Directives are more forceful than Recommendations, and Recommendations more influential than Communications.

Directives

Directive 95/46/EC of the European Parliament and of the Council of the European Union, on the protection of individuals with regard to the processing of personal data and on the free movement of such data; Official Journal of the European Communities of 23 November 1995 No. L.281 p.31

Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data, and the protection of privacy in the telecommunications sector.

Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

EC Regulation No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Recommendation 2/2001 on certain minimum requirements for collecting personal data on-line in the European Union (5020/01/EN/final WP43)

Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures OJ L 013 , 19.01.2000 p. 0019

Directive 97/7/EC of 20 May 1997 on the protection of consumers in respect of distance contracts, OJ L 144, 4.6.1997, p. 19;

Directive 2001/83/EC of the European Parliament and of the Council of 2 November 2001 on the Community code relating to medicinal products for human use.

§§ 50-53 of the Commission Guidelines on Vertical Restraints, OJ C 291/1 of 13 October 2000

93/42/EEC of 14 June 1993 on medical devices, OJ L 169, 12.7.1993;

5/374/EEC of 25 July 1985 concerning liability for defective products, OJ L 210, 7.8.1985, p.29,

Proposal; for a Directive

Proposal for a Directive Of The European Parliament And Of The Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM(2001) 404 final.

Recommendations

Recommendation 2/2001 Data Protection Working Party

Recommendation of Council of Europe 97(5) on the Protection of Medical Data

Communications

Communication (2004) 356 - e-Health – making healthcare better for European citizens: An action plan for a European e-health area

Communication on High Level Reflection Process on Patient Mobility (2004)

Communication on Healthcare and Care for the Elderly

Communication on Health Insurance Card (2003)

Communication on Quality criteria for Health Related Websites (2002)

Communication on the Web Accessibility Initiative (2001)

Commission (2004) 304 - Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the 'open method of coordination'

Opinions

Opinion of the European Group on Implantable ICT Devices (2005)

Opinion of the European Group on Ethical Issues of Healthcare in the Information Society (1999)

Reports

Yearly Reports of the High Level Group on Health Services and Medical Care to the EPSCO Council (2004, 2005)

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