European eHealth Interoperability Roadmap

Final European Progress Report

EU eHealth
Interoperability Roadmap

December 2010

About this document

The intention of this document is to propose a robust, complete and consistent global view of an EU eHealth Interoperability Roadmap, describing possible "highways" and presenting a coherent factual basis for decision making. It builds on the stakeholder requirements and consensus (vs expert view only) around a complete view of the working model needed to serve the common aim: *Sustainable Healthcare: Sharing Information and knowledge for better health. It does so by bringing together visions, concepts, principles and emerging findings from collaborative European cross–border initiatives.*

The intention of this second[1] iterative round of development of the Roadmap is to provide a composite, high-level description of the main elements that need to be addressed in order to fulfil this vision and present an initial set of recommendations.

The level of analysis should be sufficient to support planning of work and relevant decisions of the European eHealth Governance Initiative (eHGI) at strategic level. However, this document is *not* a political document nor 'the' solution for everything in (e)Health; it is not a cook book, neither a binding document nor the 'credo' for interoperability.

It is expected that the Roadmap will provide the needed factual basis to support the planning of the operational activities of the eHGI in taking forward priorities set by the High Level Governance Group (HLGG) of Secretaries of State. After consideration by this Group, the Roadmap recommendations should form the point of departure for the third iteration in the road mapping process. This will be updated and further elaborated in greater detail within the eHealth Governance Initiative process.

The document is structured in 5 chapters. Chapter 1 starts by providing an introduction to the objectives and process of development of the EU eHealth Interoperability Roadmap while placing it within the EU policy environment which is briefly presented. Chapter 2 provides the context of health policy needs that should drive the considerations of the Roadmap and sketches how eHealth acts as an enabler to support the necessary changes needed to fulfil an all-encompassing vision. While global, this vision relates to the individual EU citizen in all his/her potential roles whether as a patient, a healthcare professional, a decision maker, or an eHealth entrepreneur.

Interoperability is both a pre-requisite and a facilitator for eHealth deployment as it requires crossing boundaries – professional, cultural, organizational and technical. As a result, it stimulates profound changes in the way we understand partnerships for

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[1] *The first issue of the EU eHealth Interoperability Roadmap was delivered in March 2010 at the Secretary of State meeting in Barcelona.*

making the global shared vision happen. Chapter 3 focuses on specific challenges, objectives and outstanding issues for each of the four "pillars" of eHealth interoperability: *Electronic identification; Technical interoperability; Semantic interoperability and Legal and Regulatory interoperability.*

These interoperability areas must be organized and coordinated at both national and EU levels and which spans over the operational, strategy and political levels in chapter 4.   All considerations are brought together in a high level description of routes to achieving the vision. A possible route is presented at the granularity of "main highways" linking the various "major destinations" together. The example also shows how the European and national/regional activities may be articulated to accelerate interoperable eHealth deployment.

The outlook is then that this document should now provide the basis for the Mainstreaming Activity of the eHealth Governance Initiative and - through this - provide concrete input to decision making in support of the eHealth high level governance process. The Roadmap and its process will continue within the eHealth Governance Initiative.

In this way, a full iterative cycle of the Roadmapping process has been now completed. This cycle started with a CALLIOPE consolidated proposal on the specification of the Roadmap as a decision support instrument; was followed by a mainstreaming activity leading to a discussion document tabled in the Secretaries of State meeting in Barcelona in March 2010; and has concluded with the production of this document according to the positively received specification proposal.

CONSENSUS STATEMENT

This document has been produced by the CALLIOPE Network. CALLIOPE is a co-operative multi-stakeholder platform, sustaining a trusted, open, equitable, informed and transparent dialogue, synthesizing perspectives and opinions and producing policy proposals representing a balanced view and a consensus amongst its Members.

The Roadmap incorporates the results of several CALLIOPE workshops performed in collaboration with epSOS (six CALLepSO workshops); a workshop with EU collaborative projects focused on eID Management; a Convergence workshop with FP7 IP projects dealing with semantic interoperability and two standardization workshops organized in connection with major Standardisation events. It also incorporates input from five CALLIOPE Open Sessions organized in the period between June 2008 and November 2010. All information and relevant reports are available on the CALLIOPE website.

The discussions on the intent, focus, structure, and content of the Roadmap took place within the relevant CALLIOPE Priority Area of activities and have been chaired by *Michèle Thonnet, Ministry of Health, FR.*

The authoring of the document has been carried out by a small team consisting of *Zoi Kolitsi*, CALLIOPE co-ordinator; *Veli Stroetmann*, Empirica, DE and *Michèle Thonnet*, Roadmap Chair.

The authoring team has been supported by an editorial team consisting of   *Jeremy Thorp*, CALLIOPE Standardization Liaison, NHS, UK; *Paul De Raeve*, EFN; *Marc Lange*, *Diane Whitehouse, Stephan Schug*, EHTEL; *Michael Wilks*, CPME; *Petra Wilson,* Continua Alliance; *Jacob Hygen,* KITH, NO; *Torfi Magnusson*, UNIVICE, IS; and *Niels Rossing,* MedCom, DK.   The Personal Statements which represent views on needs and priorities of the different stakeholders have been edited by respective representatives: *Liuska Sana,* EPF; *Michael Wilks,* CPME*; Paul De Raeve,* EFN; *Mario Romao,* Continua Alliance*; Pascal Garel,* HOPE; *Marc Lange,* EHTEL; *and Jacob Hygen,* KITH*.

The first version of this document was discussed in the Athens plenary CALLIOPE meeting (September 2nd, 2010); A revised discussion document was reviewed in the Brussels Plenary meeting (November 16th, 2010). The final draft was approved by the Network Steering Committee in December, 2010 to be released for consultation within the CALLIOPE Members constituencies and the CALLIOPE Forum.

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FOREWORD

This roadmap describes a journey to a future in Europe when the immense number of ICT systems that are used in healthcare by providers and citizens will be able to capture, store, retrieve and transmit over a network in which security, authentication and non-repudiation can be assured. In this future, in spite of differences in coding and classifications, semantics and languages, the relevant data will be received by the authorized and authenticated human recipient as the same up-to-date, undistorted and meaningful information as intended by the similarly authenticated sender. Also, such transactions will be lawful, comply with all rules for data privacy and contribute positively to the quality of care, in general, and patient safety in particular. When all these demands are fulfilled we will have true eHealth interoperability.

The roadmap contributes to the work of European healthcare decision makers. European Member States – as the rest of the Western World – have realized that eHealth is an essential tool, much needed for changes in healthcare provision.

The potential of eHealth can however only be fully exploited if eHealth tools and solutions are interoperable. Since 2004 the EU Commission and Parliament, together with member states in a long series of communications and reports have highlighted this aspect and in 2009 the EPSCO Council mandated the formal establishment of the High Level eHealth Governance Group.

While it is possible to summarise *why* and *how* eHealth interoperability should be promoted and *who* the actors are, it is more difficult to suggest a common pace of change. This is because of differences between Member States in a great number of relevant aspects.

The healthcare delivery landscape is expected to change significantly in the future to cope with the dynamic change of society, such as ageing and demographic shift, as well as the rise in new healthcare opportunities. It is no longer enough to add new patches to what is already a patchwork of legacy and traditions. This is due to changes in both the demand and the supply side, some of which are outlined below. The future of healthcare will be patient-centric and with an increased focus on health promotion and health maintenance. Appropriate use of interoperable eHealth has already demonstrated its ability to underpin a strategy for modernizing the system. However, the more complex and the more fragmented the healthcare provision and the insurance systems are the more complex and fragmented will the eHealth services be. Both positive as negative lessons learned from the past must influence future decisions.

On the demand side,

- ✓ Citizens want to be empowered by being well informed and in a less asymmetrical position *vis à vis* the professionals when it comes to knowledge and decision-making about their health situation.

- ✓ Life expectancy is rising and so is the prevalence of chronic conditions. At the moment as much as 80 per cent of national healthcare budgets are spent on

chronic disease management. To address these costs, patients should be de-institutionalized and cared either at home, with their families or in the local community.

✓ Diagnostic procedures, medical treatment and technologies are increasingly complex and costly, and should be automated and digitized to the extent possible.

✓ Society and patients expect that therapy and care are optimized to the highest level of quality and cost.   Adequate, ICT enabled benchmarking of quality and performance will be needed with secondary use of individual data.

✓ Society and patients expect a continuum of care, what is also called seamless care. This implies that care should be delivered on a well-informed basis unhampered by traditional boundaries between professional specialities and organisational sectors. Information silos are out; shared information is in.

✓ Citizens are increasingly mobile and do not expect that geographical borders, be they between regions or nations, will block their access to adequate care when moving around either for leisure or for work.   Therefore, care providers must be empowered to familiarize themselves with hitherto unknown patients' health stories irrespective of time and location.

✓ Research, professional training as well as early epidemiological surveillance, warning and alert systems will make secondary use of aggregated health data of individuals.

On the supply side,

✓ As the demographic shift begins to impact there will inevitably be a shortage of skilled healthcare labour resources and medical expertise. Also, the costs of human resources will continue to represent a very high proportion of the total spending in the sector. These facts will be a driver to smarter ways of using the personnel

✓ Empowered and up-to-date informed patients and informal carers must become active and co-responsible participants in their own treatment

✓ With the increased complexity of healthcare delivery and the need for shared information new working procedures and workflows have to be established. Repetitive collection of the same data by different care providers asking in the same period for the same examinations or asking patients or their informal carers the same questions can no longer be afforded and is anyway bad service

European Member States should make use of the initiatives taken by various services of the EU Commission in terms of support to standardization, R&TD programmes and projects as well as an extensive series of reports and communications. Especially, the Large Scale Pilot Project on cross border eHealth interoperability, epSOS, working in collaboration with the thematic network of CALLIOPE should be a beacon. The use cases of ePrescription and Patient Summaries are kernel domains. Common ground will also be found with projects on other and more generic aspects of eGovernment as discussed later in this document. Cross-border solutions for eHealth interoperability may turn out to be also the solutions for regional or national interoperability.

Major developments of interoperable healthcare solutions and innovations will need public-private partnerships whether that is at the local or the European level.

The European eHealth industry should keep abreast with the global eHealth market because it has a huge economic potential but is also an area of immense competition. That is equally true for large and smaller IT systems, grid and cloud technologies, communication technologies with imbedded services, and the rapidly developing sector of smart telephony.

Interoperability requires standards and standardisation. The European Commission's efforts to promote standardisation should be strongly supported and exploited by Member States.

The financial investment and the operational costs of interoperable eHealth is an opportunity cost competing with other costs in the sector, so the economic aspect is essential for the eHealth strategy at local as well as at European level.

Niels Rossing

November 2010

Authentication (of a person): The provision of assurance of the claimed identity of a person. The identity is claimed by using a user identifier or a token and the level of verification assurance achieved is determined by validation of one or more of the following elements:

- o A PIN (Personal Identification Number) or a Password known only by the valid claimant

- o A set of biometric data related to the valid claimant

- o A private key under the sole control of the valid claimant

- o Verification by an appropriate relying party of the validity of the certificate to which the secret key is related (CWA 15264-1:2005)

Collaborative Governance comprises the rules, processes and behaviour that affect the integrity, capability and shared ownership of processes that extent over several professional, sectoral and jurisdictional domains, particularly as regards openness, participation, accountability, effectiveness and coherence [adapted from CALLIOPE governance definition].

eHealth Governance Initiative is the Member State lead mechanism for EU co-operation at political, strategic and operational level, mandated by the EPSCO Council in December 2009.

eHealth Interoperability is a characteristic of an ICT enabled system or service in the healthcare domain that allows its users to exchange, understand and act on citizens/patients and other health-related information and knowledge in a commonly interpreted useable way. In other words it is a means of crossing linguistic, cultural, professional, jurisdictional and geographical border in eHealth. In CALLIOPE, interoperability is addressed within the conceptual framework of the EC Recommendation on cross-border interoperability of electronic health record systems[2].

eHealth Interoperability of electronic health record systems is defined as the ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge. [EC Recommendation on cross-border interoperability of electronic health record systems[2]]

EU Governance refers to the rules, processes and behaviour that affect the way in which powers are exercised at European level [European Governance: a White Paper][3].

e*Services are all electronic services together comprise integrated ICT supported health services to citizens. Examples of such services are electronic identification, authentication and authorisation services, telemonitoring, access to electronic health records, ePrescribing, e-dispensation and e-reimbursement.

High Level Governance Group is the political level of the eHealth Governance initiative; its membership is Secretaries of State or individuals with an equivalent role

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[2] *Commission Recommendation on cross-border interoperability of electronic health record systems, Brussels, COM(2008)3282,*
http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf

[3] *Commission of the European Communities. European Governance: a White Paper. Brussels, 25 July 2001 (COM(2001) 428 final)*

in national governments with the responsibility for planning and deploying national eHealth solutions.

Identification is the process of obtaining information about who the requester claims to be without considering the trustworthiness of this information. (CWA 15264-1:2005)[4]

Identity (of a person) is the common sense notion of personal identity; a person's name, personality, physical body and history, including such personal attributes as address etc, of an individual person. (CWA 15264-1:2005)

Incentivisation is the practise of building incentives into an arrangement or system in order to motivate the actors within it [Wikipedia]

Information Governance is a framework of policies and procedures for handling personal health information in a confidential, secure and accurate manner to appropriate professional, ethical and quality standards in a modern health service and concerns keeping, obtaining, recording, using and sharing such information.

Infostructure is the layout of information in a manner such that exchanged information is understandable by humans and by other relevant systems and applications in or by which the data were not originally captured.

Interoperability is a characteristic of an ICT enabled system or service in the healthcare domain that allows its user to exchange, understand and act on citizens/patients and other health-related information and knowledge in a commonly interpreted way. Interoperability is a multi-level issue, including not only the technical level, but also the legal, organisational and semantic ones.

Technical Interoperability describes a state which exists between two application entities, with regard to a specific task, when one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention. In the context of health informatics, this implies full end-to-end interaction of health records from origin to point of use. [adapted from CEN TR 14300:2002]

Use case is a description of sequences of events that, taken together, lead to a system doing something useful[5] [Wikipedia]

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[4] *See ftp://ftp.cenorm.be/PUBLIC/CWAs/e-Europe/eAuth/cwa15264-01-2005-Apr.pdf. This CWA has developed the concept of Interoperable IAS – i.e. a "Set of processes, data and technology agreements required in a given environment to provide Identification, Authentication and electronic Signature services" – for accessing eServices*

[5] *Kurt Bittner, Ian Spence (2002). cited at http://en.wikipedia.org/wiki/Use_case*

Abbreviations

AAL	Ambient Assisted Living
Article 29 WP	Article 29 Working Party
CPD	Continuing Professional Development
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CWA	CEN Workshop Agreement
DPD	Data Protection Directive
eAuth	electronic Authentication
EC	European Commission
eID	electronic Identification
EIP	European Innovation Partnership
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
epSOS	European Patients Smart Open Services
ESO	European Standardisation Organisation
ETSI	European Telecommunications Standards Institute
EU	European Union
HL7	Health Level Seven
HIT	Health Information Technology
ICD	International Classification of Diseases
ICPC	International Classification of Primary Care
ICT	Information and Communication Technologies
IHTSDO	International Health Terminology Standards Development Organisation
IPR	Intellectual Property Rights
ISA	Interoperability Solutions for European Public Administrations
IT	Information Technology
eHGI	eHealth Governance Initiative
HLGG	High Level Governance Group
IHE	Integrating the Healthcare Enterprise
LOINC	Logical Observations Identifiers, Names, Codes
M403	Mandate 403
MS	Member State
MTC	Master Translation/Transcoding Catalogue

MVC	Master Value Sets Catalogue
NCP	National Contact Point
OECD	Organisation for Economic Co-operation and Development
PET	Privacy Enhancing Technologies
QA	Quality Assurance
SDO	Standards Developing Organisation
SNOMED CT	Systematized Nomenclature of Medicine -- Clinical Terms
TET	Transparency Enhancing Tools

1 Introduction

1.1 The need for an EU eHealth Interoperability Roadmap

A roadmap describes a future state, based on a vision shared by its stakeholders and provides a framework for making that future happen. A roadmap for eHealth should represent an appropriate mix of reality and vision. It should stimulate innovative change, benefit patients and citizens and be achievable for healthcare professionals, authorities and industry.

The healthcare needs that the countries or regions are trying to fulfil are changing dramatically. Today, the general picture is that each country or region is separately trying to solve the same problems. In addition, each country or region, organisation or division of the particular organisation lacks the resources and skills needed to boost innovation and would benefit from joint effort towards this.   Recently, some collaborative action at EU level has emerged[6.]

The Roadmap needs to take these developments further and transform them into a much broader approach to "sustainable healthcare". This sustainability builds upon integrated, affordable care for patients and health professionals supported by electronic services. The potential of eHealth is exploited only if it is interoperable. The European eHealth Interoperability Roadmap ("the Roadmap") builds on the vision of a desired future for all parties involved and provides a framework for making that future happen. The EU eHealth Interoperability Roadmap is to suggest action primarily at EU level, to be taken up in common so as to benefit national eHealth deployment efforts.

The Roadmap proposes integrated solutions and focuses both on new enabling technologies and on the elements required to generate, implement, and support them. In addition, the Roadmap addresses challenges to the emergence of desired solutions, including current government policy and regulations. In doing so, the Roadmap attempts an appropriate mix of reality and vision in order to stimulate innovative changes that benefit patients and citizens and are feasible for healthcare professionals, authorities and industry.

1.2 EU policy background

The evolution of the concepts which underpin the approach taken in this document is already reflected today in a number of EU-level policy documents. At the European level such redesign should attend to the rights of the mobile citizen throughout the Union.

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[6] *Collaborative EU actions today focus on patient summary and ePrescribing in epSOS, chronic disease management in telemedicine pilots in Renewing Health, e-Identification services and integration initiatives in STORK for citizen and HPRO for healthcare professional specific identification and authentication. In response to Mandate 403 of the European Commission, the EU Standardisation bodies have begun launching activities to support market delivery of interoperable solutions, based on representative use cases developed in such projects.*

✓ The need for continuity of care and safety for citizens travelling in the EU is addressed by the Draft Directive of the European Parliament on the application of patients' rights in cross border healthcare, approved by the Council in June 2010.[7] The ministers agreed on close collaboration between the Member States and the Commission in the eHealth field. In particular, the article on eHealth (currently Article 13) foresees that Member States, together with the Commission, will elaborate guidelines on patient summaries and will take action to make their transferability possible in cross-border care contexts.

✓ The Lead Market Initiative on eHealth[8] has taken a new policy-coordination approach. It is based on a better balance between supply and demand both between and within Member States with a specific focus on eHealth – namely, telemedicine and personal health systems. A proposal for a Lead Market path with measurable actions and binding targets has been provided.

✓ The Digital Agenda[9], as part of the "EU2020" approach and strategy, also promotes this approach: eHealth is placed in a cross-sectoral framework. Within the Digital Agenda the following action points are included:

   o Key Action 13: Undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services.

   o Key Action 14: Propose a recommendation defining a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012.

   o Other actions include:

      ▪ Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015 through stakeholder dialogue.

      ▪ Reinforce the Ambient Assisted Living (AAL) Joint Programme to allow older people and persons with disabilities to live independently and be active in society.

✓ The European Commission has recently launched a consultation on a pilot European Innovation Partnership (EIP) on active and healthy ageing. The EIP, due to be launched in 2011.

The Commission services though Mandate 403, have invited the European standardisation organisations to develop their recommendations on eHealth

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[7] *The Council agreed on a draft directive concerning the application of patients' rights in cross-border healthcare, on the basis of a compromise proposal at the Employment, Social Policy, Health and Consumer Affairs Council meeting, Brussels, June 8, 2010, http://www.europarl.europa.eu/oeil/file.jsp?id=5661632*

[8] *http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/*

[9] *European Commission: A Digital Agenda for Europe. Brussels, 19.05.2010, COM(2010), http://eur-lex.europa.eu/ LexUriServ/LexUriServ.do?uri=CELEX:52010DC0245:EN:NOT*

standardisation into a detailed and well-documented work programme.[10] The Mandate aims to also bring industry driven associations such as IHE and Continua into the ambit of the formal standards development organisations. The programme is intended to provide justifications, scoping documents, and deadlines for specific standardisation actions. Ultimately, there will be an improvement in the development, use and testing of eHealth standards. This new collaborative approach is expected to improve European ICT market competitiveness, and benefit health systems significantly through the integration of fit-for-purpose eHealth systems and services.

European national governments have taken important steps towards a collaborative approach to resolve cross-border challenges[11]. The European Commission supports such collaboration initiatives through both its policy initiatives and its funding instruments within the key priorities of citizen mobility and borderless healthcare. These are outlined in the eHealth Action Plan[12], which has since 2004 aimed to create the conditions for a seamless flow of information between interoperable systems for the benefit of patients.

To support this major objective, in July 2008, the Commission launched three interlinked initiatives:

(i) A Recommendation on cross-border interoperability of electronic health record systems[13], which puts forward a number of recommendations for eHealth interoperability involving policy, social, and legal aspects; and technical and semantic interoperability. At the same time, the Recommendation addresses the creation of processes and structures towards interoperability in Europe, security and privacy as well as certification issues.

(ii) epSOS, a Large Scale Pilot[14], and

(iii) CALLIOPE[15], a European Thematic Network, both co-funded through the CIP Programme.

These two collaboration actions, aimed at making progress on the agenda for interoperable cross-border eHealth, have joined forces in a strategic complementary approach. They are instrumental in addressing the current eHealth interoperability challenges. epSOS is an EU large scale project focused on developing interoperable

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[10] *Mandate 403: Mandate issued by the European Commission to the three European standards development organisations (ESOs): CEN, CENELEC, and ETSI, to develop a coordinated work programme for standardisation in health informatics, Committee On Standards And Technical Regulations, (98/34 Committee) 11/2009 EN*

[11] *Council Conclusions on Safe and efficient healthcare through eHealth http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/111613.pdf*

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

[13] *Commission Recommendation on cross-border interoperability of electronic health record systems, Brussels, COM(2008)3282, http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf*

[14] *www.epSOS.eu*

[15] *www.calliope-network.eu*

Patient Summaries and ePrescription services to be piloted within the lifetime of the project; a long term perspective is guaranteed by the commitment of the participating Member States.

The next challenge for epSOS is to achieve better integration with other public sectors. Its extension will be expanded to reimbursement and emergency services, and the eID domain. At the same time, new clinical challenges will be addressed. CALLIOPE supports this process by providing a European platform for open dialogue and strategic collaboration with the relevant stakeholders so as to advance the development and deployment of interoperable eHealth. The eHealth INTEROP project[16] is launched by the three European standardisation organisations with the support of the European Commission with a view to enable the market to deliver interoperable solutions.

In 2009, the European Commission published also the telemedicine communication on "Telemedicine for the benefit of patients, healthcare systems and society" [17].

As already indicated, these interoperability challenges are common to all countries. European action - through "exploitation" of cross-border scenarios - can add value and help accelerate developments, especially in those areas such as standardisation, clinical evidence-based processes, and exchange of best practices which are less affected by regional differences. This approach is being pursued today in collaborative pilot projects, such as epSOS, involving MS national authorities and industry. The use cases dealt with are based on common priorities, and address all the facets of interoperability challenges in a multinational, interdisciplinary environment. Process improvements, acceleration of testing, and adoption and use of cross-sectoral standards are being pursued through close co-operation with national, European and international standardisation organisations. This in turn strengthens and binds together the European health IT industry and stimulates partnerships. The immediate benefits for the public sector and health authorities mean that they can begin to rely on open and sustainable IT solutions.

Many projects and initiatives from research to competitiveness and innovation programme actions are also supported at EU level. Prioritisation and a concrete action plan are needed in order to bring them to reality for Europe's citizens.

The EPSCO Council Conclusions of December 2009 represent a strong political mandate for EU eHealth cooperation in four specific areas of interoperability:

- o *legal (including regulatory and ethics)*
- o *standardisation / technical issues*
- o *semantics*
- o *identification and authentication*

The aim is to boost deployment of eHealth services in Member States. The process will be facilitated through the establishment of the European eHealth High Level Governance Initiative and the process in Europe which shall be addressed at three levels focusing on policy, strategy and cooperation. These levels of governance are interlinked and complementary and should together provide for specifying priorities

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[16] *http://www.ehealth-interop.nen.nl/*
[17] *http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm*

and needed actions to be taken together at EU level to support our national implementations. At the policy level, the process will be driven by the High Level Governance Group (HLGG) of Secretaries of State.

1.3 The scope, intended use and application of the Roadmap

The elaboration of a sustainable EU eHealth Roadmap, "the Roadmap", was launched as an iterative process in CALLIOPE and builds on clear common priorities from the December 2009 EPSCO Conclusions and the four areas of interoperability. The Roadmap is intended to provide the High Level Governance Group with appropriate support and the basis for related decisions.

The EU eHealth Interoperability Roadmap *focuses on cross-border interoperability*. It aims to describe an approach to overcoming any current barriers that fail to enable EU citizens to fully enjoy the potential of travel with all their rights as foreseen in the Treaty.

However, in health terms, it is important to consider that crossing borders is not only a challenge with an international character. Such borders also exist between public service sectors, administrations, and professional domains. They form major obstacles to providing integrated services with a citizen focus. The approach of this Roadmap is to consider many different but interrelated aspects of eHealth interoperability. Those aspects reflect the notion of "crossing any border". Therefore the content of the Roadmap is directly transposable to the national and regional levels. Moreover, in this complex landscape, the role of the EU eHealth Interoperability Roadmap is to support the goal of person-centred, efficient, easy to use (e)health services and to pursue their convergence around the person.

Even though there is a shared target, the Roadmap recognises that there are different ways and speeds of reaching that target. These are dependent on different countries' and regions' organisation, political decisions, national legal and regulatory frameworks, and levels of development of national infrastructure.

The Roadmap defines common steps with a focus on eHealth in support of citizen-centred services. It proposes integrated solutions and focuses both on new enabling technologies and on the elements required to generate and facilitate those.

The Roadmap offers a route towards the common vision, which progresses from today to tomorrow, helping decision makers identify, select and further develop appropriate alternatives. It is developed through an iterative process around specific priorities set by the EU High Level eHealth Governance Group. Ideally, the Roadmap will be widely adopted by a range of decision makers in their medium- to long-term planning cycles. The process and respective output could be tailored to the particular circumstances and healthcare priorities of a country or region.

The Roadmap also recommends actions to improve the capacity of healthcare to deal with disruptive innovation throughout the innovation chain. This would involve better integration and reduced time from research and development to full service deployment.

1.4   The Roadmap development process

The process of current and future development of the Roadmap involves pooling the needed competence and expertise in an open collaboration. This encompasses health authorities, competence centres and other EU level organisations, patients, health professionals, experts, academics, payers, and industry. This collaboration is currently in place in the form of the CALLIOPE Thematic Network. CALLIOPE is a co-operative multi-stakeholder platform, sustaining a trusted, open, equitable, informed and transparent dialogue, synthesizing perspectives and opinions and producing policy proposals representing a balanced view, accompanied by a clear statement of the level of consensus achieved.

It is envisaged that this process will now migrate to, and be incorporated, in the integrated eHealth Initiative framework of activities. At the same time, it will maintain its momentum, its multi-stakeholder character, and collective competence.

Each issue of the Roadmap will reflect an updated "snapshot" of the future, generated over specific time intervals, and address current priorities. Each issue will describe the practical implementation steps that need to be taken both at EU and national levels to achieve EU eHealth Interoperability.

The first issue of the Roadmap was produced in spring 2010. As a first step, it provided a description of the possible characteristics of the eventual Roadmap. It included the scope, process of development, main focus and intended use. It was submitted for consideration to the High Level Governance Group in March 2010, so as to ensure that this policy support instrument would be in full alignment with Europe's policy priorities on eHealth in terms of both content and pace.

This second issue of the Roadmap builds on the first positive response to the proposals by the Group. It provides the next step in the composition of a complete view of the working model of a Roadmap needed to serve the common vision. It does so by bringing together concepts, principles, and emerging findings from collaborative EU cross-border projects and pilot activities. This is laid out in the agreed Roadmap content organisation framework.

This second issue of the Roadmap also proposes a set of recommendations. After they have been considered by the Secretaries of State, they should form the point of departure for the third iteration of the Roadmap. This second issue will not include a detailed action plan. Rather, it will be updated, further elaborated, and detailed through the work of the eHealth Governance Initiative.

2 Context

2.1 Health policy needs

EU Member States face similar challenges of meeting the increased need for care which are caused primarily by the rapid aging of the population and the unprecedented increase in patients with chronic disease. Partly as a result of these developments there has been a significant growth in the number of patients with several chronic co-morbidities, as well as a wider range of other age-related conditions and infirmities. In a publicly financed health system, these sets of demands are transformed into demand for care and a strain on shrinking healthcare budgets.

On the demand side, society and patients expect that therapy and care are optimized to the highest level of quality. Indeed, the enormous progress in health research and technology provides many new treatment possibilities. While these are increasingly effective, they are - with a few exceptions - considerably costlier than the treatments they replace. The options for permanent cures remain however remarkably few. At the moment as much as 80 per cent of the total healthcare costs are spent in the area of chronic disease management. At the same time, there is or will inevitably be a shortage of skilled healthcare professionals, while the costs of human resources will typically be a significant proportion of the total spending in the sector.

Many ethical dilemmas challenge political decisions with regard to the proper allocation of scarce resources, while rising costs clearly threaten the ability of society to finance healthcare. If an increasing part of the costs are shifted to patients, the threat to the equity principle is obvious.

The historical origins of national healthcare systems across the EU vary. This is reflected in their structure, their work force and their financing. Nevertheless, all are converging towards similar future visions concerning their health services delivery system and the reforms needed under their common epidemiological and financial pressures:

Patient centred care: The individual – patient, citizen or informal carer – becomes an integral part of the care team who collaborates with healthcare professionals in making health related decisions. Cultural traditions, personal preferences and values, family situations, and lifestyles are respected. The individual is therefore empowered to become an "active node" in the regional, national [and prospectively international] health system network.

From curing disease to creating health... Personalised care is furthermore directed to health promotion, disease prediction, prevention, and individualised therapy.

... and care integration: Patient-centred care requires that transactions between providers, departments, and healthcare settings are coordinated and efficient. Care integration provides an effective means to reducing waste and to balancing health needs against demands for care. It aims to realise a new model of cross-sectoral, person-centred service delivery that will break down boundaries between different organisations' missions and resources. Integration presupposes that

the care providers are able and willing to work together effectively, and apply new ways to divide/share labour between institutions and professionals.

Health in all policies: Generally, healthcare does not have a monopoly, in health production. Much of the health of populations is dependent on other social and environmental factors. The health systems also depend for their own functioning and efficiency on the strategies and policy choices made by other public sectors. Likewise, they in turn have an impact on the functioning and efficiency of other sectors, such as the employment sector. Thus, healthcare systems have a remarkable opportunity to control costs by extending influence outside their own domain.

Rethinking the basics: The planning of an effective care system should then cross several boundaries: these include professional, institutional, geographic, and sectoral boundaries. The seamless care environment should be one where the ratio of effectiveness to cost reaches its highest value. Examples include the avoidance of duplication, and the enabling of a distributed care environment. Needs would be matched to demand, and the whole social network – from tertiary hospitals to the home – would assume an appropriate role in the continuum of care. Eventually, a re-distribution of labour across actors will be necessary.

Sharing benefits and risks: Strategic partnerships for healthcare reform can make it possible to manage complexity, to handle risks at their most effective level of competence and reflect value appropriately. This end-to-end value chain would be associated with any reimbursable integrated service. Open, transparent collaboration with key stakeholders is an important enabling mechanism for change.

Information and incentives: Two elements and their interplay are considered especially relevant for changing healthcare delivery based on value for patients – information and incentives. Substantial improvement in the system of healthcare will require that stakeholders have easy access to information about the state and performance of the whole health system, or any of its sub-system, and can use this information for their decision-making and any adjustments to incentives and rewards.

The quality and safety imperative: Quality and safety of care cannot be compromised. Continuous improvement can only be achieved if accurate information is available in a meaningful and sharable way. The development and maintenance of the health infostructure (i.e. the information infrastructure) is a pre-requisite to support a knowledge-driven health workplace. It requires appropriate organisational infrastructures.

Legislation as a facilitator: Legislation must become a facilitator to innovation by supporting the dynamics of change while providing full protection and legal and ethical certainty. This is achieved in synergy with other enablers including standardisation, clinical governance and through fostering security and quality cultures under an integrated framework of trust that is enforced and protected by law.

Technological progress alone cannot address the eminent quality, safety and cost-effectiveness deficit. To render healthcare sustainable, health policy must urgently ensure that full use is made of appropriate resource-saving approaches and smarter
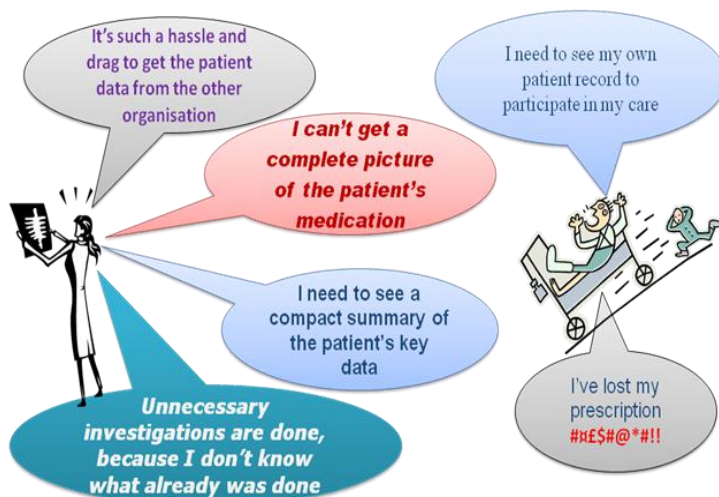
ways of using human and other resources. This implies also fostering professional management and governance and drastically improving efficiency in "health production" processes. The needed changes must originate at the healthcare system level; however, they must share a single focus and the commitment of all stakeholders to reduce the burden of disease and disability.

Change requires that healthcare systems develop an ability to adopt service innovation, most often highly disruptive at the beginning, through major paradigm shifts in all strategic areas including planning, implementation and funding of services. ICT enabled delivery processes must be appropriately re-engineered to become more efficient, person-centred and sustainable; and services must be integrated around people's needs.

As a fundamental principle, continuity of care requires that health professionals share work paths and exchange information about and with patients at appropriate points in the care or treatment process. This in turn means supportive infrastructural arrangements such as shared patient records, collaboration and a clear, transparent, incentives structure.

2.2 Personal Statements

As a patient, I expect to get high quality personalized healthcare on an equal access basis, regardless of my social status and where I am located, with full respect of my privacy. I want to be in the centre of the care process and benefit from personalised care. I wish to be empowered and coached to choose where I need to go to be cared; when ill, to stay at home as much as possible and spend as little time as possible in hospitals. I want to be mobile and to be guaranteed safe care anytime and anywhere with the doctor, the nurse or the pharmacist treating me having access to my health data - medication that I take, allergies and chronic conditions - just like at home. To be able to trust the healthcare system, I need guarantees that my privacy is protected, my personal

Sources: Questionnaire to 4000 physicians, The Finnish Medical Society, THL and Aalto University (2010, manuscript in preparation) Hyppönen & Niska, Kohti kansalaisen sähköisten terveyspalvelujen rakentamisen hyvää käytäntöä, Stakes 9/2008 (in Finnish)

preferences are observed, the information needed to care for me safely is available as appropriate and I am part of any decisions regarding my condition.

As a citizen, when in good health I want to have the possibility to maintain my health status and prevent illness. I expect the healthcare system to provide the information I need to keep well and healthy and to have in place screening and prevention programmes and devices that monitor my health and can help identify as soon as possible any symptoms of health problems I may have.

As a healthcare professional, I start working in the morning with all my patients' profiles readily available. My electronic identity makes me an active node in the system: I can access my patients' electronic health records and all other patient information I need: admissions, discharges, referrals, laboratory results, medication, nutritional status, mobility needs and disabilities, allergies, professional and carer contact points and second opinion services. These services are user-friendly and designed to help me minimise the risk of errors, especially in cases with patient communication barriers and allow me to assign my time to the benefit of patients. I know how many registered people I am in charge of today, on whom and I am able to plan my day's journey by sharing information with my colleagues in a secure environment that allows me to guarantee my patients' right to privacy.

Within this healthcare system of shared knowledge and information, I .can follow up any development in the patients' health status at home. Consequently, as a healthcare professional, I provide a holistic approach to care, of high quality, safe and patient centred based on real patient's needs.

My colleagues have identified Ms. James as a person with special needs, and have duly noted this in her EHR. Ms. James does not need more test as no complications where observed but instead needs more care because of the surgical wounds not healing due to her diabetes. While planning her discharge I contact the primary care team in her village to inform them about all Ms. James' needs. I am able to emphasise her current situation adding her expressed needs for social care because she lives alone. Tomorrow, I hope Ms. James will feel more confident because the primary care team member will be waiting for her and her closest pharmacy will know which medication she has to take.

As an ICT service provider, I am an active player in the system of integrated, interoperable, high quality, efficient, affordable and secure e*Services for health and social care such as telemedicine and personal health systems solutions, electronic health records and ePrescribing services. I am also a contributor to the value chain. As a member of the EU ICT industry, I enjoy the benefits of policy-coordination for a borderless market, an integrated economic area, supported by legal certainty and harmonised rules, standards and guidelines. I am both a key contributor to and beneficiary of the development, use and testing of such standards and guidelines.

"Borderless" of course is more than a geopolitical matter; I also encounter no borders between sectors, between IT providers or between professions, and none that prevent IT systems to evolve in time and accommodate new technologies. Reducing the burden of bureaucracy makes me more competitive, increases the quality of my services, and reduces waste in my production costs. I am an active stakeholder and contributor to a new collaborative governance, because I believe that pursuing the goal of significant benefits for health systems through fit-for-purpose, integrated eHealth systems and services will also contribute effectively to improving European ICT market competitiveness.

As a healthcare manager, I am provided with the evidence and tools that I need to effectively manage healthcare provision. What is expected from me is to deliver high quality and efficient care to patients by steering and keeping my work on track to meet goals and agreed targets. I can draw on all kinds of information and create reports that are needed for the control of my processes, monitor quality and resources. I am empowered to learn continuously, improve performance, and manage risks.

I can meet all the obligations for internal and external reporting by using and in turn providing dependable information. I can perform correlations that are based on historical data that can guide my future planning and improvement strategies. I can increase my evidence base by sharing information and knowledge with others. This is possible because my system of applications and data registries is fully interoperable under a robust and auditable information governance that enables a trusted exchange of data in a fully secure and legally compliant system. This system has furthermore to be designed and implemented so as to be accountable to all partners in the patient pathway. This complexity is no longer a problem for me. Standardisation makes it possible for all partners to be empowered to manage the complexities in their own areas of the value chain - which are also their areas of core expertise – and to undertake their mission.

As a healthcare politician or a healthcare policy maker, I am an active supporter of and contributor to an accountable, citizen-centred, high quality, safe, and sustainable health and social protection system based on shared knowledge and information. Whether I am making decisions on health promotion, service provision or reimbursement policy, I interact with my counterparts in other governmental sectors in a trusted relationship of reciprocal benefit, beyond the simply managing of the daily functioning of my system. I am challenged to meet the needs of an ageing society, improve quality of care, and maximise the social benefits. For this, I provide financial incentives for a major health and social care reform based on shared care, shared knowledge and shared information. Major reforms such as personalised care for the chronic and elderly patients at home, have demanded a great deal of disruptive innovation, but we can achieve this together because we provided for legal, and standardisation enablers of change. Most importantly, we have a Collaborative Governance in place that allows us to cross sectoral boundaries, sustain an honest and transparent dialogue and profit from a multidisciplinary stakeholder engagement. High quality, accessible and affordable health and social care services are reconciled transparently around the citizens in a way that hides the huge technical and organisational complexity behind them.

As a public policy decision maker, outside the healthcare world, I am an active supporter of and contributor to an accountable, citizen-centred, high quality, safe and sustainable health and social protection system of shared knowledge and information. When I have to make a decision in my own policy field, I interact seamlessly with my colleagues in the other governmental sectors in a trusted relationship of reciprocal benefit, beyond simply managing the daily functioning of my system: I am challenged to meet the needs of the population of citizens I have to serve. I fully recognise that in whatever domain I am in charge, we all need to have a healthy population and that the health sector is one of the most important employment forces for our country or region. Any decision made in the health sector influences mine.

A means of collaborative governance reconciles the needed multidisciplinary and multi-sectoral work – irrespective of how the government is organised – for the benefit of all, in a non-discriminatory way. This is a new way of working that enhances transparency and increases teamwork in helping each of us to re-use basic

standardised components or solutions such as common identification, repositories, and rules.

In my multiple roles, I receive services that reconcile all my different needs and personal visions. To achieve this new reality my public administration has engaged in collaborative work under common governance and a shared fit-for-purpose, regulatory framework. It has made these integrated services possible, effective, and fully trusted.

Most EU countries or regions and many large healthcare providers have at least a partial vision of their own place in the future. However, they all face uncertainty about the technology applications that future markets will create, what future users will demand, and when and for what purpose new technologies will be needed. Drawing these visions together to create an agreed common strategy and collaborative action is expected to greatly increase the chance of making each individual vision part of tomorrow's reality. While such a strategy should be sufficiently long term, its milestones and actions should also cover both short- and medium-term time horizons.

2.3   eHealth as an enabler of change

eHealth has the potential to be an enabler of major transformation. The 2010 OECD report "Improving Health Sector Efficiency: the role of information and communication technologies"[18] underlines that numerous findings illustrate the potential benefits that can result from ICT implementation. These can be classified according to four broad, inter-related categories of objectives: increasing quality of care and efficiency; reducing operating costs of clinical services; reducing administrative costs; and enabling entirely new modes of care.

eHealth has the ability to support a person-centric healthcare delivery and the active participation of the patient in healthcare processes. A new paradigm has emerged that would support citizen-centred approaches across sectors in electronic public service delivery beyond health. This responds to citizens' expectations of receiving fully integrated services which cater to the full range of their specific needs in a holistic approach. Therefore health and social care need to be redesigned with the support of Information and Communication technologies (ICT) so as to reconcile[19] numerous public e*Services across sectors. These e*Services would support sharing of information and knowledge and would streamline multi-sectoral workflows. Hence, they have the potential to strongly contribute to continuity and safety of care.

The draft EU Directive on patient rights to cross-border healthcare will establish the legal certainty of citizens to exercise their healthcare rights in the EU. It recognises eHealth as a major enabler for its implementation.

For eHealth to be an enabler of change, eHealth implementation processes will also need to be re-engineered in order to be better accepted, widely adopted and used, and hence sustainable. At EU level, action is being taken to improve framework

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[18] *Improving Health Sector Efficiency. The role of information and communication technologies. OECD Health Policy Studies, 2010*

[19] *"Reconciliation of services" is meant as a way forward to (e)Health (cross-border) services built upon non ambiguous, commonly agreed use cases that spanning across several EU Member States".*

conditions for businesses to innovate, speed up setting of interoperable standards, and make full use of demand-side policies, e.g. through public procurement and smart regulation. Furthermore, European efforts to build the info-structures needed, as common re-usable components for interoperability, should be strengthened. These issues are dealt with in chapter 3.

2.4 Responding to health policy needs

The new paradigm should be reflected in the policy and legal framework. It should pave the way for a new way of working to re-engineer the healthcare processes. It can set the direction and provide the inspiration and the necessary conditions for the empowerment of the actors of change to engage in re-engineering the way health and social care are provided. Policy development and its transformation into strategy must, in order to succeed, start with a strong focus on improving, streamlining, and integrating service delivery processes.

Perhaps the most challenging areas in terms of complexity, actors involved, and the extent and span of the service ecosystem, are the two domains of chronic disease management and integrated care. At the same time, these are among the highest priorities in terms of rapidly rising demand and costs of care. An example which illustrates a composite view of how such a complex ecosystem may fulfil the multiple visions of all its actors is provided in Annex I.

Supporting the dynamics of change will furthermore necessitate strategies to shorten the innovation cycle from research to implementation, deployment, adoption and routine use. European efforts should also take into account the full innovation chain and disruptive innovation loop. This involves the challenge to integrate research results that address real citizens' needs into health service provision faster and, in turn, provide immediate input to advanced research and development areas.[20]

In the future, serving citizens' rights to reimbursable cross-border care will require citizens to have access to fully integrated, seamless services. In turn, this will imply the need for eHealth implementations to make the transition from a use-case based approach to integrated eHealth services. Similarly, large scale pilots at EU level are solving problems at a prioritised use-case level and in several sectoral contexts.[21]

The draft EU Directive on patient rights to cross-border healthcare adopted in first reading by the Ministers of Health and Social Affairs on June 8, 2010, will become a major legal instrument for cross-border care, by removing administrative barriers and sector specific constraints, and using a person-centric approach to provide citizens with services. It will thus make it possible to provide *seamless and fully integrated multi-sectoral services to the citizen*. This is therefore a promising area for Member States to work together in order to accelerate these developments: Many Member

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[20]. *Examples include research in the areas of personal health systems, modelling and simulation of the human body and diseases – the Virtual Physiological Human. Through its recent Innovation Union Flagship Initiative, the EC aims to refocus Research & Development, and innovation policy, onto the challenges facing our society including health and demographic change.*

[21] *epSOS for health; STORK for government; Netc@rds for insurers.*

States are making investments into integrated care[22]; this provides an opportunity to build approaches in common.

A working model that could support the implementation of the draft Directive would need to cater to this person-centric approach. The ultimate user will be the citizen. Still, a consolidated, aligned and convergent view will be needed that incorporates the perspectives of all the actors involved: whether these are patients, professionals, governments, industry, or payers. From a citizen's perspective, health and wellbeing services should be accessible in a transparent way and through a single entry point even when they are the result of the integration of several e*Services. This is then an expression of an evolution from single sectors - and even specialised sectoral services - towards *integrated multi-sectoral workflows*. These address the needs of citizens in a holistic way in their different private or professional roles related to health and well-being services. In this view, a citizen is a "customer" who can be addressed by general interest service providers, whether she/he is a patient, a professional, or simply a contributor to the services.

This emerging concept places priorities on similar approaches to standardisation, business development, healthcare provision, and professional bodies for many different services and their related occupations and professions.

These dynamics are evident in all areas of EU activity. However, they are still being addressed under several sector- or European Commission Directorate-specific actions. The proposed cross-border health services Directive has the opportunity to pull such EU action together to address the major objective of serving patients' rights to cross-border care. Facilitating this integrative process at both EU and national levels is one of the major objectives of the CALLIOPE road mapping activity.

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[22] *eHealth Strategies, www.eHealth-Strategies.eu*

3 Enabling eHealth deployment

This section considers the main reconciliation challenges of the many visions of the different stakeholders to make each the reality of delivering services that maximize the potential of eHealth. Interoperability is both a pre-requisite and a facilitator for eHealth deployment as it requires crossing boundaries – professional, cultural, organizational and technical – and stimulates profound changes in the way we understand partnerships in making the global shared vision happen. Specific problems, objectives and outstanding issues are dealt with for each of the four areas of eHealth interoperability: personal electronic identification; technical interoperability; semantic interoperability and legal and regulatory interoperability. These interoperability areas must be organized and coordinated at both national and EU level and spans over the operational, strategy and political level.

3.1 Crossing boundaries in eHealth

Today in Europe, we can see more and more eHealth initiatives launched at national, regional or local level which aim to enable health professionals to access, at any time and any place, the electronic health records of their patients through fully interoperable and secure Electronic Health Records. However, this access is often limited by various "borders", whether they are national, regional, local, organisational, professional or occupational.

From the perspective of the provision of high quality healthcare these borders are barriers for the continuity of care. More importantly, they may become a threat to the sustainability of eHealth as systems need to accommodate the changing technological and organisational environments and evolve with time: *there is no sustainable eHealth without interoperable eHealth.*

A fundamental principle of continuity of care is that health professionals share information about and with patients as well as with other professionals across a number of disciplines, over the whole pathway of the care process. Sharing the necessary information, however, requires that information captured within a particular care episode in a given context by a healthcare professional can be interpreted in exactly same way by another professional, often of a different professional discipline, downstream in the care pathway. This is probably one of the most challenging areas of interoperability as it reaches down into the heart of the clinical content and the interpretation of the medical knowledge within it.

ICT enabled delivery processes must become more efficient, person-centred and sustainable and services must be integrated around the person's needs. Eventually, the services we bring to the citizens must be co-ordinated beyond the healthcare domain and a multi-sectoral approach is needed. Change therefore requires that our systems develop an ability to adopt service innovation in all strategic areas including planning, implementation and funding of services.

Existing borders between public administrations within the EU but also within each country or region need to be crossed and collaboration between the public and private

sectors must be facilitated through innovative business approaches. Public private partnerships and alternative resourcing and incentive models that are based on pay for performance, use and adoption of eHealth services are required, including reimbursement policies across the whole value chain.

Improving the capacity of healthcare to deal with disruptive innovation throughout the innovation chain requires also better integration and reduced time from research and development to full service deployment. Many actions and initiatives from research to competitiveness and innovation programme actions are supported at EU level. Prioritisation and a concrete action plan are needed in order to bring them to reality for Europe's citizens. The necessary investment decisions will only be taken in a timely fashion if evidence is provided on the benefits of eHealth, the sustainability conditions and the consequences of failing to act.

3.2   Interoperability challenges

Evidently, interoperability is a major challenge in eHealth which needs to be addressed within and across Member States. Interoperability as a term has been defined in several ways in projects and initiatives, which however converge around the notion that eHealth interoperability is a characteristic of an ICT enabled system or service in the healthcare domain that allows its user to exchange, understand and act on citizens/patients and other health-related information and knowledge in a commonly interpreted way. In other words it is a means of crossing linguistic, cultural, professional, jurisdictional and geographical border in eHealth.

In CALLIOPE, interoperability is addressed within the conceptual framework of the EC Recommendation on cross border interoperability of electronic health record systems[23]. In the EC Recommendation, "interoperability of electronic health record systems" is defined as the ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge.

Implementing interoperability of electronic health record systems requires a complex set of framework conditions, organisational structures and implementation procedures involving all relevant stakeholders. Various actions need to be undertaken at four levels, namely (i) the overall political, (ii) the legal and organisational,(iii) the technical and the (iv) the semantic levels and should in addition include actions for education and awareness. While actions are needed to be taken up jointly at each of these levels, these actions need to be articulated also across domains.

The 2010 OECD report on the role of ICTs in the health sector[24] recognises that the development of standards to enable interoperability is both a political and an implementation challenge which cannot "be easily solved by the natural operation of market forces … nor by the intervention of health authorities alone: joint industry and government commitment is necessary".

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[23] *Commission Recommendation on cross-border interoperability of electronic health record systems, Brussels, COM(2008)3282,*
http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf

[24] *Improving Health Sector Efficiency. The role of information and communication technologies. OECD Health Policy Studies, 2010*

Interoperability and standards effectively build on ground evidence, best practices and consensus through a long and resource-demanding process. Quite often the discussion is affected by cultural and social barriers. Therefore, interoperability should be addressed through EU action in a culturally neutral, international environment through collaborative effort. The 2010 OECD report stresses on the need for open collaboration at international level and strong user engagement and recognises the additional challenge of consistent implementation of commonly defined and agreed standards in order to achieve interoperability in practice. Therefore, besides technological specifications, appropriate incentives, consensus building and other enabling policies all have to be in place.

Terminologies and ontologies, representations of medical logic and standardized structures of ICT applications such as electronic patient records, registries, repositories, together with the rules and agreements that ensure that [patient] information is consistently and securely captured, transferred, stored, organised, transformed and managed can be referred to collectively as an "infostructure". The infostructure is based on and adds value to the infrastructure[25]. A governance model that would allow the main actors across Europe to jointly contribute to the development of the infostructure and to pool resources and knowledge at the European level will enable the management of vast amounts of information from various sources, in various languages, and will facilitate new knowledge discovery.

Eventually an EU infostructure can be the place to look for commonly agreed health information standards, profiles and specifications, communication protocols, rules and architectures for data aggregation, common terminologies and data models. When transferred consistently to national level, semantic interoperability across languages would be supported.

As our ability to share data across borders increases, the risks to compromise privacy of personal health data, new legal and ethical challenges emerge as for example in making appropriately supporting citizens choices to permissions to access their personal data and also interpreting such permissions appropriately e.g. in complex care situations or in the secondary use of this data.

The national legal frameworks need also to evolve to follow and support this complex evolution and across all facets of interoperability, support innovation and provide legal certainty and the incentives for the needed partnering for e*Services in support of their health systems sustainability and for better health. Cross border interoperability furthermore requires to understand diversity and the different security cultures and strive for agreements on establishing appropriate conditions for the free flow of health data across borders.

These challenges are further elaborated upon in the following sections.

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[25] *Both terms infra- and infostructure refer to the necessary foundations or groundwork that must be laid. For example, in the field of transport, infrastructure would refer to the highways, whereas infostructure would refer to the road signs, traffic regulations, safe management of traffic, providing information on traffic congestion, etc.*

3.2.1 Towards secure, unambiguous and portable electronic identification of EU citizens

Having an electronic identification is key to accessing electronic services: it can provide access to a person's [health] data based on *freely given, specific and informed consent*. The overall vision for better health and citizen-centred health delivery requires that governments recognize every person's *entitlement to a personal electronic identification* as the first step to honouring the fundamental right of access to services in the Information Society.

Maintaining these rights for mobile citizens in the EU would furthermore require governments to ensure cross-border recognition of identity and address the need to deal with the different security levels which may be applied by the Member States for the protection of personal data, at policy, technical and organisational levels. In line with this, the Directive of patient's rights (article 14), proposes that an eHealth priority must be the identification and authentication of patients and professionals.

The example of creating and maintaining the 'Schengen space', is relevant also for healthcare: MS agreed on a governance process, built trust through agreeing on and implementing daily operational procedures based on the recognition of the national ID cards and/or passports that complied to agreed process of issuance of identification documents (carriers) of a common specifications. This is then translated as a right of the citizen to travel in a borderless Schengen space.

KEY CONCEPTS

Identification of individuals is a generic process. It is highly likely that there are key elements of identification that are common to individuals involved in the provision and use of health services, whether these users are healthcare professionals (HCP), patients, or others. By assigning attributes to the identity (ID) it is possible to differentiate various roles of a citizen (such as a patient, a HCP, a person entitled to insurance protection, or a tax payer, etc).

Authentication must provide assurance that the identity of a person and of an entity is genuine. There may be different level of assurance however, depending from the security level of the technology and procedures in used. This is to be distinguished from an *electronic signature* which guarantees the authenticity of origin and integrity of content.

Authorisation of health professionals to access data is a mechanism that protects the privacy of the data and must furthermore establish trust. It guarantees that the health professionals maintain their right to access patient information and perform electronic transactions within the remit of their currently valid identified role.

Security services are closely linked to eID management. Eventually, the required level of trust is established through appropriate s*ecurity policies* appropriate *governance* and *audit*.

Serving the goal of providing the best possible person-centred, simple, efficient, easy access to eHealth and social care services through common standardised interfaces

and a highly integrated service management mechanism would mean tipping the scale towards user convenience at the expense of increased technical complexity. This technical complexity should however stay hidden from the user to ensure convenience.

BACKGROUND AND ACHIEVEMENTS

Everyone needs to have an electronic identity as his/her passport to the Information Society. The increased mobility of European citizens in their different roles calls for action towards cross border recognition of electronic personal identification, and authentication. The legal recognition of electronic signature has been already largely achieved.

A cornerstone for building capacity for full recognition of citizens' rights all around Europe is the identification of an individual through common policies and auditable processes, based on mutual trust and agreements between Member States.

The added value of using eID is already recognised as an important lever to secure, improve and facilitate public and private (e)services. In order to avoid silos and "fragmentation" of a person in separate roles, the use of eID is a potential solution to go beyond a single sector approach. In fact the Digital Agenda foresees actions towards cross border recognition of eID and eAuth and the setting-up of a Governance Structure (Key action 16).

Dealing with each specific role of a person, and the different level of liability that this role implies remains a challenge. This is especially true for eHealth, where identification of an individual must be also associated to his/her particular role in the healthcare process and hence to the individual's rights to access sensitive personal data.

A CEN Workshop Agreement has focused on electronic Identification and Authentication [with smart cards] (CWA 15264-1:2005)[26] which provides useful support for a cross-sector eID interoperability. The CWA has considered that a person has a unique identity but has different roles which may vary with time and places (e.g. patients/health professional, doctor/nurse, employee /employer, representative of an organisation, with signature capability). In the CWA, these roles are linked to an "eService Community" to which a person is part of, and may or may not be regulated by rules, depending on the eService offered by that community.

The "role" issues and the need to establish interoperability across the "role" or "e-community" providers for the 5 regulated healthcare professions has been explored by the HPRO card project. For most of the other roles a similar top-down approach may not be possible. Interoperable role management could usefully be developed in a bottom-up approach, by using the concept of eService community that a person is subscribing too on a compulsory or voluntary basis.(see CWA 15264-1:2005).

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[26] *See ftp://ftp.cenorm.be/PUBLIC/CWAs/e-Europe/eAuth/cwa15264-01-2005-Apr.pdf. This CWA has developed the concept of Interoperable IAS – i.e. a "Set of processes, data and technology agreements required in a given environment to provide Identification, Authentication and electronic Signature services" – for accessing eServices*

It must be noted that the epSOS approach to cross border eID, which has concentrated on federated identity, verification of identifiers, multiplicity of identifiers and a Framework Agreement that defines tasks and responsibilities for a National Contact Point is broadly supported by the eHealth stakeholder representatives in CALLIOPE. The question of whether a European Union-level action is needed on the issue of "multiplicity of identifiers" has, been debated. The conclusion was that *for the time being, there is no consideration to urge Member States to use one unique ID but rather one unique ID mechanism.* STORK is furthermore investigating the operational conditions for using eID across border for caring for patients and initiating the reimbursement process (where applicable).

A further scoping of the discussion is however required. Indeed, in the context of eHealth services, establishing interoperability of the mechanisms using eID and authenticating the person, requires focusing on using an authenticated set of personal identification data (whatever they might be) to access data and services.

Likewise, the content and nature of that data set and/or document used in the country or region where the identification mechanism has been created could vary from one country or region to another, but using them in a cross border context requires that they all share some kind of a common interface. The mechanism itself used to create a certified link between a person and a set of personal data and/or an ID document is therefore out of the scope of this discussion.

OPEN ISSUES AND POSSIBLE ROUTES

An EU framework for electronic identification for borderless healthcare requires an environment similar to this of the Schengen Treaty. Its building blocks consist of appropriate and secure mechanisms for: delivery of national electronic identities (eID); authentication of each eID; secure (cross border) transfer, and control of its usages. Clear rules (from legal through to organisational, semantic and technical) should be discussed and set up in order to create a fully operational EU framework as well as the needed supporting info-structure and infrastructure.

There are different approaches to eID management in Member States today. From a person-centred perspective, it may be argued that the goal should be a single electronic Identity (eID) with a concurrent capable mechanism for authentication and role management. From a service-centred perspective, one could argue that the goal should be to enable using any eID mechanism, as long as it provides the required level of assurance about the identity of the person.

Beyond the "one or many" question, there is a need to streamline the operational conditions for using eID across border for caring for patients and initiating the reimbursement process (where applicable).

While this may be technically feasible today, it requires a collaborative governance environment and harmonised organisational processes across the different domains. Through this process, it will become possible to prepare the ground for agreements to share a single digital electronic identification mechanism and clear definitions of roles, rights and their management. This in turn will call for a certain degree of reengineering of identification, authentication and authorisation processes around commonly agreed rules. Three major open issues are identified.

A Common European Framework for eID Management: Establishing a Common European Framework for eID Management and a time frame for its implementation at all levels is a major challenge requiring much more analysis of the issues involved, than simply political direction.

Supporting a unique eID does not necessarily imply supporting by one unique carrier. Several different carriers such as eID cards, mobile phones, credit cards etc., may be used with their respective relevant, interoperable info-infrastructure. There are several issues associated to this debate such as what a person may (or should carry) to establish identity; whether these are electronically accessible; dealing with different carriers for different purposes. These will need further consideration.

Enabling cross border recognition of eID for healthcare purposes:

For cross border care it will necessary that for example a UK NHS patient identification number is recognised by a French hospital system. In principle, an EU level mechanism will be needed to federate the national eID management systems, common services, infrastructure and infostructure for identifying countries, type of service requested, roles and actors.

European Governance for eID Management: Last but not least regulatory provisions and a governance mechanism to sustain the European cooperation for cross-border eID management will be required.

RECOMMENDATIONS

It is recommended that the EU eHealth High Level Group, together with European Commission

✓ Initiate preparatory actions towards a Common European Framework for eID Management by setting clear relevant priorities in all associated interoperability areas, i.e., legal, organisational, technical and semantic and particularly in defining:

    o a realistic and appropriate level of security for electronic processing and transfer of health related information and adopt an associated framework of policies, processes, standards and safeguards as well as security audit policies, which will reflect a balance between national requirements and what may be commonly accepted as tolerance margins for international exchanges.

    o an acceptable level of assurance that the identity of a person and of an entity is genuine, i.e. authentication,

    o an acceptable level of trust and guarantees in mechanisms for authorisation of health professionals in order to ensure that privacy is protected while the health professionals maintain their right to access patient information and perform electronic transactions within the remit of their currently valid identified role.

✓ Invite a common implementation proposal for enabling cross border recognition of eID for healthcare purposes based on knowledge and what has been shown to work in the main eID EU projects in this area (epSOS, STORK, HPRO card).

In order to support these initiatives, the EU eHealth High Level Group, together with the European Commission,

✓ Should consider the requirements of EU level governance in the form of regulatory provisions and a mechanism to sustain the European cooperation for cross-border eID management for healthcare purposes.

3.2.2   Towards an internal market for eHealth services- technical interoperability

There is wide recognition of the relevance of coordinated standardisation activities to realise the benefits of eHealth. Standardisation is an indispensable element of national and regional eHealth implementation plans and roadmaps. The recent survey of national eHealth strategies funded by the European Commission (eHealth Strategies study) reveals an increase in standards related activities in almost all European countries – in eight countries more than in 2006-2007 (eHealth ERA study).

The work on the epSOS pilot specifications has demonstrated however that much additional support is needed to bring standards into real implementations. This in turn has highlighted the need for action at Member State and European level to consider global and specific approaches to standardisation.

The Standardisation Task Force within CALLIOPE has progressed this work with the objective to consider European eHealth standardization implications for the roadmap, building on the work of the epSOS pilots and other current relevant initiatives and has proposed Europe-wide and national activities to support standardization.   The CALLIOPE Standardisation Report[27] includes over 40 recommendations, identified for the European Commission (EC), the new High-Level Governance Group (HLGG), Standards Development Organisations (SDOs) and Member States (MS). This report, and its recommendations, are expected to be taken forward to the eHealth Governance Initiative for further consideration.

KEY CONCEPTS

While both technical and semantic interoperability are largely the result of the implementation and application of standards, this section deals with technical interoperability of health informatics systems.

Health informatics[28] is the intersection of clinical, information/information technology management and management practices to achieve better health. It involves the application of information technology to facilitate the creation and use of health related data, information and knowledge. Health informatics enables and supports all aspects health services.   In this context, health is taken to mean a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity[29].   Technical Interoperability describes a state which exists between two application entities, with regard to a specific task, when one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention. In the context of health informatics, this implies full end-to-end interaction of health records from origin to point of use.

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[27] *CALLIOPEStandardisation Report, www,calliope-network.eu*

[28] *Adapted from the Canadian Informatics Association, www.coachorg.com*
[29] *Adapted from the WHO definition for health*

BACKGROUND AND ACHIEVEMENTS

It is important to set the proposals for standardisation into a wide current context. A number of European initiatives have published proposals in relation to health, to standardisation and to eHealth standardisation in particular. The Europe 2020 strategy has set the context for smart, sustainable and inclusive growth, with the supporting Digital Agenda identifying a set of actions. Sustainable health implies the need for transformational change, in which eHealth has an important role to play. Developments in standardisation highlight the need for openness and transparency, with the need to demonstrate appropriate representation and hence relevance. An important aspect is that of access, both to the standardisation process and to the resulting outputs for local use. An important principle is FRAND (standards to be provided on fair, reasonable and non-discriminatory conditions).

To further advance the interoperability agenda, the European Commission issued in 2007 a mandate to the three European standards development organisations (ESOs): CEN, CENELEC, and ETSI, to develop a coordinated work programme for standardisation in health informatics, known as Mandate M/403. In support of this mandate, the eHealth-INTEROP project was founded.[30] Its aim was to provide a focus for standards prioritisation and development, using the five-step process: (i) use cases; (ii) consideration of available standards; (iii) profile development or adaptation; (iv) interoperability specifications and (v) review. In this context the work of the industry-led guideline organisations such as integrating the Health Enterprise (IHE) and the Continua Health Alliance are also being brought into play. The work of such organisations will directly contribute to the realisation of fully operational standards and guidelines in the eHealth domain.

It is important to bear in mind the full lifecycle of technical and standardisation activities: business need, development, adoption, adaptation or localisation, accreditation and standardisation. These aspects all need to work together as a system to build trust. However this needs all stakeholders to be fully and actively engaged.

There are four viewpoints that need to be reconciled: healthcare users, who need IT support which is understandable, affordable and adoptable; suppliers, who make money by delivering value; policy leads, whose main perspective is the improvement in health; and patients and citizens.

Ideally, each of these will be able to contribute to developments and see their needs fulfilled. An important part of the recommendations is to enable this dialogue to be successful.

The following are seen as critical success criteria for standardisation activities, building on current initiatives and best practice:

- o Relevance: that standardisation activities are seen as relevant to business objectives and current activities;

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[30] *www.ehealth-interop.nen.nl*

- o Openness: that standardisation is seen as an open and inclusive process which removes rather than presents barriers for progress;

- o Engagement: that all parties are able to contribute, from prioritisation of business requirements through development, implementation and maintenance;

- o Affordability: that resulting standards are affordable, and demonstrating a clear return on investment.

- o Sustainability: that the framework for development of interoperability standards is sufficiently open and flexible to allow continues adaption and development as the solutions and market evolve.

The aim is that successful completion of the recommendations will ensure these criteria are met.

OPEN ISSUES AND POSSIBLE ROUTES

From these initiatives a number of key themes have been identified. Each has been discussed, and a set of recommendations derived.

Business objectives: from a health perspective, there are clearly shared drivers, aims and objectives across Member States. These need to be captured and turned into clear requirements, with a process of prioritisation and use case description that allows all stakeholders to agree the way forward. Recommendations include proposals for the process of prioritisation of new areas for standardisation, the creation of a framework to support the ways in which innovation can influence standards, market analyses, use-case development and the wider involvement of users.

Harmonisation is needed but often national needs are regarded as difficult to reconcile with wider European and international needs. It may be necessary therefore to introduce a step-wise approach in which national and regional needs are addressed first but where clear pathways to European and international harmonisation are planned. If this is not done, there is a significant risk that to achieve European and international harmonisation national and regional work would need to be undone and re-engineered.

The use cases must be based on real needs (these should be captured with strong user engagement and properly described). Experience within epSOS has been instructive here, as project teams from many Member States have sought to agree common specifications that apply to all, but which acknowledged specific differences (e.g. in relation to local rules on prescriptions).

Benefits: The benefits of standardisation have been proven and are accepted already in many areas of life – notably in banking where citizens now freely access their funds through automatic teller machines wherever they are in the world with a high degree of confidence in the security of the system. In healthcare however the case for standardisation has not yet been as forcefully as it might. Whilst evidence is emerging on the benefits of standardisation, the case has not been fully accepted and more work is needed to demonstrate the value of participation in development and subsequent use of standards, and to encourage Member States to engage in standards

implementation. The recommendations support the need for a wider dialogue on how standards bring value to healthcare, with a framework for contribution from participants.

Policy and strategy: the EC is proposing a structured set of activities to support standardisation, for ICT and more generally. These activities need to be reflected at Member State level. The principles of openness and transparency need to apply, with the co-ordination of dialogue with all stakeholders. European Standards Organisations as well as the relevant industry led fora, have a role in advising policy makers and providing support on the convergence of technologies. For Member States there are recommendations for local representation, local standards strategies, establishment of committees for eHealth standards, and a recommendation that the European Commission should compile (and maintain) state-of-the-art overviews of national standardisation activities and good practice.

Access including balanced representation: there is clearly still a widely-held perception that standardisation is a closed activity for specialists, taking a long time and leading to expensive outputs with difficult license models. The recommendations therefore include the development of an extended panel of experts and the promotion of fora and consortia for progressing specific standards areas. This should include drawing on the substantial expertise of industry groups much more actively. There is a large issue still around access to standards materials and there is a need to assess IPR policies and potential licensing and funding models. Other recommendations include translation of supporting standards materials into other languages, with re-usable specifications.

Supporting the market: an important part of "access" is also supporting the creation of a viable market for systems and services, with the potential to operate, not just in Europe, but globally. The aim is a default position of global standardisation where possible, with European or national standards only where needs dictate. ESOs should provide thought leadership for Europe-wide standards which might become international. Each Member State should consider the use of standards to support open markets and, together with the EC should consider a European-wide accreditation scheme. On the part of the European Union this will entail also addressing potential clashes between open completion in a European market and the mandating of standards and guidelines in public procurement.

Implementation support: there remains the perception that standards are complex and hard to implement; at present there is no up-to-date information on how widely standards are used. A number of activities are underway to support adoption, implementation and use. There needs to be lifecycle management of standards, and activities to investigate uptake and use, with the sharing of experiences. There is a specific proposal to require EU-funded projects to evaluate the use of standards and profiles.

It is recommended that the EU eHealth High Level Group, together with European Commission:

✓ Enable the establishment of European-wide standards, interoperability testing and certification and accreditation schemes for eHealth where appropriate and particularly
- o encourage review of national standardization and harmonization activities;
- o implement a peer assessment system of standards use across Member States where relevant and to provide evidence of market uptake and use;
- o support EU actions for further exploring different funding models for access and use of e-Heath standards;
- o take forward into the eHGI process, the Recommendations of the CALLIOPE Standardisation Task Force , for careful further consideration and actions

✓ Provide direction, prioritize use cases and co-ordinate the prioritization of business areas for standardization based on balanced proposals by stakeholders;

✓ Ensure systematic sharing of experiences of best practice in standards use.

The implications of transposing these directions and priorities are that Member States will be called upon to:

✓ Consider legislative frameworks for innovation
- o that recognise standardisation - including certification and accreditation - as one of the major facilitators of innovation in eHealth and encourage maximal use of standards;
- o help the choice and/or production of standards and - where appropriate - their mandatory application.

✓ Launch processes, consistent with European and global dimensions, leading to the selection of standards and the incentivisation of their use and particularly
- o establish appropriate multi-stakeholders platforms that would empower business and healthcare professional experts to contribute to use case development;
- o establish national standards committees or, where they exist, review membership and engagement to ensure sufficient representation of major stakeholders;
- o encourage stakeholder representation in standards development and standards policy committee meetings.

3.2.3 Towards a European-wide infostructure - semantic interoperability

It is widely recognised that semantic interoperability is the key factor to achieving a wide range of benefits of eHealth implementations to improve the quality and safety of patient care, public health, clinical research, and health service management. CALLIOPE's view of interoperability is based on the EC Recommendation which defines "interoperability of electronic health record systems" as the "ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge." In this context, semantic interoperability means ensuring that exchanged information is understandable by humans and by other relevant systems and applications in or by which the data were not originally captured.

Semantic interoperability addresses issues of how to best facilitate the representation, transmission and use of meaning across seamless health services, between providers, patients, citizens and authorities, research and training. Its geographic scope ranges from local interoperability (within, e.g., hospitals or hospital networks) to regional, national and cross-border interoperability. The information transferred may be at the level of individual patients, but also aggregated information for quality assurance, policy, remuneration, or research.

The semantic challenge – more than any other – requires massive, joint efforts of various stakeholders crossing geographical, language and cultural borders, across specialty and for lay persons. Benefiting from European-wide synergies, improving consensus and identifying successful approaches to common challenges, expertise, knowledge and solutions that could be shared, becomes highly relevant. Various common components and shared solutions need to be brought together in an emerging European-wide infostructure to advance semantic interoperability and support cross-border exchange and seamless care.

KEY CONCEPTS

Achieving a high level of semantic interoperability is only possible if a clear sharing of roles between three health informatics elements is in place: 1) a reference model, 2) archetypes / templates structure and 3) terminology which are all necessary. None of these components can produce full semantic interoperability alone. Therefore, efforts must involve combined expertise in all three domains and aim at the interplay of all three components while serving real life clinical needs; they must also respond to concrete, well captured user requirements be it for direct patient care or public health purposes.

At a European level agreeing on common priorities and specific applications or use cases is a first important step to coordinate efforts geared towards semantic activities. In a cross-border setting the overall aim is for better structured and coded electronic patient records allowing for unambiguous automatic transcoding and translation into languages of other Member States. As a first step, core requirements may be considered such as health documentation in priority areas for patient safety and continuity of care.

In the context of a complex European multi-lingual and multi-cultural environment, as underlined by SemanticHEALTH[31], sharing clinical meaning does not automatically imply (and cannot require) identical terms and data structures. The goal of semantic interoperability is to be able to recognise and process semantically equivalent information homogeneously, even if instances are heterogeneously represented, i.e. if they are differently structured, and/or using different terminology systems, and/or using different natural languages. This equivalence needs to be robustly computable, and not just human readable, in order for guidelines, care pathways, alerting and decision support components to function effectively and safely across EHRs that have been combined from heterogeneous systems.

BACKGROUND AND ACHIEVEMENTS

A recent survey by the eHealth Strategies study confirmed that semantic interoperability is seen as the grand challenge by European countries. By now ten European countries are members of the International Health Terminology Standards Development Organisation (IHTSDO) and discussions about the use of SNOMED CT are underway in many other countries. A variety of nomenclatures and classifications is in use. For instance, ICD-10 is in use in eighteen countries whereas ICD-9 is still being used in seven countries some of which apply both versions in different implementations. In many countries, health institutions choose or develop semantic standards according to their local needs. The Continua Health Alliance[32] is currently in the process of putting in place a licence agreement with IHTSDO which will ensure that the Continua Alliance use cases support SNOMED CT. If this agreement is finalised before this RM is closed we would like to include a reference on this point here. An interesting initiative to coordinate such developments has been launched in Belgium with the aim to analyse the feasibility of a federal "terminology service" to deal with all terminologies and classifications used in the country or region through a federal "controlled medical vocabulary".

Recognising the relevance of semantic interoperability, the EC Recommendation on interoperability of EHR systems addressed semantic issues in detail. The Swedish presidency also called for collaborative action in this domain. SemanticHEALTH, an EC funded project, delivered a roadmap for research and deployment, recommending a policy of incremental steps and a focused, modest approach to terminology development. This should include the creation of semantically sound and focused, limited subsets of terminology relevant to the health improvement priorities of Member States.

At a cross-border level, epSOS has provided a unique pragmatic example for developing elaborated semantic services based on the use cases of cross-border patient summary and ePrescription. The ultimate goal is the communication of (and access to) information that can be processed, while keeping unchanged the structure and contents of the original documents or datasets in each country or region. This is achieved through *commonly adopted definitions, content, vocabulary and structures.*

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[31] *http://www.semantichealth.org/*

[32] *http://www.continuaalliance.org/index.html*

The content of Patient Summary and ePrescription services, or the data elements, is thematically grouped into *value sets*.

These are mapped onto existing code systems. The cross-mapping between the code systems with regards to the terms employed in the epSOS Master Translation/Transcoding Catalogue has been done with the contribution of the medical and semantic specialists of the epSOS involved Member States. Terminology Access Services are also provided in order to ensure on-the-fly interoperability between different Member States.

A myriad of other past and on-going efforts in EU projects exists. The urgent need to making optimal use of resources and experiences has brought into life the *concept of EU-wide convergence* around topics of semantic interoperability. The convergence concept relates to better exploiting EU and nationally funded projects and implementation initiatives through benefiting from European-wide synergies. It aims at improving consensus between projects and identifying successful approaches to common challenges, expertise, knowledge and solutions that could be shared and further developed to a European-wide infostructure. Five EU-funded projects[33], including CALLIOPE, are currently exploring opportunities for convergence. The proposal is that, as a first step, a web site is established, providing links to terminologies used, a wiki for all definitions developed and used in projects as wells as a 'cartography' of data models and common building blocks.

OPEN ISSUES AND POSSIBLE ROUTES

Semantic interoperability requires a combination of healthcare practice standards and health informatics standards, and therefore many of the considerations outlined above in the section on standards apply here as well. As already noted, pooling resources to address interoperability challenges in common is especially relevant for the area of semantics. The use of open collaborative tools to jointly develop terminologies as well as the development of tools needed to deploy them; common approaches to testing, evaluation, quality assurance, maintenance of semantic resources are typical areas for joint efforts.

Issues to address at European level include the following:

Use case approach: To faster advance these key area joint efforts should be based on agreed high priority, real life use cases. These may focus on (chronic) disease management and integrated care. All relevant stakeholders should work closely together to develop the technical and the corresponding semantic solutions for the concrete use cases. This means that terminology and translation services should be developed *together* with data structures, i.e. a tight linkage between document / data structure to be shared and the used terminology that provides the content for these structures is critical. This should be closely linked to the development of respective care pathways by healthcare professional representatives.

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[33] *DebugIT , PSIP, EU-ADR, epSOS and CALLIOPE*

Health professional engagement: This is a critical issue requiring immediate attention and agreed mechanism for sustainable engagement. Health service providers need to understand the strategic relevance of semantic interoperability and serious professional involvement. The European eHealth Governance Initiative should support European professional associations to work on the prioritised use cases in a coordinated way. Widespread engagement with both vendors and providers on requirements and gaps of the potential solutions as well as with the primary user community should be a prerequisite for any semantic interoperability implementation.

Costs and funding models: like with any other standards, terminology development is costly. Different funding models e.g., national licensing model, subscription fees, etc., exist and should be explored further bearing in mind who benefits most and how to balance costs and incentives.

Intellectual Property Rights (IPR): similar as in the case of other standards, this is considered a fundamental barrier to implementation and assessment activities. Terminologies / semantic standards *must become freely available at the point of use* to enable shared records to be understood anywhere internationally. This will benefit to not only healthcare providers but also small innovative IT companies and academics - for research and educational purposes.

Demonstrating the value of semantic interoperability: there is a great need for evidence on the added value of the adoption of semantic standards. Existing evidence should be identified, good practice shared, evaluation and monitoring of use and benefits should be integral part of all efforts.

Bridging between coding systems, classifications and terminologies is a key issue. Harmonisation and cross mapping of major terminologies, including LOINC, ICD-9/10/11, ICPC should receive attention. Joint feasibility studies/projects on harmonisation should be undertaken. Based on the work on ICD-11, there should be a major effort to bring greater convergence and harmonisation of the various national terminologies. As for all these terminologies, human anatomy is a common point of reference (most diseases, signs, symptoms, procedures can only be exactly described and defined referring to anatomical entities), it would be a major achievement and a solid basis for cross mapping if those terminologies referred to the same source of anatomical terminology.

The recently announced collaborative agreement between the World Health Organization (WHO) and the International Health Terminology Standards Development Organisation (IHTSDO) to try to harmonise international recognised WHO classifications and SNOMED CT is acknowledged as a great step in this direction. Diverse international classifications and nomenclatures are often complementary tools with different legal and license obligations. When used together appropriately, they make it easier to summarise information from individual patients' health records into aggregate results needed for health policy, health services management, and research.

The focus of efforts on terminologies should be on sound, *ontology-based, user centred development of small, limited in scope and focused sets of terminologies* related to the prioritised health services related to business use cases. Alongside lexical and linguistic support in different European languages, respective *agreed*

information and data models along with *bindings to terminologies* are important requirements.

Evaluation, quality assurance (QA), and maintenance of terminology resources should also be addressed at EU level. Wide-scale evaluation is needed, for instance, for the use of terminologies with re-usable clinical models of content and process (such as archetypes).

Coordination and sustainability: Already SemanticHEALTH recommended the establishment of sustainable national bodies (e.g., national centres for multilingual, multicultural adaptation of international classifications and terminologies), linked in respective European networks. In response to a survey, stakeholders in CALLIOPE recommended to establish one or more *(virtual) European Competence Network(s)* or Centre(s) for guidance, evaluation, QA, maintenance, exchange of experiences, best practices in development and use of ontologies and terminologies, clinical content and process models. The urgent need for one or more reference centres where the "clients" (users, projects, industry, etc.) could find the necessary knowledge, advice and support to solving their concrete problems and avoid divergent efforts and duplication was stressed repeatedly. Multi-lingual terminology and classification / coding services should also constitute part of these activities.

Similarly, epSOS participants concluded that, in the longer run, the maintenance of the epSOS semantic resources needs to be officially performed by one or more European entities. This should include also a quality assurance process. epSOS has shown that two types of (EU) maintenance of the developed semantic services are needed: a functional process and a physical storage space for the epSOS Master Value Sets Catalogue (MVC) and the Master Translation/Transcoding Catalogue (MTC). The physical location of the storage place was deemed politically sensitive requiring a political decision on whether or not a particular country or region can be a host for content concerning the whole European community. Following the epSOS experience, there is value in establishing and sustaining a *network of national experts,* partly formal and partly community and R&D based.

It is to be expected that a *broad collaboration* in the area of semantic interoperability involving health professional societies, industrial associations, standards development organisations, researchers, patients' groups and other key players will be established under the 7th Framework Programme of the European Commission as a network of excellence (NoE). The NoE will aim to define a common agenda and the means for sustainable governance in this crucial area.

Awareness raising, education and Continuing Professional Development (CPD)[34]: Effort should be made to increase awareness and education of the value of consistent clinical documentation, in order to support shared care, care pathways, patient safety, and better re-use of health record information. Furthermore, long term attention and investment are needed for the development of human capacity and skills in terminologies and ontologies, and other semantic resources.

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[34] *Continuing Professional Development (CPD) is the systematic maintenance, improvement and continuous acquisition and/or reinforcement of lifelong knowledge and skills of health professionals. See CIVIL SOCIETY RESOLUTION on CPD,*
 http://www.efnweb.eu/version1/en/documents/CivilSocietyResolutiononCPD17102006EN_001.doc

Overall, there seems to be consensus about the need for a major European effort - in close collaboration with global players, in particular the USA and Canada.

Four major areas for EU action to develop in common semantic resources and achieve higher level of semantic interoperability have been identified:

Priorities: based on agreed high priority, real life use cases related to (chronic) disease management and integrated care. Terminology and translation services developed *together* with data structures and linked to the development of respective care pathways by health professional representatives.

Health professional engagement: support European professional associations to work on the prioritised use cases in a coordinated way. This will ensure that efforts are driven by real clinical and public health needs.

Broad collaboration of stakeholders, incl. international SDOs and relevant industry bodies. This should be organised and sustained at a European level.

Collaborative governance is needed, which should span over three layers:

- o *Steering layer*: This layer should provide a framework for collaboration and governing rules. These include agreed boundaries, goals, objectives and expected outcomes. It should set the rules to achieving the objectives and establish a favourable environment to reach the envisioned outcomes.

- o Business layer: The business layer should deal with the business (use) cases for each of the stakeholders involved, the costs and benefits of the solutions and their economic impact. It must be informed by the empirical layer in order to develop strategies for success and feedback to the steering layer. It should aim to utilise results from various European and national strategic initiatives and projects.

- o Empirical layer: This layer of collaboration is absolutely important and needs to provide a proof-of-concept since lots of semantic efforts have been based on beliefs and not on success stories of proven benefits. Work should focus on concrete, prioritised use cases in a narrow domain. It is mandatory that the scope of the work is very focused and limited, e.g., one particular disease. It is recommended to focus initial efforts on common chronic diseases such as cardio-vascular disease, diabetes, etc., which represent a great burden to European health systems.

It is recommended that the EU eHealth High Level Group, together with European Commission:

✓ Consider the area of semantic interoperability as an area largely catering to multinational collaboration and empower a collaborative governance framework that will facilitate collaboration of the various stakeholders, incl. international SDOs and relevant industry bodies at all three layers: steering, strategic and empirical.

✓ Provide direction, prioritize use cases based on high priority diseases common to all MS.

✓ Support co-ordination of work of national and European professional associations to engage into the development of terminology and translation services developed together with data structures and linked to the development of respective care pathways.

✓ Encourage the definition of appropriate quality standards for data in medical records and other electronic medical data/documents which are to be shared across borders.

✓ Address the challenges of multilingual semantic mapping.

In addition all Recommendations concerning Standardization for technical interoperability apply also to semantic Interoperability.

3.2.4 Legislation and regulation as facilitators - Legal and regulatory interoperability

The central tenet of CALLIOPE on legislation, ethical codes and professional regulation in healthcare is that they can, and should, be used as a facilitator of cross-border care. The EU level commitment to this is already evident in the spirit of the Draft Directive on Patients' Rights in Cross-border care, but more is needed to ensure that the concept is enhanced at every level of regulation.

As already noted, while this Roadmap focuses on cross-border interoperability in eHealth it aims to also support eHealth deployment at MS level through common action taken together at EU level. In what concerns the legal, regulatory and ethical issues surrounding eHealth, much may be addressed at a collaborative EU level, by exploiting, for example, the approach to overcoming barriers that prevent EU citizens from fully enjoying the potential of travel across European borders with all their rights as foreseen in the Treaty fully respected – including the right to access healthcare services or the right to deliver such services.

The Roadmap focuses on those aspects in which law can be a facilitator for innovation, though appropriately bringing into place standardization and regulation as key enablers for innovation as well as through providing the necessary legal protection for privacy and safety in eHealth services.

It is noted that when an eHealth solution is the primary vehicle for delivery of [cross border] care, for example a second opinion delivered by video conferencing with simultaneous capture and transfer of bio-data, then the legal and ethical issues are wide and will arise not only in terms of the data sharing, but also in terms of identity certification, professional accreditation, liability for shared care and other issues yet to be identified. The legal and regulatory issues include also administrative regulations such as those of reimbursement, and – in the context of cross border care - the mutual recognition of professional qualifications and the complex issue of entitlement to care; these are however outside the scope of this Interoperability Roadmap.

Whether [cross-border] care is provided virtually (e.g. via telemedicine) or provided to a patient who is physically outside his or her usual country or region of residence, the quality of the care will be greatly enhanced if data about the patient can be securely and safely interchanged. Legal and regulatory tools can build the trusted domain for sharing of appropriate patient information by addressing issues such as data protection, ethical issues of data handling and patient consent. In this context we focus on legislation as an enabler of **a trusted domain** in which data can be exchanged with confidence and in confidence.

KEY CONCEPTS

The establishment of Trust both in the national and the cross border context is a pre-requisite to data exchange. An *EU Trusted domain* for eHealth should be one where national trusted environments for health data exchange are federated through national nodes; each such node should play an active part in this environment if, and only if, it complies with agreed normative standards in terms of structure, behaviour and security policies. Trust is built by adopting common policies and standards around

important issues - such as integrity, availability, privacy and confidentiality of health related data; and their audit.

The concept of a trusted domain must also seek to balance the sometimes competing interests in access to information for good medical decision making and the right of the patient to control who has access to personal data and for what purposes. eHealth for cross-border care must address the need to ensure that patients have access to adequate and understandable information about who can access their information and for what purpose. On one hand, patients can then rely on their legal right to control over their own information and on the other hand, healthcare professionals can comply with their legal and ethical duty of ensuring the patient has freely consented to information sharing. Systems must also address the fact that sometime medical emergencies will require that information is shared without consent (where the patient is incapacitated) and must ensure that transparent systems are in place to provide full audit of any occasion in which data are shared without consent.

The cross-border data exchange scenario will primarily require a step-wise approach to harmonising security and audit policies and practices for cross-border services in compliance with legal requirements which will allow for mutual recognition of health data handling procedures and trust in those procedures. What will eventually be needed is an innovative and trustworthy response to the security, quality, and safety challenges in healthcare. The creation of an EU trusted domain (in eHealth) has elements that are legislative, normative and organisational.

BACKGROUND AND ACHIEVEMENTS

At national, EU and international level, the protection of personal data processing is dealt with by several fundamental documents and standards[35] spanning many years – from the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 1981 to the draft international standards on the protection of privacy with regard to the processing of personal data - including their transfer abroad - were adopted in the form of an international Resolution at Madrid's Privacy Conference in 2009**.**

As a general rule, the existing guidelines and legislation in force provide that European and international transfer of personal data may be carried out when the State to which such data are transmitted, as a minimum, is able to provide the level of protection specified in those documents. In practice however, it will be necessary to establish also a genuine culture of trust and security for all healthcare and management staff. Such trust and security is not possible, however, without an agreement on technical standards for identification management authentication and electronic signatures (see section 3.2.1.) The EU has already gone some way to building this environment of trust through the introduction of common EU framework for electronic signatures (Directive 1999/93/EC), but there is still a large variation in their use and applications in the healthcare sector. Member States should therefore explore further harmonisation of

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[35] *Convention 108 and its Additional protocol; Directive 95/46/EC; OECD guidelines;- Resolution of Madrid's Privacy Conference 2009.*

approaches and solutions for technical measures to ensure trust in key tools for eHealth.

The Commission has recently performed a policy review based on a public consultation to revise the EU's 1995 Data Protection Directive, the intention being to propose legislation in 2011. [36]

The proposed Directive on Patient Rights to cross-border care is expected to improve legal clarity around patient rights and obligations in cross-border situations. Modifications to Article 13 (eHealth) have not reduced the importance of data protection and ethical issues, but do require a review of how MS action can be co-ordinated. The need to work towards common quality and safety standards for healthcare services has been identified. Relevant initiatives are already in the pipeline[37]. eHealth is recognized as an important means to implement the Directive. For this to be achieved, however, it is necessary to take advantage of on-going work at EU level[38] in order to resolve both interoperability and quality aspects of data, systems and documents.

Many of the challenges that relate to the cross-border transfer of European's health data cannot however be resolved only through legal or regulatory means. Since 1999 it has been recognised at EU level that data collection, use, and retention of data are more closely related to the behavioural expectations of various health professions and occupations, and of citizens[39] than can be easily addressed through simple legislation. Both policy approaches and technological availability have altered considerably since 1999. However, many of the ethical challenges related to the cited public concerns, value conflicts, and ethical principles (including human dignity, autonomy, justice, beneficence, non-malfeasance, and solidarity) pose an equal number of dilemmas for the coming decade (2010-2020).

Solutions to a number of the criteria outlined in the European Group on Ethics' Opinion of 1999 need to be re-visited. This needs to be done within an international, cross-border, and cross-sectoral setting, and in the context of changing professional-patient relationships. A convergence of possible approaches needs to be at least attentive to the range of European diversity in such cultural, ethical, and behavioural contexts. It is imperative that these considerations take place in settings that are more localised than at the purely international or national levels.

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[36] *A comprehensive approach on personal data protection in the European Union, COM(2010) 609 final http://ec.europa.eu/justice/news/consulting_public/0006/com_2010_609_en.pdf*

[37] *EUNetPaS (European Union Network for Patient Safety supported by the European Commission within the 2007 Public Health Programme. Its purpose is to establish an umbrella network of all 27 EU Member States to encourage and enhance their collaboration in the field of Patient , thus maximising efficiency of efforts at EU level.*

[38] *EHR-QTN is a Thematic Network project that prepares the health community across Europe for systematic and comparable quality assurance and certification of e-Health products, more specifically of the Electronic Healthcare Record systems.*

[39] *European Group on Ethics (1999) Opinion on the European Group on Ethics in Science and New Technologies to the European Commission. Ethical Issues of Healthcare in the European Union. No 13. 30 July 1999, http://ec.europa.eu/european_group_ethics/docs/avis13_en.pdf*

Addressing this level of complexity in national laws could benefit from the establishment of an integrated trust framework, bringing together legislation with the national standardisation, certification and accreditation framework on eHealth, for example, though framework laws. This would allow for the disengagement of the dynamic innovation elements from the rigid body of laws and allow them to develop, evolve and prove their value inside the standardisation certification and accreditation environments. The latter comprise fundamental organisational infrastructures for innovation. This should in turn contribute to strengthening the capacity of healthcare to deal with disruptive innovation throughout the innovation chain from research and development to full service deployment, without compromising the robustness and the level of legal protection.

OPEN ISSUES AND POSSIBLE ROUTES

The main challenges to reinforcing trust and removing barriers to the appropriate transfer of medical data in eHealth enabled cross-border care are summarised below. There are several possible routes available to addressing these challenges. In the Roadmap context, the following three challenges remain a point of focus:

Data Protection and Confidentiality: Data Protection has been regulated at EU level and the relevant directives have been transposed into national legislation. Hence, there is sufficient legal certainty in this domain. However much diversity exists in the way this transposition is put into practice, not surprisingly given the cultural diversity in Europe The recommendations of the Article 29 WP[40], [41] aim to support common interpretation for the Data Protection Directive while its foreseen revision is expected to provide additional clarity. In order to improve clarity we need to develop a solid understanding of how Member States are tackling these issues and the rationale for the different choices which they have made. Together MSs should provide clarity and outline an approach and a strategy for jointly adopted choices based on commonly accepted approaches and governance with respect to data protection, while respecting sovereignty of Member States in these matters. Associated issues include:

Security: The specification of a realistic appropriate security level, which can be gradually enhanced, will allow MS to implement basic cross-border services and continue to optimize, align and gradually improve them. What is urgently needed is to establish a *common trust / security framework* with the aim to tackle effectively the different security levels which may be applied by the Member States for protection of personal data, integrity and authorship of documents, access control and role mandate management. This can be achieved in part by maximising the use of Privacy Enhancing Technologies (PETs) and Transparency Enhancing Tools (TETS) and adhering to realistic, efficient and auditable commonly agreed governance principles for cross border services. An agreed EU level security policy for cross border data exchange should also be translated into behavioural change.

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[40] *Working Document on the processing of personal data relating to health in electronic health records (EHR), 15 February 2007, WP 131*
(http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131_en.pdf)
[41] *document WP 169*
http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2010_en.htm

Ethical and normative challenges: The European Group on Ethics' cited recommendations of a health data-related Directive and a patient charter deserve renewed consideration with foresight for the socio-economic and sectoral changes due to occur over the next 10-year period. Clearly, organisational, professional, behavioural, and localised approaches need to be allotted appropriate weight. Mechanisms that relate to (a) appropriate codes or guidelines of ethics, conduct, and behaviour (b) appropriate education and training, and (c) expectations (and associated training) of ordinary citizens and patients and (d) the level of consent needed for sharing of data within and beyond the immediate healthcare team could be developed.

Legal and Regulatory Issues related to data sharing between Health systems: A number of legal and regulatory issues will need to be addressed: they include training and accreditation for data handling, liability, professional conduct, work protocols, traceability and audit.

Healthcare professionals will be expected to deliver health services on the basis of health information produced in one or more other Member States, which will be derived not only from health settings, but also domains such as care, social security, pensions, and insurance. As a result many agencies will be active contributors to realizing cross border eHealth.

In the absence of EU level harmonisation in the health service sector, building trust for cross-border eHealth must, in addition to other challenges, address patient safety issues. This will require an understanding of the operational processes at both the service provision level and at the level of the respective national authorities' level. From the perspective of eHealth this will require cross border recognition of documents such as e-prescriptions as well as operative health data for clinician's decision-making. Certification of quality of eHealth systems and services, against commonly accepted standards may provide the needed tools for such mutual recognition and acceptance.

Dealing with EU level Agreements: EU level Agreements on cross-border access to health data will eventually need to be reached.

The approach of epSOS is based on the designation of National Contact Points (NCPs) as legal entities with specific duties for the project, relies on an internal mechanism of governance based on guidelines. The NCP is allocated the overall responsibility for data protection and it is therefore envisaged as an organisation delegated by each MS to act as a bidirectional technical, organisational and legal interface between the existing different national functions and infrastructures. It is legally competent to contract with other organisations in order to provide the necessary services which are needed to fulfill support services and processes and the needs of their cross border delivery. An epSOS NCP is identifiable in both the national and the EU domain as a communication gateway and as a mediator as far as the legal and regulatory aspects are concerned.

However, as no legislation of any country or region foresees such duties at the moment, it is necessary to consider the establishment of a European dispute resolution service as a prerequisite to deploying cross border eHealth services. A useful example can be found in the social security area where there is a legal basis for disputes settling (based on Regulation 883-2004) and an official body driven by MS has

been established. Also in the ISA[42] framework (former IDABC), the MS are the driving force and the European Commission is the facilitator.

It should however be kept in mind that, in general, EU level legislation relevant to eHealth is contained mainly in Directives rather than Regulations which must be transposed into national laws, and thus variations in the transposition of a Directive may arise. Therefore, the establishment of a formal dispute settlement body for eHealth related issues might be useful.

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[42] *http://ec.europa.eu/isa/*

It is recommended that the EU eHealth High Level Group, together with the European Commission

✓ Initiate a process that will lead to Agreements on
  o a realistic and appropriate level of security for electronic processing and transfer of health related information;
  o a shared policy on the definition and handling of patient consent to electronic processing and cross border transfer of health data that meets expectations of European patients and medical staff;
  o a process for monitoring, assessment, review and continuous improvement to reflect progress in technological solutions, harmonisation of security, quality and safety practices.

The implications of transposing these Agreements are that Member States will be called upon to:

✓ Review their national legislation with the aim to support innovation without compromising adequate protection of citizen's right and particularly:
  o review and continually adapt their security frameworks for health data to achieve cross border health data exchange; this shall include a practical process for patient consent;
  o consider legal approaches that can support dynamic change by appropriately exploiting the role of national standardisation and regulatory frameworks in the development of quality, safety and trust;
  o establish through appropriate legal instruments open transparent stakeholder platforms representative of the eHealth ecosystem also by transferring CALLIOPE experience where appropriate.

In order to support these initiatives the EU eHealth High Level Group, together with European Commission, should

✓ Issue and adopt a commonly agreed EU Information Governance to comprise a guide for MS to conform to requirements for cross border health data exchanges.

✓ Initiate the process for the establishment of a permanent coordination mechanism that will cater to monitoring conformance and deal with disputes and breaches of Agreements in the form of a European Arbitration service.

3.3 Fostering adoption of eHealth services

Managing technological complexity often becomes an enormous task for health services. Keeping pace with technological advancement and adapting to new developments has proven both costly and has consumed a great share of effort in the past. Indeed, this is usually not a core competence of healthcare organisations. On the other hand, healthcare challenges and the change management required to continuously improve the core process, i.e., the delivery of healthcare, have become too demanding and require to fundamentally reconsidering the way we do business.

A thorough *assessment of the costs and benefits* of the traditional way of building these new competencies into healthcare and exploring *new models of cooperation* with strategic partners who can bring core competencies as needed. Both require appropriate incentive policy as well as measuring and monitoring outcomes.

Incentives: Most governments have recognised the need to introduce incentives to promote the adoption and use of ICTs in eHealth. The 2010 OECD report *"Improving Health Sector Efficiency: The role of information and communication technologies"*[43] has outlined three ways in which governments can intervene - direct regulation, economic instruments and persuasive measures.

The OECD report further outlines a broad range of financial incentives used in different countries. These depend on factors such as the choice of the technology, the structure of the healthcare system, and the prevalence of a particular payment scheme (e.g. per capita, fee-for-service schemes) and can be financial (direct payment or reimbursement) but also non-financial such as time saving, a better working environment, increased satisfaction, better professional context. All contribute towards improved motivation and increased likelihood of adoption.

Most of the financial incentive programmes in operation today rely on some combination of the following main types of arrangements: d*irect subsidy* through private and/or public grant programmes; bonuses or add-on-payments that reward providers for adopting and diffusing ICTs or for improved quality, *(extra) payment for care* delivery facilitated by eHealth applications; and *disincentives such as withholding payments from providers/financial "penalties" because of poor performance or compliance.* The pay for performance (P4P) model is a mix of the above and is a relatively new trend in third party reimbursement models.

The extent of follow-up obligations (and associated incentives), and more generally of *incentives for continuity of care* between the hospital, primary and social care systems, will be central to the prospects for the facilitation of mainstream implementation of eHealth and integrated care. How this works across diverse European systems is currently not well documented, neither as regards continuity of care in general, nor eHealth support in particular. Unless it is a fee-for-service regime, a key aspect will be what amount to pay for a certain severity of a chronic disease to the integrated care network, how to share this amount among institutional, ambulatory and community service providers, and how to assure a fair sharing of responsibility for quality assurance and performance.

Business models: Next to the payment/reimbursement perspective for the individual healthcare practitioner, both industry and organisations adopting eHealth solutions also need sustainable business models for providing new, improved or more efficient services. In spite of some successful eHealth-related "business areas", such as teleradiology, tele- consultation (in remote areas), selected telemonitoring, and – not the least –social care ventures, which have been sustained over longer time periods, the unusually high rate of failure of eHealth ventures strongly underlines the need for

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43 Improving Health Sector Efficiency. The role of information and communication technologies. OECD Health Policy Studies, 2010

well designed business models and plans. Such clear, well-developed business models and plans are the success factor both in a public and a private service context.

Business models must identify clearly spelled out value propositions and indeed deliver such value-added services to their clients, which usually requires a comprehensive commercial approach, particularly also for public authorities which need to be accountable for public spending. Win-win propositions for various stakeholders at the same time (patients, professionals, organisations, payers) need to be identified and analysed.

Today in Europe we find several *business models* which may be grouped in four broad categories:

o *Public utility*: these initiatives are created and maintained with the assistance of central government/local state funds.

o *Provider and payer collaboration*: this type of collaborative model is created for/by healthcare providers and payers within a geographical region or for a particular group (e.g. farm workers). These initiatives can be set up as either for-profit or not-for-profit organisations; however, the key to this category is the collaboration between and mutual benefits for participating payers and healthcare professionals.

o *Not-for-profit*: the not-for-profit initiatives are driven by their charter to help the patients and the community in which they provide services. Their tax-exempt status can help to reduce funding challenges and costs, may also involve, depending on national laws, special tax credits/incentives.

o *For-profit* (often resulting from the conversion of a not-for-profit initiative at a mature stage): for-profit initiatives are created with private funding. These organisations look to reap financial benefits from their services for their owners/shareholders.

Irrespective of their specific nature, the way these various approaches align costs and revenues and extract value from ICT solutions for each stakeholder will determine their sustainability in the longer term. This requires, an assessment of the viewpoints and respective roles of the main stakeholders, but also attention must be directed to the financial implications for the multiple actors involved (purchaser, insurance/health plan, hospital, healthcare professional towards realignment of financing and fair cost and revenue sharing.

3.4 Resource considerations

To realise interoperability, resources are needed. Resources may be of a financial nature, but may also concern people, tools, assets, organisations or environmental and infrastructural endowments on which to develop. Here only initial considerations on human and financial resources will be outlined.

Human resources: EC funded research on "supporting and boosting investment in eHealth"[44] concluded: *"The most important part of eHealth investment that needs expanding is the eHealth skills and knowledge of healthcare staff and ICT suppliers' staff. An expanded capability is essential to achieve more success and so help to boost eHealth investment."* This experience is echoed around the world, and particularly in the very complex domain of interoperability investing in human resources, skills, training, education and continuing professional development (CPD) is mandatory.

Developing and expanding the human capital can be supported by many different modalities, such as financial measures, non-financial measures e.g. legal and regulatory interventions in education and licensing of medical professionals, and awareness and stakeholder relations measures. Establishing and sustaining relevant education and training institutions would be another option.

Financial resources: To implement and execute an interoperability policy – be it at the national, regional or local level - by health service providers, industry or other stakeholders – and the related governance structure, certain policy measures or instruments need to be applied. Concerning the provision of financial resources, the following measures[45] can be identified:

- o Tax breaks (e.g. accelerated depreciation structures or deductions for specific investments or expenditures)

- o Tax allowances (e.g. for specific investments)

- o Subsidies (e.g. on RTD or implementation expenditures)

- o Reimbursement rules (e.g. for coding services)

- o Specific allocations in national or regional (government) budgets

- o Provision of direct financial resources for infrastructure establishment and maintenance

- o Consolidating available resources within organizations (e.g. Competence Centres for rendering public services, R&D institutes), education and training institutions, physical and virtual networks

- o Appropriate use and exploitation of EC Regional and Structural Funds, and European Investment Bank instruments

- o Public-Private Partnerships (PPP)

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[44] *Cf. http://www.financing-ehealth.eu/downloads/documents/FeH_D5_3_final_study_report.pdf*

[45] *See also the EC commissioned study Financing eHealth. Bonn, empirica 2008. http://www.financing-ehealth.eu*

A great challenge, when planning for interoperability implementation, is to agree upon a realistic budget and how to cover it. The responsibility of the various parties and stakeholders (country or region/ministry of finance/national health service, region, industry, care provider, insurance, etc) should be agreed upon, and their willingness and ability (affordability) to provide for the financial resources and/or investment must be assured. This will also involve coordination at the various levels, to avoid duplication of tasks between e.g., regions or stakeholder groups. A lack of *consistent and coherent planning* may turn out to be very costly, and even a threat to interoperability, especially if the investment is driven by a wish to stay autonomous. Providing the financial means which also ensure sustainability in the longer term seems not likely without *first establishing an overall fiscal plan*.

The same applies at the European level, but on a larger scale. Clearly, this suggests *activity and resource coordination*, perhaps mediated by the EC through its policy intervention instruments, like through the new High Level eHealth Governance Initiative. Here Member States could discuss with the EC and European Stakeholder representatives ways and means to make progress also at this front.

Justifying significant spending on eHealth interoperability projects and infrastructures out of public resources is a common challenge, which requires a sound justification and evidence base on the societal and individual benefits to go with it. This will require to also invest in sustainable mechanisms to measure progress and the health as well as socio-economic impacts achieved.

Furthermore, when, e.g., legislation on eHealth is still pending, this also has repercussions on financing. Such interdependencies also need to be taken into account when developing strategies for resourcing interoperability activities.

RECOMMENDATIONS

It is recommended that the EU eHealth High Level Group, together with European Commission:

- ✓ Co-ordinate activity and resources targeting eHealth Interoperability, through policy intervention instruments, and discuss with the EC and European Stakeholder representatives ways and means to make progress at this front.
- ✓ Actively support the exchange of national, regional or local experiences with working on alternative co-operation models and strategic partnerships.
- ✓ Support relevant EU action around major common priority areas in order to
  - o achieve a deeper understanding of value adding partnership models that permit the decomposition of complexity and allocation of responsibilities for addressing it amongst the partners and where it may be best addressed according to their knowledge and skills;
  - o encourage pilot actions that will provide the knowledge on the dynamics of value chains and cost and benefit implications for all actors.

It is recommended that the Member States:

- ✓ Ensure consistent and coherent planning for interoperability and ensure sustainability in the longer term by making provisions in the overall fiscal (e)Health plan.

- ✓ Should invest in human resources, skills, training, education and continuing professional development (CPD).

- ✓ Engage into an open and transparent dialogue with EU and local ICT industry towards establishing and reinforcing trusted partnerships for addressing technological challenges together in a win-win approach.

- ✓ Consider reviewing their legal and regulatory frameworks to accommodate market innovation and new models for reimbursement, funding and resource allocation for eHealth.

- ✓ Provide justification and evidence base on the societal and individual benefits of eHealth interoperability and invest in sustainable mechanisms to measure progress health as well as socio-economic impacts achieved.

3.5 Monitoring progress

As argued in the preceding paragraphs, focus on integrated care and a redesigned value-driven health system require availability and access to high quality information at the right place and the right time for all stakeholders involved to allow for instant and reliable decision support as well as a set of appropriate incentives. Both require measuring and monitoring outcomes. EU collaboration provides an excellent opportunity to build a substantial body of knowledge and evidence at EU level and effectively share lessons learnt about benefits and costs of choosing one incentive or reimbursement system over another.

The 2010 OECD study highlights the absence of independent, robust monitoring and evaluation of programmes and projects. Besides a formal evaluation to justify initial budgets, a formal post-implementation evaluation to determine the actual payoff from the adoption and use of ICTs is critical. The study underlines that measuring the impacts of ICTs is difficult for a number of reasons such as the multidimensional effects of ICT implementation and different contextual conditions, the cultural transformation and change management required. The study calls on governments to strengthen monitoring and evaluation as "high-quality evidence represents a fundamental source for the decision-making processes … Governments have much to gain in supporting the development of *reliable and internationally comparable indicators to benchmark ICT adoption* and ensuring that systems for monitoring ICTs are sufficient to assist in meeting the improvement goals. Risk, delay and cost can be minimised by learning from good international practices."

The European Commission and Member States have committed to the development of common indicators and have started – guided by OECD - cooperation with the USA (Office of the National Coordinator for Health IT) to develop agreed definitions and a limited set of common indicators for ICT adoption.[46] A set of 15 indicators organised have been proposed according to the following four categories or steps: Adoption; Modes of Use/Purpose of Use; Critical Success Factors; and Outcomes/Impacts. The ability to get consensus and provide an initial starting point would be best achieved by focusing on indicators that measured adoption and modes of use/purpose of use (i.e., the first two categories).

The interest in cooperation is strong as the process of developing surveys to monitor adoption and use is very labour-intensive, and a common goal for the international community should be to streamline methods and learn from each other.

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[46] *A meeting to further scoping a proposal for international work was held on March 16, 2010, as a satellite session back-to-back with the World of Health IT conference in Barcelona.*

It is recommended that the EU eHealth High Level Group, together with European Commission:

- ✓ Supports collaborative activities aiming to build collectively the substantial body of knowledge and evidence at EU level.
- ✓ considers the OECD model survey approach and indicators for adoption.
- ✓ supports specific actions and a support mechanism to help MS to effectively share lessons learnt about benefits and costs of choosing one approach over another as well as about the incentive mechanisms and reimbursement systems.

4 Addressing open issues: Together in the EU

Chapter 4 focuses on the processes needed to address open issues. It encompasses a number of considerations including interdependencies, opportunities for consolidation and choices to be made. Such considerations will – in a next stage – allow for the specification of actions to be taken collaboratively in order to support acceleration of national eHealth deployment.

4.1 EU Collaborative Governance

In order to address the open issues identified in the previous section jointly in the EU, it is necessary to establish a continuous collaborative process which will allow for extensive synthesis around the national and regional diversity and the many visions of the key stakeholders. Naturally this co-operation will need to be organized at EU level, however with strong links to the national eHealth platforms and stakeholder communities. In fact, a major challenge for the coming decade, during which eHealth is to be deployed broadly in real life will be to encourage stakeholders to work together with public authorities towards this common goal. This involves facilitating effective collaboration between the policy level and the operational level. The breadth and complexity of the issues that need to be addressed as well as the integrity imperative for such a process require that an appropriate EU Collaborative Governance for eHealth is set up.

In December 2009, the EPSCO Council Conclusions provided the mandate for EU eHealth cooperation and the establishment of an eHealth High Level Governance process in Europe[47]. The creation of a Member State driven collaboration platform for eHealth is a unique window of opportunity to build national solutions on common European or global standards that enable continuity of care across administrative and national borders. In response to this mandate, the eHealth Governance Initiative (eHGI) is planned to be launched on January 1st 2011. This Initiative has considered that European eHealth Governance is needed at the following three levels:

- At the policy level, to set out higher level political objectives, define common priorities and policy measures to guide and steer the developments.

- At the strategic level, to agree on concrete strategies for developing and implementing integrated, value adding eHealth services for EU citizens.

- At the operational level, to allow for a deeper and narrower focus in various areas such as information governance, safety and ethics, security policies and services; public–private partnerships for increasing certainty and accelerating deployment of eHealth services; implementing the EU infostructure and sustaining convergence services; re-engineering of the standardisation process; maintaining the links to national stakeholder groups, etc.

At the policy level a "European Governance" must be established. The term refers to the rules, processes and behaviour that affect the way in which powers are

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[47] *http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/111613.pdf*

exercised at European level[48]. Five "principles of good governance" reinforce those of subsidiary and proportionality: openness, participation, accountability, effectiveness and coherence. They underpin democracy and the rule of law in the Member States, but they apply to all levels of governance – global, European, national, regional and local.

At the strategic and operational levels, the establishment and maintenance of an open, transparent and capable platform for multi-stakeholder trusted dialogue is key to the success of eHealth adoption and use. Crossing boundaries in eHealth can only be achieved if the EU eHealth Interoperability Roadmap and the process of its creation is owned, followed up and therefore trusted by its multiple stakeholders.

The establishment of "collaborative governance" is essential for ensuring interoperability, avoiding duplication, optimize use of resources, ensure coherent action in a range of crucial areas such as security and privacy, as well as to providing a framework and capacity for seamless services[49]. Strong coordination and collaboration among actors is considered a key prerequisite for knowledge creation, sharing and dissemination, for the delivery of public services and for the creation of public value.

This multi-layered governance is also considered in the resolution of 5 May 2010 on a new Digital Agenda for Europe of the European Parliament, which stipulates that the ownership of the 2015 EU agenda by all political and geographical levels (EU, national and regional), as an essential prerequisite for its effective implementation[50].

CALLIOPE has started out by introducing its collaborative governance drawing from the EU Governance White Paper and from partners' experiences. This provided the basis of the collaboration and an open trusted environment where dialogue and synthesis could take place. At major milestones of the work plan, it was possible to review it and optimize it to response better to the needs of its stakeholders.   The CALLIOPE collaborative platform has proven its process capability of delivering the present Roadmap to its level of integrity and broad acceptance.

The CALLIOPE collaboration platform facilitates the sustainability of a trusted, open, equitable, informed and transparent dialogue; it synthesizes perspectives, opinions, and views; and it produces proposals that represent a balanced view and which are accompanied by a clear statement of the level of consensus that the proposals achieve. This process means that all stakeholders have an equal footing in CALLIOPE's discussions. They have equal ownership of the process and its results.

The CALLIOPE Experience shows that the following key elements are prerequisites for good results:

[48] *Commission of the European Communities. European Governance: a White Paper. Brussels, 25 July 2001 (COM(2001) 428 final)*

[49] *C. Centeno, R. van Bavel and J-C. Burgelman: eGovernment in the EU in the next decade: The vision and key challenges. European Commission, Joint Research Centre (DG JRC) Institute for Prospective Technological Studies, August 2004, Technical Report EUR 21376 EN*

[50] *European Parliament resolution of 5 May 2010 on a new Digital Agenda for Europe: 2015.eu (2009/2225(INI)).   http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0133+0+DOC+XML+V0//EN&language=EN*

Collaboration and shared goals: this form of collaboration needs clear governance, shared processes that aim at reaching agreements in core areas and efficient management and support structures. On this foundation, sound expert work, commitments and collective engagement may be pursued.

Trust and Confidence: Sustaining a commonality of purpose, and collaborative effort towards common goals, implies creating and maintaining **trust** within the partners and **confidence** in the process. Both concepts are built on sound ethical principles, often nurtured by long-lasting relationships. Sharing a vision and a common value system is characteristic of sound partnerships. Values, competency, and commitment must co-exist as pre-requisites to ensure the *integrity* of the collaborative platform. Stakeholders' representatives also need to learn how to work together on numerous practical questions relevant to eHealth deployment and service use.

Flexibility and responsiveness: eHealth is a fast-changing landscape. The collaboration experience provides an impetus for continuous change and improvement. It is obvious that this dynamic landscape is unlikely to be stabilised in the short or even medium-term. eHealth Interoperability is by its very character a moving target. It is subject to a continuously evolving policy and technology environment, and timing.

Networking and Capacity-building: All stakeholder groups have their own mission and roles, agenda, vocabularies, and constraints. They are also different with regards to the experience and expertise that their members possess about information and communication technologies (ICT) in general, and eHealth in particular. For some stakeholder groups, eHealth has been on their agenda for more than a decade; for others, it has only come on the scene as a topic relatively recently. A collaborative platform should respect the governance structure and processes in stakeholder organisations and encourage inclusive consensus. Furthermore, a collaborative platform needs to take advantage of its networking capabilities to pool expertise which comes from all the different areas of Europe (and even beyond) in order to make that expertise available through different forms of support action[51] to Member States according to their needs and requests.

Resources and active engagement: Value can be delivered by a collaborative platform only if it includes actual work that is based on a collective engagement, undertaken through shared processes, and with a view to deliver tangible outcomes. Such a platform must therefore be adequately resourced in a timely way.

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[51] *The term "support action" is used here in a very generic way, i.e., an action that provide support and sustenance. It is **not** used in the limited way that is specified by an EC-co-funded study instrument.*

<div align="center">RECOMMENDATIONS</div>

It is recommended that the EU eHealth High Level Group, together with European Commission:

- ✓ Elaborates –at the onset of the collaboration process – a two layered EU collaborative Governance based on current EU practice and the CALLIOPE experience and particularly:
    - o EU Governance to be applied in EU policy development and decision making within the eHealth High Level Governance Group;
    - o Collaborative Governance to guarantee the continuing openness, transparency and capability of the Roadmap development process in its future iterative editions.
    - o the needed documentation and processes to be applied and monitored by the Secretariat function of the eHGI

It is recommended that Member States:

- ✓ Consider the establishment of national multi-stakeholder platforms. Such platforms
    - o should be appropriately empowered and hence formally established;
    - o may be appropriately mandated in relation to their participation to the EU level dialogue;
    - o could exploit the commonly elaborated and successfully tested CALLIOPE experience.

4.2   Bringing it all together - adoption of a common working model

For any ICT enabled healthcare service to go into practical application, it is necessary to be able to rely on existing operational national infrastructures and an infostructure that has been developed to the level necessary to meet the respective requirements of any given eHealth application.

In principle, while the national eHealth infrastructures should be fully in place, the Infostructure will develop gradually around specific use cases within the framework of collaborative governance. Such framework is a pre-requisite to a distributed working model for the management and exploitation of health related data, information and knowledge across sources, actors, languages and jurisdictions. These two pre-requisites are shown in figure 1[52] as two transversal foundation layers of eHealth. Similarly, any cross border eHealth application, will need to have in place additional cross border components associated to both layers.

National, regional and EU level priorities may be expressed as use cases or integrated services. They will normally reflect health system priorities and will aim at realizing specific objectives. As discussed in the previous section and to the extent that they reflect a degree of innovation they will require a certain degree of re-engineering of processes and workflows across disciplines, organizations and jurisdictions. Exploiting the full potential of ICT in healthcare will require a supportive role of ICT experts; however these activities should be driven by the end users and beneficiaries of these services, hence the involvement of practice based leaders is of utmost importance.

The greatest challenge in practice is however managing the needed change and especially the organizational complexity of a multidisciplinary environment.   While new technological challenges will need to be addressed, the focus is shifting more and more towards human factors and the cultivation of a trusted collaborative environment that will sustain an open and transparent dialogue and eventually make this change possible. The right hand column expands across all domains of infra- and info-structures as well as the eHealth services and reconciles all policy and financing aspects needed for eHealth deployment.

The transition to a new way of working needs to be an informed decision of both healthcare authorities and the key players that will make it happen.

 It is the responsibility of the national/ regional governments to provide leadership and support for the development of the needed foundations.

It is then the responsibility of the health professionals, providers and the ICT industry to bring in the leadership, focus, creativity to leverage such foundations and new technologies to create value and benefits to patients.

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[52] *The overall concept is borrowed from ISO TR 14639 Health informatics - Capacity-based ehealth architecture roadmap. The aim of the TR is to provide a generic and comprehensive context description to inform architectural structuring of national enterprise-wide Health Information Systems with the particular intention of assisting nations which are in early or mid stages of developing such systems.*
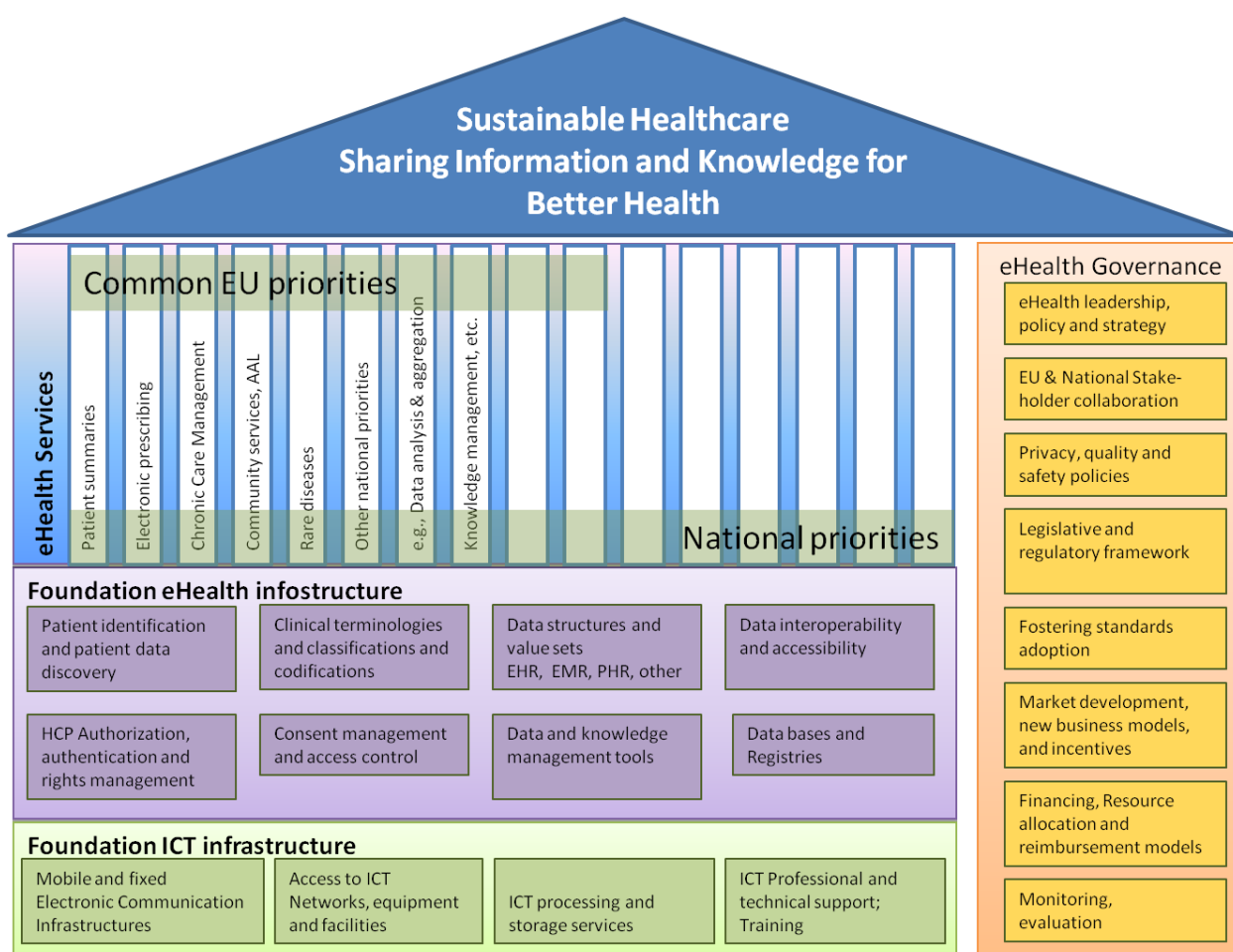
Figure 1: Bringing it all together

More specifically:

The ICT Infrastructure foundation layer may be considered to encompass

the national fixed and mobile electronic communication infrastructures, access to the ICT Network and services including security services; the needed ICT processing and storage infrastructure and professional ICT technical support and training. Such infrastructure should be future oriented and should seek to address both national and cross border eHealth needs;

The eHealth infostructure foundation layer contains all data structures,

codifications, terminologies and ontologies, data interoperability and accessibility standards, stored information and data as well as rules and agreements for the collection and management of these data and the tools for their exploitation. At the EU level, such a European infostructure may be composed of biomedical and health/medical research and knowledge databases, public health data repositories, health education information, electronic patient and personal health records, data warehouses, etc. It will require leadership and management, sustained organisational structures, well-governed processes and funding as well as a supportive, secure ICT infrastructure/network and the associated semantic services.

The eHealth services layer contains all the components which directly contribute to high quality care and improved accessibility and cost containment, such as patient summaries, ePrescribing, chronic disease management, home monitoring, tele-consultation, tele-radiology and others. These services typically reflect the national priorities. Many of them are common to all EU member states and therefore are candidates for priorities that should drive the common EU activities.

The eHealth governance column which holds together all layers and brings under a single umbrella national/EU strategy and leadership to drive eHealth deployment; a collaborative framework with all key stakeholders; policies and mechanisms for the adoption and use of standards, as well as for safety and quality of generated information and data protection of shared personal data. The governance should also address effectively incentives, financing models and development of partnerships and new business models.

The legislative and regulatory framework should be enabled by this collaborative governance to support innovation and ensure the needed level of protection and legal clarity for service development and provision. Relevant ethical and professional codes and standards should also be examined to ensure that the utilisation of eHealth tools and solutions does not compromise any ethical duties which may exist.

In due course the use of eHealth tools should indeed be mandated within ethical codes so that a definition of good practice would include using eHealth solutions where appropriate. The Governance should be systematically informed through monitoring and evaluation activities which include transparent feedback mechanisms.

## 4.3 Bringing EU and the national/regional activities together

Figure 2 attempts to illustrate how EU level collaboration can relate to national/regional activities on eHealth in an articulated way. This example defines common steps and proposes an integrated approach, linking policy and operational levels together around the common strategy proposed by the Roadmap. It also links the national/regional level to the international which may again be treated within the EU and the global perspective, especially in what concerns standardisation.

This example offers a possible route towards the established common vision and supports a common understanding of the concepts. It must be borne in mind however that although the vision for eHealth Interoperability is a shared target, there are different ways and speeds for Member States to reaching it, according to countries' and regions' organisation of health and legal systems and priorities.

It is also noted that the intention here is not to be detailed and complete in terms of covering all aspects of eHealth Interoperability, but rather to perform a reality check and a demonstration of the key concepts underlying this Roadmap within this model which is simplified in order to serve these purposes.

A walk through this graphic representation of a high level representation of the articulation of EU and national activities is provided in the following paragraphs.

Figure 2. EU eHealth Interoperability Roadmap: Main Highways
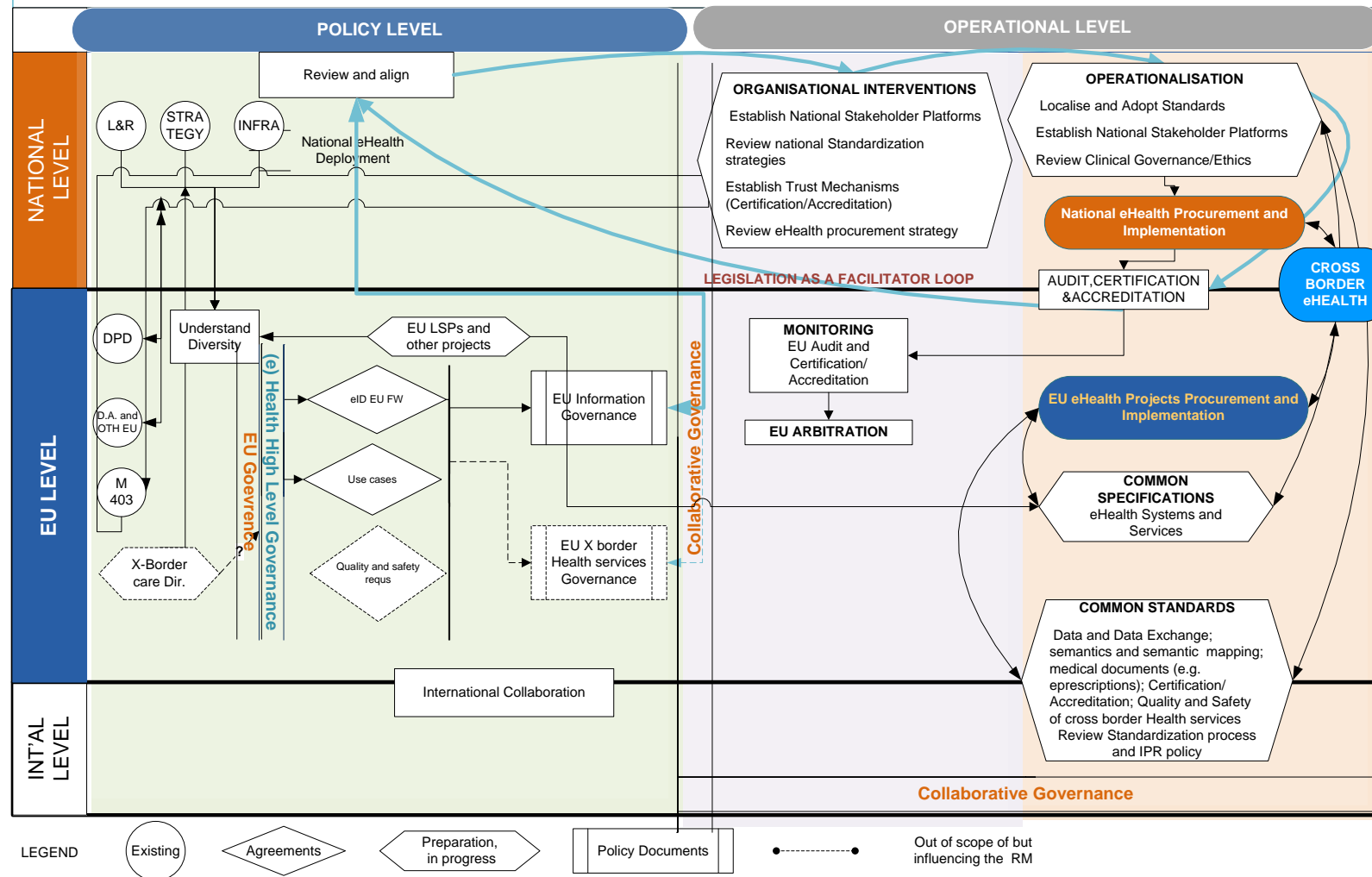
The starting point will always have to be the existing national/regional legal frameworks, eHealth and government strategies and infrastructures. Especially in what legal and regulatory frameworks are concerned, these also form the starting point for EU directives such as the Data Protection Directive (95/46/EC) on the protection of individuals with regard to the processing of personal data and on the free movement of such data which regulates the processing of personal data within the European Union and which is an important component of EU privacy and human rights law. The same is true for the draft Directive on the application of patients' rights in cross-border healthcare.
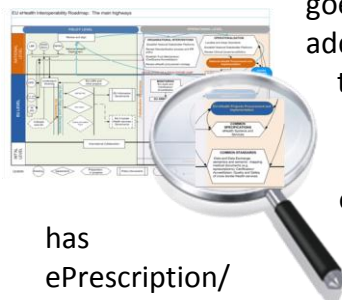
When EU directives are transposed into national legislations, there is often broad variations in the way these transpositions are achieved, leading to variation in practice. epSOS and other LSPs help expose these variations in a consolidated manner, such as variations in the security levels applied. The establishment of the EU eHealth High Level Governance provides for an appropriate forum where such Agreements may be achieved at the right policy level. At this level, it is also necessary to agree on a common set of priorities on health challenges, eHealth services or use cases where common effort and resources should be focused on EU level collaboration. In addition, providing health services based on shared data at the EU level will need a certain level of harmonisation of quality standards pertaining to electronic health records and coding practices.

Such Agreements will be made possible in an EU policy environment of the EU eHealth High Level and its associated EU Governance.

Standardisation is central to innovation. It is a typical international level activity which goes beyond the EU boundaries. The M403 requires that in addition to the standards development process, it is important that standardisation organisations explore ways to improve the uptake and use of standards. epSOS is an example of an EC supported project which –though a multinational co-operation and in partnership with the European ICT industry - has delivered European specifications for Patient Summaries and ePrescription/ eDispensation services for mobile European citizens. This specification draws appropriately from many different standards to create profiles for these two use cases which have then been implemented into national infrastructures and have undergone interoperability testing.

A major challenge to be taken up at both EU and the national level is to explore different funding models for access to and use of e-Health standards.

Adopting international/European standards and commonly developed open specifications can then provide the needed certainty for acceleration of eHealth deployment and market development. The adoption process should however reflect robust localisation activities.
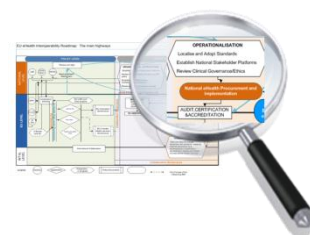
The localisation will require appropriate composition of experts' teams and capable, processes. A characteristic example is the task of localisation of the semantic bolus of resulting from the respective specification of common European use cases; taking the case of epSOS, this involved an exercise of converting the Master Value Catalogue to national localised Master Translation Catalogues, through translation, review and validation before its clinical application. Another exemplary area is this of professional practice and the relationship of healthcare professionals with their patient which will require careful consideration of the national regulations of professional conduct and ethics.

Evidently, work taken up in common in Europe can support national priorities and plans, but this will not occur automatically. This benefit can only result from a systematic approach to co-ordinating the EU and the national levels. As a first step, the EU dialogue can be sustained if it can be received by mirroring national stakeholder platforms. CALLIOPE has resulted in several lessons that are to be learned and national platforms may potentially benefit from this international experience.

It is expected that the national standardisation organisations will also review their national standardisation strategies in the light of EU co-operation actions drawing upon the Mandate 403 as well as the emerging EU level experience on standards and certification for electronic health records and associated data collection practices. A comprehensive national standardisation framework can support the procurement of eHealth systems and stimulate new approaches to eHealth deployment through review of national eHealth procurement policies, financing models and partnerships for eHealth.

Building robustness into the integrated trust framework across the entire process from the projects' work bench to implementation of standards and certification of the applications will create a trust and accountability framework. This in turn can allow national legislation to consider legal frameworks that appropriately consider standardisation as part of the system of legal, regulatory and organisational interventions that provide legal protection and certainty. This approach will permit to move the dynamic elements outside the rigid bodies of law and hence allow innovation. This will then convert legislation and regulation from a barrier into a facilitator for eHealth.

Eventually the cross border eHealth employed on a routine basis will need to be regularly monitored by an EU level co-ordination mechanism and through common reporting policy, process and indicators. The benefits of working with common EU standards, mutually recognised certification/ accreditation schemes including security and security audit are evident for the purpose of this oversight function as well.

Finally, through sustaining an effective European collaboration and through properly linking the EU and the national levels at several intersection points and by means of an appropriate collaborative governance, we may arrive at a situation where cross border eHealth interoperability is not an
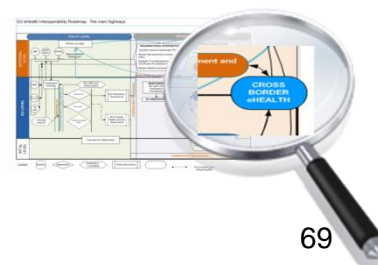
additional implementation but is fully integrated as a characteristic of national eHealth deployment.

5 Outlook

This document has attempted to unfold the main elements, both in terms of drivers and barriers that are known to affect eHealth deployment and has synthesized a composite view of the broader environment and the many facets of EU eHealth Interoperability.

This document has stayed at a level of abstraction, that has been considered sufficient and at the same time non-discriminatory to support decision makers to identify, select and further develop appropriate alternatives. It is a document that is agnostic to any particular national or regional situation or solution or specific stakeholder priority. It makes a number of Recommendations that are provided as input to the eHGI towards a more detailed specification of its work plan within its remit, stated objectives and defined action lines.

As a first step, it will support the eHGI *mainstreaming process,* i.e., the process that will prepare and bring this document to the High Level Governance Group, in response to their invitation to CALLIOPE to present a policy support document in line with the specification presented and accepted as suitable in their Barcelona meeting.

More specifically, while the Roadmap intends to establish the factual basis for decision making, the Mainstreaming activity will take the work one step further, building on the richness of the roadmap content in order to

- propose appropriate routes for reaching the priorities set by the HLGG (mainstreaming)
- produce a document of a style and language appropriate for decision makers-health authorities (briefing note)
- ensure that the process is totally understandable and could be relayed to the whole eHealth community
- lead to greater engagement of stakeholders in the process
- initiate the next step of the iterative process of the Roadmap

Through the same process it must be made possible to provide the needed support for the prioritisation of use cases and services that should be addressed within the EU level collaboration by the High Level Governance Group.

The mainstreaming activity is expected to occur within the eHealth Governance Initiative during the period January – April 2011.

Annex I.

Re-engineering workflows and clinical processes- the example of chronic disease management

Lessons that can be learnt from the successful mainstreaming of innovative community care services for chronic disease management suggest that the mere technical implementation of applications may be one of the less complicated steps making such services part of the daily clinical activity. Instead, the bottleneck obstructing progress has often been the lack of a 'conveyor belt of care' in terms of coordinated services which could be facilitated by appropriate technologies. In essence, the major innovation lays in the adaptation or re-engineering of organisational flows, involving many professionals, all working for different organisations but coming together to offer one integrated pathway in health and social care to support continuity of care. Strategic visions to break through existing 'silos', understanding how the technology can play a part, but not be driven by it, are key success factors.

Collective experiences – also based on epSOS experience - show that the bench-learning loop from research to adoption and routine use may be streamlined around the following key elements:

Empowerment

> Clinical leadership, establishing priorities and the associated clinical and business cases, understanding and accepting constraints, recruiting partners for the joint learning endeavour, planning and funding representative project

Service development

> Standardisation of services and their delivery, implementation of semantic, technical and organisational pre-requisites, acquisition of appropriate ICT support and link to national infrastructures, securing needed legal, regulatory and cross-sectoral organisational interventions

Testing, learning and optimisation

> Preparation of a representative expandable pilot, making a test run, examining results and learning, informing the deployment strategy

Deployment, adoption and routine use

> Establishment of a deployment strategy and business model, procurement of a service, selecting partners, launching, running and monitoring the service, , adoption and routine use.

Evaluation, continuous improvement and feedback to research

> Establishment of a retroaction loop based on periodic interactive concertation with all the concerned actors in order to evaluate and assess the implementation, deployment, service delivery and effective usage and added

value; to allow continuous improvement of the service and to anticipate needed changes and new demand to the research area.

Change requires the highest level of leadership support, and should be guided and promoted by healthcare and social care professionals. Change management is most effective when it fully engages with all actors involved, be they from the clinical, social care, administrative or policy realm. Health delivery processes need to be examined, particularly where they cross organisational and management boundaries, they will require redesign and clear specification of these interfaces. Health technology innovations must follow, support, and offer opportunities for such process innovations, but not be seen as the driving force. This necessitates open and continuous communication on the change process and particularly sufficient resources for comprehensive and continuing training measures.

Change is not a costless exercise. It requires sufficient financial resources over an extended period of time. Investments that have to be made in technology, staff and support costs to achieve the change and render it sustainable may outweigh narrow cash savings achievable from, for example, reduced hospital, long term admissions or more efficient workflows, particularly in the shorter term. Substantial additional investments may be required up-front, long before ICT-enabled service innovation can actually 'pay off'. Grants may inject much needed resources to mainstream the further application of technology within health and social care and support services. Incentives and reimbursement are key to enabling new business models needed to support the new way of working once the services are deployed.

The complex ecosystem of actors and functions, chains of value and chains of actions, beneficiaries and benefiters should – like any ecosystem - come together and be sustained under its own natural laws depicted by its collaborative and multi-level governance. The following table attempts to provide a composite view of this ecosystem. This table should not be considered an absolute "cook book" but one of the possible routes to achieving the personal vision. Eventually, whatever the choices made, the aggregate outcomes along each of the columns would add up to fulfilment of each personal vision. Their total sum shall then deliver the global vision:

"[*I] in my multiple roles receive services that reconcile all my different needs and personal visions. For this to become real my public administration has engaged in collaborative work under a common governance and a shared, fit for purpose, regulatory framework, which makes such integrated services possible, effective and fully trusted.*"

Table 1: Re-engineering workflows and clinical processes: The chronic disease example					
I. EMPOWERMENT					
CITIZEN / PATIENT	HCP	MANAGER	ICT PROVIDER	DECISION MAKER	POLITICIAN
Be an informed and influential voter and healthcare consumer				Develop and continuously improve the national (e)Health strategy for quality, safety and sustainability of health and social care systems.	Provide leadership and direction for change
	Establish the clinical case			Identify and empower patients representative organisations, clinical leaders, clinical innovation centres	
	Specify patient cohorts that will be the beneficiaries of the new services. Assess the potential to improve clinical outcome, the social factors and the quality of life	Assess the potential to improve the overall cost-utility ratio for the health and social care system			
Understand financial implications and exert influence	Establish the business case				Support competitiveness and innovation by appropriate legislative interventions and other relevant initiatives
		Assess the business case viability Define IPR policy Identify sources of funding and reimbursement		Provide incentives and pursue cross-sectoral policy co-ordination	
	Recruit the core partners and establish the project				
	Verify feasibility within the existing legal and regulatory framework and national eHealth info-infrastructures. Understand the constraints and balance ambition against realism. Describe the project and secure funding			Support innovation in eHealth	Support the establishment of national info- infrastructures for e*Services

II.	SERVICE DEVELOPMENT: GETTING STARTED		

Establish the Integrated service blueprint • Understand clinical requirements and citizens/patients preferences • Elaborate the service scenario and the service delivery specification • Identify functions needed and describe end-to-end workflows • Re-distribute the labour allocate tasks • Define values in the value chain and assign value contributors		Adopt clinical governance under the quality and safety imperative Support through legal and organizational interventions
	Secure the ICT nervous system • Resolve semantic interoperability issues across disciplines and sectors involved • Resolve technical interoperability issues across interfaces, applications and devices • Resolve organisational interoperability issues with national infrastructures (e.g. eID and secure network services) • Design and Procure appropriate ICT platform and /or services	Establish a collaborative governance framework Make standardization a facilitator for innovation - Enable change through the design, development and application of standards Support the development of a reusable Health Information System respecting EU/international standards and profiles Support the design, development of the national technical and organisational infrastructures for eHealth

III.	TESTING, LEARNING AND OPTIMISATION			

	Prepare for the pilot • Acquire Data Protection clearance to pilot • Sign Agreements with value chain partners for pilot IPR Design the study • Recruit and train healthcare professionals to the pilot	Prepare the needed tools & test plans	Support the tests phases	Keep informed of the progress
Make a Test Run • Recruit patients • Inform and train patients and carers • Acquire patient consent • Create and implement integrated care plans • Monitor patient health and well being	Monitor, usage, utility and costs		Identify pros & cons	

Examine Results and Learn • clinical outcomes; social factors and quality of life • usage, volumes, transactions, costs • satisfaction, acceptance • needed improvements and fine tuning • share knowledge openly			Analyse the outcomes & lessons learned	Support & inform about the results and next steps (GO / no GO decision)

	IV.	DEPLOYMENT, ADOPTION AND ROUTINE USE			
		Establish Deployment Strategy • Establish the deployment business model • Secure the business model & organise sustainability • Plan accession to the services for healthcare providers • Propose an awareness and information campaign.		Adopt into the public service portfolio Provide legal certainty for deployment Prepare adequate communication strategy	Provide visibility for the deployment phase : official communication campaign
		Deployment • Acquire Data Protection clearance to commission service • Seek partnerships for deployment • Sign Commercial Agreements with value chain partners • Set up the service and organise logistics • Manage the service and its delivery • Manage contracts • Manage subscriptions to the service-users • Monitor, improve, expand and extend		Share knowledge and influence other sectors Design and organize the evaluation process Initiate the optimisation / evolution process	Support and assess sustainability Be regularly informed about adoption & routine use

Annex II.
CALLIOPE Steering Committee

This document has been released for consultation by the CALLIOPE Steering Committee, the Members of which are:

Bartels, Erwin – Bundesministerium für Gesundheit (BMG), Germany

Belona Graça, José Luís – Ministério da Saúde, Portugal

Breas, Robert – Nationaal ICT Instituut in de Zorg (NICTIZ), Netherlands

Brosch, Peter – Bundesministerium für Gesundheit (BMG), Austria

Chave, John – Pharmaceutical Group of the European Union (PGEU)

Chronaki, Catherine – HL7HELLAS, Greece

Cuschieri, Rossano – Ministry for Social Policy, Malta

Denjoy, Nicole – European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)

Destrebecq, Frédéric – Union Européenne des Médecins Spécialistes, (UEMS)

Garel, Pascal – Standing Committee of the Hospitals of the European Union (HOPE)

Gil-Zorzo, Esther – Ministry of Health and Social Policy, Spain

Grode, Andreas – Gesellschaft Für Telematikanwendungen Der Gesundheitskarte MBH (gematik), Germany

Hygen, Jacob – Norwegian Center for Medical Informatics (KITH), Norway

Kolitsi, Zoi Institute of Computer and Communication Systems (ICCS), Chair of TC 14-1 ELOT, Greece

Künecke, Peter – IHE Europe

Kleinebreil, Line – Primary Care Diabetes Europe (PCD Europe)

Lange, Marc and Schug, Stephan H – European Health Telematic Association (EHTEL)

Linden, Fredric – Sveriges Kommuner och Landsting (SALAR), Sweden

Magnusson, Torfi – University of Iceland, Department of Engineering (UNIVICE), Iceland

Meglic, Matic – Future Challenges Centre (CSI), Slovenia

Moravcová, Eva – České Národní Fórum Pro eHealth, (CNFeH), Czech Republic

Nicolas, Luc – Fps Public Health Food Chain Control and Environment, Belgium

Pejakic, Ivan – Zavod Za Telemedicinu (ZTM), Croatia

Rossing, Niels – MEDCOM, Denmark

Sanna, Liuska – European Patients' Forum (EPF)

Schwebag, Mike – Ministry of Health Luxembourg, Luxembourg

Skauli, Kristian – Norwegian Directorate for Health, Norway

Swennen, Philippe, Association Internationale de la Mutualité (AIM)

Tartu, Monika-Kadri - Estonian eHealth Foundation (EeHF), Estonia

Thonnet, Michèle – Ministère de la Sante, de la Jeunese et des Sports, France

Thorp, Jeremy – NHS Connecting for Health, United Kingdom

Wilks, Michael – Standing Committee of European Doctors (CPME)

Wilson, Petra – Continua Health Alliance (Continua)

Wyss, Stefan – Swiss eHealth Coordination office, Switzerland

Zorko, Martina – Health Insurance Institute (ZZZS), Slovenia

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