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Comparison of European Health related ICT Projects

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Resumo Alargado

Introdução: No mundo globalizado dos nossos dias, é expectável que os profissionais de saúde prestem os seus serviços a pacientes estrangeiros nalgum ponto das suas carreiras. A diferença de idiomas, sistemas de saúde e infraestruturas são barreiras para uma prestação de cuidados semelhantes aos que os cidadãos conhecem nos seus países de origem. Novas soluções interoperáveis para a partilha de informação clínica a níveis transfronteiriços figuram, por isso, na lista das prioridades digitais da agenda política dos Estados-Membros da União Europeia (UE) (1). A adoção da Diretiva 2011/24/UE do Parlamento Europeu e do Conselho, de Março de 2011, sobre os Direitos dos Pacientes nos cuidados de saúde transfronteiriços, representa o auge da liberdade dos cidadãos para receberem cuidados de saúde noutros Estados-Membros da União Europeia, com qualidade e segurança (2). Com o objetivo de facilitar 'a prestação de serviços públicos Europeus, promovendo a interoperabilidade transfronteiriça e inter-sectorial' (7), a *European Interoperability Framework* (EIF) estabelece uma série de recomendações que promovem várias políticas e iniciativas na UE, ao mesmo tempo que define quatro dimensões para a interoperabilidade: legal, organizacional, semântica e técnica.

Objetivo: O objetivo do presente estudo é abordar o desafio da transição de soluções-piloto para uma infraestrutura transfronteiriça de larga-escala, que apoie os Estados-Membros da União Europeia na prestação de serviços públicos, especialmente no setor de saúde.

Metodologias: Esta revisão aborda, empiricamente, informação publicada e não-publicada sobre eHealth e sistemas de partilha de dados clínicos, resumindo e correlacionando as conclusões mais importantes de diferentes fontes. É particularmente centrada na análise transversal de quatro projetos Europeus: epSOS, eSENS, Trillium Bridge e EXPAND.

Resultados: As Diretivas de Proteção de Dados 95/46/CE e dos Direitos dos Pacientes nos cuidados de saúde transfronteiriços 2011/24/UE são os principais instrumentos legais abordados em todas as iniciativas, não obstante da existência de legislações nacionais. Métodos de trabalho estabelecidos no âmbito das organizações de saúde necessitam de ser adaptados e otimizados, de acordo com as novas arquiteturas de comunicação, mas serão os usuários os principais responsáveis pela sua integração nos seus próprios sistemas, procedimentos e culturas de trabalho. A interpretação universal de dados em saúde pode ser alcançada com terminologias mutuamente aceites, sistemas de codificação e criação de meta-informação, como o mapeamento da *Health Level Seven Release 2* (HL 7 R2). O padrão de comunicação *Clinical Document Architecture* (CDA) estabelece uma estrutura consistente entre sistemas de informação clínica utilizados na Europa.

Conclusões: Ainda existem inúmeras barreiras para uma prestação transeuropeia eficaz de serviços públicos. Apesar de um certo nível de complexidade que ainda marca os sistemas de informação em saúde, são várias as vantagens da sua utilização: o acesso rápido e seguro a dados de saúde relevantes para as decisões clínicas, confidencialidade dos mesmos, centralização e organização de acordo com classificações médicas internacionais, bem como a promoção de controlo estatístico e otimização de desempenho (12). A interoperabilidade não é uma finalidade ou uma questão de presença ou ausência, é antes um processo que poderá ser melhorado ao longo do tempo (59). Mais estudos serão necessários para entender como poderemos melhorar os nossos sistemas de informação, para uma partilha sustentável de dados cada vez mais complexos, como a informação em saúde.

Palavras-Chave

eHealth, interoperabilidade, *assets*, registos médicos eletrónicos, Europa.

Abstract

Introduction: With the globalized world of our days, health professionals are expected to provide their services to foreign patients at some point in their careers. Different languages, health systems and infrastructures are barriers to a sound provision of health care as people have been used to in their home countries. New interoperable solutions for the exchange of clinical data at cross-border levels are now listed as new digital priorities in the political agenda of the European Union (EU) Member States (MS) (1). The adoption of the Directive 2011/24/EU of the European Parliament and the Council of March 2011 on Patient's Rights in cross-border health care was the pinnacle to assure citizen's freedom to receive health care in another EU Member State, with quality and safety (2). With the purpose of facilitating 'the delivery of European public services by fostering cross-border and cross-sectoral interoperability' (7), the European Interoperability Framework (EIF) establishes a series of recommendations that promote several EU policy initiatives, while defining four dimensions for interoperability: legal, organizational, semantic, and technical.

Objective: The purpose of the present review is to address the challenge of stirring from point-solution pilots to a large-scale deployment of cross-border facilities that support EU Member States in delivering public services, especially in health sector.

Methodologies: This study empirically addresses published and unpublished information in eHealth and clinical data exchange systems, summarizing and correlating the most important conclusions of different sources. Particularly, it is centered in a transversal analysis of four different European projects focused on providing solutions for cross-border health care services: epSOS, eSENS, Trillium Bridge and EXPAND.

Results: The Data Protection Directive 95/46/EC and the Patient's Rights in cross-border health care Directive 2011/24/EU are the major legal instruments to comply with by all initiatives, notwithstanding the existence of national legislations. Established workflows within heath organizations need to be adapted and optimized according to new communication architectures, but users are ultimately responsible for integrating them in their own systems, procedures and working cultures. A universal interpretation of health data can be achieved with mutually accepted terminologies, coding systems and creation of metadata, such as Health Level Seven Release 2 (HL 7 R2) mapping. The Clinical Document Architecture (CDA) communication standard establishes structure consistency among health IT systems used in Europe.

Conclusions: There are still numerous barriers in effective delivery of public services in a pan-European setting. Although a certain level of complexity is still present in health information systems, several advantages can still be highlighted such as rapid and secure access to health data relevant for the decision-making at the care point, confidentiality promotion, centralization and structuring according with medical standards and the promotion of statistical control and performance optimization (12). Interoperability is not an ending or a question of being present or absent, but rather a process that can be improved over time (59). More studies are needed to understand how we can better connect our IT systems towards a sustainable exchange route of richer and even more intricate data, as sensitive as health information.

Keywords

eHealth, interoperability, assets, electronic health records, Europe.

Index

List of figures

List of tables

List of abbreviations

ADMS	Asset Description Metadata Schema
APB	Advisory Policy Board
ATC	Anatomic Therapeutic Chemical Classification System
BB	Building Blocks
CA	Consortium Agreement
C-CDA	Consolidated Clinical Document Architecture
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CIP/PSP	Competitiveness and Innovation Program within the ICT Policy Support Program
CQM	Clinical Quality Measures
CTS2	Common Terminology Service
DAE	Digital Agenda for Europe
EC	European Commission
EC-HHS MoU	Transatlantic eHealth/health IT Cooperation Memorandum of Understanding
e-CODEX	e-Justice Communication Via Online Data Exchange
EDQM	European Dictorate of the Quality of Medicines
eHealth	Electronic Health
eHGI	eHealth Global Initiative
eHN	eHealth Network
EHR	Electronic Health Records
EIF	European Interoperability Framework
epSOS	Smart Open Services for European Patients
eSENS	Electronic Simple European Networked Services
EU	European Union
FA	Framework Agreements
HCP	Health Care Professionals
HHS - ONC	US Department of Health and Human Services - Office of National Coordinator
HIS	Health Information Systems
HITECH	Health Information Technology for Economic and Clinical Health
HL7	Health Level Seven
ICD-9/10	International Statistical Classification of Diseases and Related Health Problems
ICT	Information and Communication Technologies
ID	Digital Indentity
IHE	Integrating the Healthcare Enterprises
ISA	Interoperability Solutions for European Administrations

LOINC	Logical Observation Identifiers Names and Codes
LSP	Large-Scale Pilots
MS	Member States
MTC	Master Translation/Transcoding Catalogue
MU-2	Meaningful Use Stage 2
MVC	Master Value Sets Catalogue
NCP	National Contact Points
NwHIN	US Nationwide Health Information Network
PCC	Patient Care Coordination
PEPPOL	Pan-European Public Procurement Online
PN	Participating Nations
PS	Patient Summaries
SDDS	Services Directive Digital Signature Service Tool
SDO	Standards Development Organization
SLA	Service Level Agreements
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms
SPMS	Serviços Partilhados do Ministério da Saúde, E.P.E.
STORK	Secure Identity Across Borders Linked
TN	Thematic Network
ToC	Transitions of Care
UCUM	Unified Code for Units of Measure
US	United States of America
VS	Value Sets
VSAC	Value Set Authority Center
WCAG	Web Content Acessibility Guidelines

Chapter 1. Introduction

With the globalized world of our days, health professionals are expected to provide their services to foreign patients at some point in their careers. However, tourists, business travelers, exchange students or regular cross-border commuters rarely think about health care when travelling abroad. Even less they worry about how the relevant medical information travels with them. Different languages, health systems and infrastructures are barriers to a sound provision of health care as people have been used to in their home countries. Appropriate treatment for these patients is particularly difficult as access to comprehensible medical documentation might not exist.

A collaborative approach to address these challenges became, therefore, necessary. New interoperable solutions for the exchange of clinical data at cross-border levels are now listed as new digital priorities in the political agenda of the European Union (EU) Member States (MS) (1). The adoption of the Directive 2011/24/EU of the European Parliament and the Council of March 2011 on Patient's Rights in cross-border health care was the pinnacle to assure citizen's freedom to receive health care in another EU Member State, with quality and safety (2). Hence, a 'voluntary network connecting national authorities responsible for eHealth' is supported by Article 14 and represents the legal basis of the 'eHealth Network' (eHN), created to expand electronic health systems (3).

Over the last few years, technological expansion and Information and Communication Technologies (ICT) have stimulated innovative perspectives for professionals, patients and different organizations beyond borders, in particular with the expansion of interoperable features for different health care systems. Interoperability is 'the ability of two or more systems or components to exchange information and to use the information that has been exchanged' (4). It encompasses an agreement of several actors, by exchanging information and knowledge through supported working models and respective ICT systems.

So as to support this exchange of data in distributed information systems, interoperability assets are needed to establish common data structures and interactions, and to ensure a comprehensive communication between parties. The Asset Description Metadata Schema (ADMS) describes an asset as 'an abstract entity that reflects the intellectual content' whose characteristics are 'independent of its physical embodiment' (5), whereas TOGAF9 suggests 'an architectural work product that describes an aspect of an architecture' (6). Both definitions include dynamic embodiments such as guidelines, terminologies and specifications that can be reused and changed over time.

With the purpose of facilitating 'the delivery of European public services by fostering cross-border and cross-sectoral interoperability' (7), the European Interoperability Framework (EIF) establishes a series of recommendations that promote several EU policy initiatives, while defining four dimensions for interoperability: legal, organizational, semantic, and technical.

But ultimately, what does interoperability mean and why it is important in the health care sector? What is the current situation of some of the cross-border health related ICT projects in Europe? How are these initiatives contributing for interoperable health systems? What are the main obstacles? These are some questions, this review aims to explore.

This work is organized as follows: chapter 2 outlines the objectives, chapter 3 details the methodology used; interoperability is correlated with ICT systems and its relevance within health care sector explored in chapter 4; key interoperability assets of health related ICT projects in Europe are addressed in chapter 5; discussion, and conclusions and suggestions for future work are presented in chapters 6 and 7, respectively.

Chapter 2. Objectives

The purpose of the present review is to address the challenge of stirring from point-solution pilots to a large-scale deployment of cross-border facilities that support EU Member States in delivering public services, especially in health sector.

This is achieved through the analysis of different health related ICT projects in Europe, namely:

- epSOS – Smart Open Services for European Patients;
- eSENS – Electronic Simple European Networked Services;
- Trillium Bridge – Bridging Patient Summaries across the Atlantic;
- EXPAND – Expanding Health Data Interoperability Services.

The specific objectives of this study are as follows:

1. To define interoperability in the context of ICT systems;
2. To assess key interoperability assets of different health related ICT projects in Europe;
3. To discuss the benefits and constrains in the deployment of facilities in delivering cross-border health care.

Chapter 3. Methodologies

Section 3.1 Type of study

As this is a document review study, it empirically addresses published and unpublished information in eHealth and clinical data exchange systems, summarizing and correlating the most important conclusions of different sources. Particularly, it is centered in a transversal analysis of different European projects focused on providing solutions for cross-border health care services.

Section 3.2 Data collection

This review would not be possible without a close cooperation with the Portuguese Ministry of Health, specifically with the SPMS – *Serviços Partilhados do Ministério da Saúde, E.P.E.*. Several documents (related legislation, project deliverables, official reports, and other online sources) were provided and served as the backbone for the analysis of the following cross-border initiatives:

- epSOS – Smart Open Services for European Patients;
- eSENS – Electronic Simple European Networked Services;
- Trillium Bridge – Bridging Patient Summaries across the Atlantic.
- EXPAND - Expanding Health Data Interoperability Services.

Moreover, PubMed search engine was used for a better understanding of the field in discussion. The following expressions were introduced: ‘eHealth’, ‘Europe’, ‘Electronic Health Records’, ‘Electronic Health Data’, ‘Interoperability’, and ‘Interoperability Assets’. Five articles published between 2005 and 2013 were considered on the elaboration of this review.

Chapter 4. Interoperability, ICT systems and health

Section 4.1 Interoperability and ICT systems

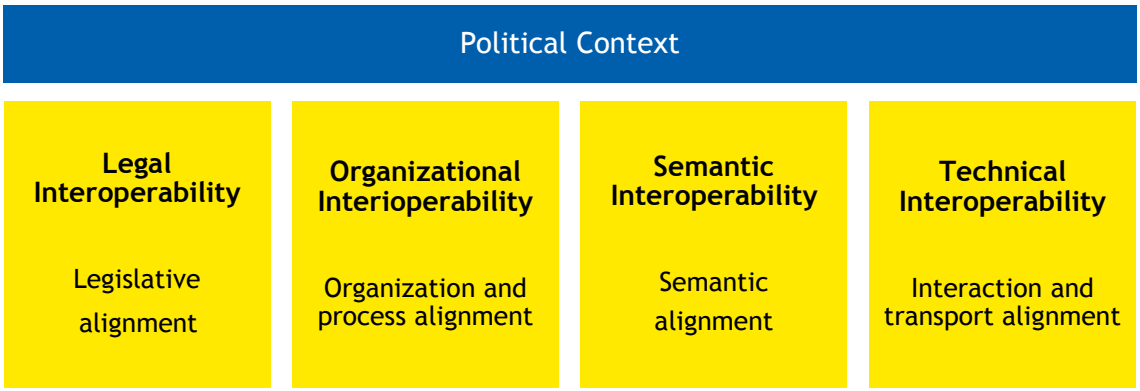
There are several definitions for interoperability involving different perspectives on interoperation. While some focus on the ability of systems to interoperate (8), other focus on the ability of people to interoperate by using systems to achieve certain goals (9).

Within the context of public service delivery, the Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 defines interoperability as 'the ability of disparate and diverse organizations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organizations, through the business processes they support, by means of the exchange of data between their respective ICT systems' (1).

A simpler definition would be the 'capability of the entire process, involving people, systems, procedures, and organizations, to interoperate using information systems (IS) in order to achieve its objectives' (10). Therefore, interoperability is a broad concept that is best understood as a shared value of a certain community.

The European Interoperability Framework (EIF) defines four levels of interoperability (7). Each of these levels has to be taken into account when implementing cross-border facilities:

Table 1 - Levels of Interoperability according to the European Interoperability Framework (EIF). Adapted from (7)



Political forces play a significant role in improving public administrations and promoting support mechanisms for worldwide citizens. A cross-border effective cooperation is only possible if the Member States (MS) agree upon their work, timeframes, and common priority setting under the umbrella of the EU. Adopting legislation for this matter shall take into account the scope, priorities and resources needed. The Interoperability Solutions for European Public Administrations (ISA) Program (11) is an example of political support.

Public administrations are governed by national or regional legal frameworks. Work is needed in harmonizing disparities between legislation in different Member States (MS), especially related to data exchange and protection. The approach is mainly based on specific and binding European Directives and their transposition to national legislations, which affect how and what can be communicated (10).

How is the cooperation between different Member States organized towards a common goal? The organizational dimension of interoperability is addressed with the creation of Framework Agreements (FA) and Service Level Agreements (SLA) that specify obligations of each part involved in cross-border business processes. They also define expected levels of service, support procedures referring, when necessary, to underlying semantic and technical agreements.

By processing information from external sources in a meaningful manner, with the understanding and complete preservation of its precise meaning relies the concept of semantic interoperability. Sector-specific data structures and data elements (e.g. reference taxonomies, schemes, code lists, data dictionaries, sector-based libraries and others) are assets that need to be agreed by the involved parties.

Several aspects of linking information systems (interconnection services, data presentation and exchange) are related to the technical level of interoperability. Those can be implemented through the adoption of interface specifications, communication protocols, messaging specifications, data formats, security specifications or dynamic registration and service discovery specifications, and so forth.

Section 4.2 Interoperability and health information systems

There is no doubt that Information and Communication Technologies (ICT) have been playing an important role in our society, but also in health sector. Well-developed IT infrastructures, with web technologies, database systems, and network platforms are increasingly shaping health care market of our days.

The supply of health services is a complex task for itself. It naturally mobilizes knowledge, processing of information, communication between health care professionals (HCP), and demands not only physical components but also formal integration systems within health organizations. In its turn, each health organization has large amounts of data production every day, in different types, natures and storages, calling upon different platforms and architectures, both in structure and means of data presentation.

In the middle of this heterogeneous scenario, interoperability measures how accurately, effectively and consistently different entities communicate, cooperate, and exchange clinical information as Electronic Health Records (EHR) by different health information systems (HIS). A health information system is ‘a mechanism of storing, processing, analyzing and transmitting information required for planning, organization, execution and evaluation of health services’ (12) to better achieve the sector’s primary goal: health care.

Chapter 5. Interoperability assets of health related ICT projects in Europe

Section 5.1 About epSOS

Figure 1 - epSOS: Smart Open Services for European Patients (13)

epSOS is a European eHealth interoperability large-scale pilot (LSP) co-funded by the European Commission (EC) for 6 years (launched on 1st July 2008) with 36.5M€ under the Competitiveness and Innovation Program within the ICT Policy Support Program (EC CIP/PSP Program) (14) with 47 Beneficiaries from 20 EU member countries and 3 non-EU members, consisting of national ministries of health, competence centers, and industry consortium with the goal to design, build and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health systems in Europe (13).

Figure 2 - European countries involved in epSOS (13)

It aims to improve medical treatment of citizens while abroad by providing health professionals with the necessary patient data in a secure electronic format, whether in an unexpected of unscheduled medical situation (emergency or accident) or in planned medical care. In particular, it focuses on offering seamless health care to European citizens by building and evaluating a service infrastructure.

epSOS main services are (15):

A. Patient Summary (PS): provides the treating doctor with general information (e.g. name and gender) and the most important medical data for patient treatment (e.g. allergies and surgeries). A basic dataset defined as 'a set of essential health information that is required from the clinical point of view to be sent to deliver safe care to the patient' in an unscheduled scenario, and an extended, non-compulsory dataset of 'desirable health information from the clinical point of view' (16) are foreseen. Within the first group, there is a mandatory dataset of information that must be given a valid value, without which the PS will be rejected. The full structure of the epSOS PS is presented in table 2.

B. e-Medication services:

    a. e-Prescription - electronic prescribing of medicine with the use of software by a legal authorized health professional and electronic transmission to a pharmacy where it can be dispensed;

    b. e-Dispensation - electronic retrieval of a prescription, dispensation to the patient as indicated by the e-Prescription, and report back to the e-Prescription once the medicine is dispensed.

Table 2 - epSOS Patient Summary data set (16)

PATIENT DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Identification	National Health Care patient ID	National Health Care patient ID	Country ID, unique for the patient in that country. Example: ID for United Kingdom patient	Basic	Yes
Personal information	Full Name	Given name	The Name of the patient (Example: John). This field can contain more than one element	Basic	Yes
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Basic	Yes
	Date of Birth	Date of Birth	This field may contain only the year if day and month are not available. Eg: 01/01/2009	Basic	Yes
	Gender	Gender Code	It must contained a recognized valid value for this field	Basic	Pending decision by WP3.6 (in some countries 'gender' is needed for univocal identification of the patient)
Contact information	Address	Street	Example: Oxford	Ext	No
		Number of Street	Example: 221	Ext	No
		City	Example: London	Ext	No
		Post Code	Example: W1W 8LG	Ext	No
		State or Province	Example: London	Ext	No
		Country	Example: UK	Ext	No
	Telephone No	Telephone No	Example: +45 20 7025 6161	Ext	No
	E-mail	E-mail	Example: jens@hotmail.com	Ext	No
	Preferred HCP/Legal organization to contact[13]	Name of the HCP/Legal organization	Name of the HCP/name of the legal organization. If it is a HCP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Basic	No
		Telephone No	Example: +45 20 7025 6161	Basic	No
		E-mail	E mail of the HCP/legal organization	Basic	No

	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	Ext	NO
		Given name	The Name of the Contact Person/guardian (example: Peter. This field can contain more than one element)	Ext	No
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Ext	No
		Telephone No	Example: +45 20 7025 6161	Ext	No
		E-mail		Ext	No
Insurance information	Insurance Number	Insurance Number	Example: QQ 12 34 56 A	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext)	MANDATORY Yes/No
Alerts	**Allergies and intolerancess**	Allergy description	Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	Basic	No
		Allergy description id	Normalized identifier	Basic	No
		Onset Date	Date of the observation of the reaction	Ext	No
		Agent	Describes the agent (drug, food, chemical agent, etc) that is responsible for the adverse reaction	Basic	No
		Agent id code	Normalized identifier	Basic	No
History of past illness	**Vaccinations**	Vaccinations	Contains each disease against which immunization was given	Ext	No
		Brand name		Ext	No
		Vaccinations id code	Normalized identifier	Ext	No
		Vaccination Date	The date the immunization was received	Ext	No
	List of Resolved, Closed or Inactive problems	Problem Description	Problems or diagnosis not included under the definition of 'Current problems or diagnosis'. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem)	Ext	No
		Problem Id (code)	Normalized identifier	Ext	No
		On set time	Date of problem onset	Ext	No
		End date	Problem resolution date	Ext	No
		Resolution Circumstances	Describes the reason by which the problem changed the status from current to inactive (e.g. surgical procedure, medical treatment, etc). This field includes free text' if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical Procedure, medical device etc, eg:	Ext	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
			hepatic cystectomy (this will be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)		
	Surgical Procedures prior to the past six months	Procedure description	Describes the type of procedure	Ext	No
		Procedure Id (code)	Normalized identifier	Ext	No
		Procedure date	Date when procedure was performed	Ext	No
Medical problems	List of Current Problems/Diagnosis.	Problem/diagnosis description	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (eg: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (eg: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (eg: dyspepsia, migraine and asthma)	Basic	No
		Problem Id (code)	Normalized identifier	Basic	No
		Onset time	Date of problem onset	Basic	No
	Medical Devices and implants	Device and implant Description	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc that are important to know by the HCP	Basic	No
		Device Id code	Normalized identifier	Basic	No
		Implant date		Basic	No
	Major Surgical Procedures in the past 6 months	Procedure description	Describes the type of procedure	Basic	No
		Procedure Id (code)	Normalized identifier	Basic	No
		Procedure date	Date when procedure was performed	Basic	No
	Treatment Recommendations	Recommendations Description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	Ext	No
		Recommendation Id	Normalized identifier	Ext	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
		(code)			
	Autonomy/Invalidity	Description	Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments	Ext	No
		Invalidity Id code	Normalized invalidity ID (if any, otherwise free text)	Ext	No
Medication Summary	List of current medicines. (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.).	Active ingredient	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No
		Active ingredient id code	Code that identifies the Active ingredient	Basic	No
		Strength	The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	Basic	No
		Pharmaceutical dose form	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Ext	No
		Number of units per intake[15]	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No
		Frequency of intakes	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	Basic	No
		Duration of treatment	Example: during 14 days	Basic	No
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	Basic	No
Social History	Social History Observations	Social History Observations related to: smoke, alcohol and diet.	Example: cigarette smoker, alcohol consumption...	Ext	No
		Reference date range	Example: from 1974 thru 2004	Ext	No
Pregnancy History	Expected date of delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, day and month are required.	Ext	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
			Eg: 01/01/2010		
Physical findings	Vital Signs Observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	Ext	No
		Date when blood pressure was measured	Date when blood pressure was measured	Ext	No
Diagnostic tests	Blood group	Result of blood group	Result from the blood group test made to the patient	Ext	No
		Date	Date in which the blood group test was done. This field may contain only the year if day and month are not available. Eg: 01/01/2009	Ext	No

PATIENT SUMMARY DATA (Information about the PS itself)					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
Country	Country	Country	Name of country A	Basic	Yes
Patient Summary	Date Created	Date Created	Data on which PS was generated	Basic	No
	Date of Last Update	Date of Last Update	Data on which PS was updated (data of last version)	Basic	Yes
Author/Nature of the patient summary	Author of the patient summary	Author oof the patient summary	To highlight if the data is collected manually by an HCP or is collected automatically form different sources (eg: hospital doctor repository, GPs…etc) through predetermine clinical rules.	Basic	No
Legal entity	Responsible of the PS data	Responsible of the PS data	At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed	Basic	No

5.1.1 Legal and organizational interoperability

The project is also strongly linked to Directive 2011/24/EU on the application of Patients' Rights in cross-border health care (2). European eHealth Governance has been established at the political level (article 14 of the Directive through the eHN - eHealth Network); strategic level (the eHGI – eHealth Governance Initiative (17) follow up of the CALLIOPE Thematic Network (18)); and operational level (epSOS).To this end, the Directive states that MS shall recognize the validity of medical prescriptions issued in other MS if those medicines are authorized in their country, thus guaranteeing the safety, quality and efficiency of care that they will receive in another EU Member State.

Security requirements vary widely amongst Member States. However, national legislation shall not block exchange of data in the EU, according to article 1 paragraph 2 of the Data Protection Directive 95/46/EC (19).

The project operates in a complex policy environment in order to assure that real life situations are correctly recognized and addressed. It's important to note that epSOS services are provided on a pilot basis, and therefore no changes to the national legislation governing the provision of health services are required as they are provided in compliance with the EU regulatory framework.

Each Participating Nation (PN) is represented in epSOS by a National Contact Point (NCP) (20). The NCP is an organization legally mandated by the appropriate authority of each Participating Nation (PN) to act as a bidirectional, organizational and legal interface between the existing national functions and infrastructures. It is competent to contract with other organizations to provide epSOS services, needed to fulfill the epSOS Use Cases, acts as a communication gateway and as a mediator for legal and regulatory aspects of such delivery. Besides being an active component of epSOS environment, it is compliant to normative interfaces, such as structure, behavior and security policy compliance.

Therefore, major specifications for a secure operational environment are formalized in a security policy, the epSOS Legal Framework Agreement (FA) (21). It is implemented in the form of national level contracts in the PN, helps establishing the NCPs, and governs the cooperative model of data exchange and form the documented basis for the trusted bonds between parties exchanging data. At the same time, it promotes transparency and the legal right of patients to data privacy in a cross-border health care setting, and represents a pre-requisite to engage with the pilots. This common blue print is used as a guideline for national contracts gives place to epSOS Trusted Domain amongst NCPs (22). This domain exceeds national or regional territories where epSOS services can be found, assuring that these can be delivered seamlessly to populations travelling between countries in the network.

5.1.2 Semantic interoperability

Agreement on shared semantic understanding is the basis for all communication (23). Several semantic catalogues and references are taken into account when dealing language diversities:

- HL7 CDA R2 (Clinical Document Architecture release 2.0): map of data elements in Patient Care Coordination (PCC), with the definition given by both sources and targets to ensure equivalence (24).

- MVC (Master Value Sets Catalogue): code system of terms used within certain parts of the epSOS pivot documents (e.g. demographics, clinical problems) based on different international classifications (25):

    - ICD 9/10 – International Statistical Classification of Diseases and Related Health Problems

    - SNOMED CT – Systematized Nomenclature of Medicine Clinical Terms

    - ATC – Anatomical Therapeutic Chemical Classification System

    - EDQM - European Directorate for the Quality of Medicines

    - UCUM - Unified Code for Units of Measure

- MTC (Master Translation/Transcoding Catalogue): in addition to the original terms, their translation in different languages and the possible cross-referencing (transcoding) with other code systems used at national levels (26).

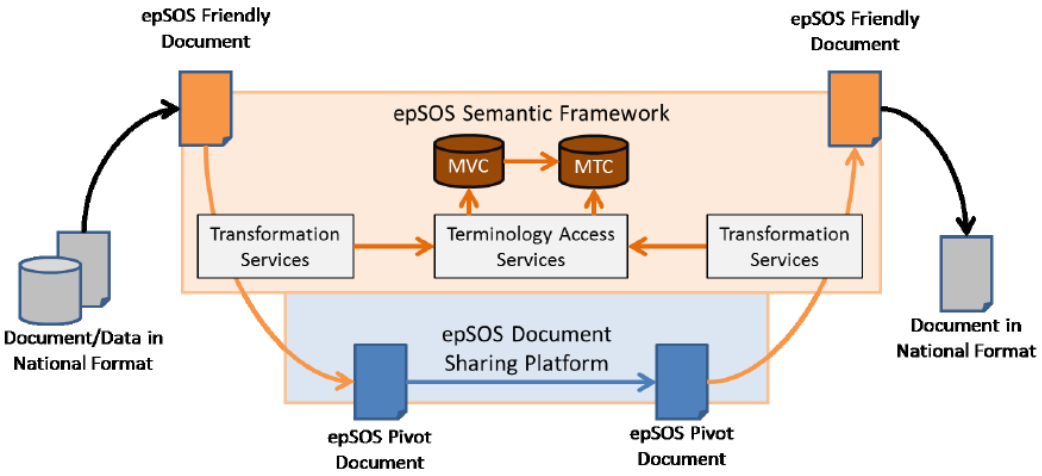


Figure 3 – epSOS Semantic services (27)

5.1.3 Technical interoperability

epSOS architecture promotes cross border exchange of clinical data as well as other services through a flexible connection between the national infrastructures and each Participating Nation (PN), through their National Contact Points (NCP).

The image below describes the main components (building blocks) of each NCP and how they cooperate in two different scenarios: country of affiliation (A) and country of treatment (B) (28).

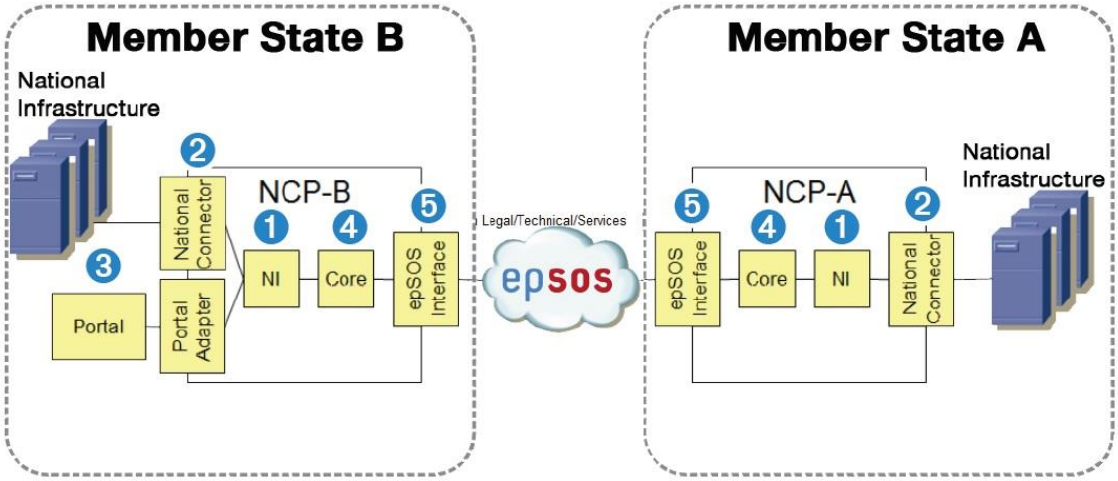


Figure 4 - epSOS Basic Architecture (28)

This architecture is based on IHE (Integrating the Healthcare Enterprise) (23) profiles and services implemented on the web. Communication only takes place after being formally initiated by the consumer and not by the service provider. These services are provided by the NCPs which also have a gateway role.

The main epSOS components are (29):

1. National Interface: country-specific, it connects epSOS Common Components and the National Connector;

2. National Connector: country-specific, responsible for accessing the national infrastructure and fulfilling the national requirements. It's not part of the epSOS Common Components;

3. Portal and Portal Adapter: - Graphic User Interface used by the health professional when providing epSOS services (Patient Identification, Patient Summary, e-Prescription and e-Dispensation) to patients. They are part of the epSOS Common Components. Two

options are available - epSOS portal or a portal solution is created nationally, a portal adapter (web service) will be required.

4. Core elements: Common Components defined within the epSOS project and belong to NCP's business layer architecture. They consist of the IHE X* protocol terminator services, the Security Manager, Policy Manager, Consent Manager, Audit Manager and Repository, the Semantic Transformation Manager, the Terminology Service Access Manager and the component to synchronize NCP configuration and Terminology repository.

5. epSOS Interface: it consists of the Inbound Protocol Terminator (country A) and Outbound Protocol Terminator (country B). It's part of the epSOS Common Components.

Section 5.2 About eSENS

Figure 5 - eSENS: Electronic Simple European Networked Services (30)

eSENS is a European project initiated by the European Commission (EC) for 3 years (launched on April 1st 2013) with 27M€ under the Competitiveness and Innovation Program within the ICT Policy Support Program (EC CIP/PSP Program) (14) with 22 beneficiaries from 18 EU member countries and more than 100 partners. Public administrations, IT industry and EU businesses gather together with the goal to consolidate, improve and extent technical solutions to foster electronic interaction across the EU (30), in a seamless communication between countries. It supports the creation of a Digital Single Market, by combining and strengthening 'building blocks' (31) – e-Delivery, Semantics and e-Documents, e-Identity and e-Signature - of the existing LSP, such as:

- PEPPOL (Pan-European Public Procurement Online) (32): it fosters electronic communication between businesses and any European government institution, developing and implementing technology standards for public electronic procurement (e-Procurement).

- SPOCS (Simple Procedures Online for Cross-Border Services) (33): it aims to build the next generation of online portals (Point of Single Contact – PSC) with high-impact electronic procedures that can reduce barriers for cross-border businesses.

- STORK (Secure idenTity acrOss boRders linKed) (34): it aims to establish a European electronic identity (e-ID) interoperability platform that can promote new e-relations across border simply by presenting a national e-ID.

- epSOS (Smart Open Services for European Patients) (13): as exploited in the previous section, it aims to design, build and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe. epSOS attempts to offer seamless health care to European citizens. Key goals are to improve the quality and safety of health care for citizens when travelling to another European country.

- e-CODEX (e-Justice Communication via Online Data Exchange) (35): it aims to improve the cross-border access to citizens and businesses to legal means in Europe and to promote interoperability between legal authorities in the EU.

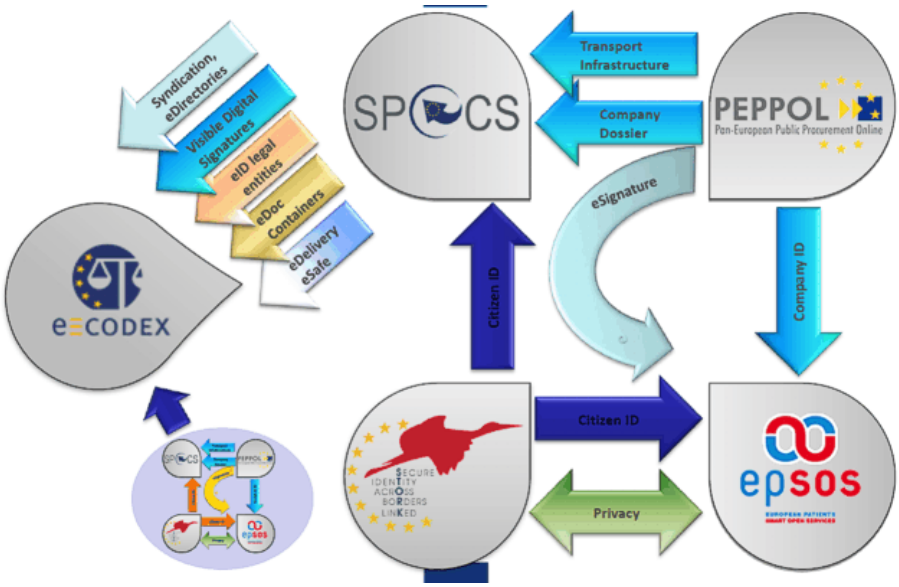


Figure 6 – Large Scale Pilots (LSP) launched by the European Commission (EC) (36)

Travelling, doing business or leaving abroad will be easier as electronic business set ups, electronic procurements for businesses, access to EU legal systems, and to health care services abroad in case of emergencies processes are being facilitated by eSENS LSP.

With the aim of demonstrating that ICT deployments among EU countries is feasible in real-life scenarios, four domains have been initially identified for intended piloting (31):

- e-Procurement: to support the implementation of the proposed public procurement Directive (37) and the continued standardization of public procurement processes.
- e-Health: to provide cross-border access to health services within the EU.
- e-Justice: to simplify access to cross-border legal procedures and means for citizens and businesses.
- Business Lifecycle: to enable seamless cross-border processes and procedures between administrations and businesses to be executed online.

As this list is still open to expansion, project partners are currently defining the detailed scenarios to be piloted based on the expertise of previous LSPs.

5.2.1 Legal and organizational interoperability

eSENS project is connected to several EU policies and initiatives.

In this context, the European e-Government Action Plan 2011-2015 (38), pursuits an efficient use of public resources, and aims to achieve the goals of The Malmö Declaration, towards a global leading knowledge economy, a true Single Market with seamless e-Government services and efficient and effective public administrations (39).

On the other hand, the project will support the creation of a digital infrastructure that will enable the delivery of the social and economic benefits that the Europe 2020 Strategy (40) aims for, in particular by promoting a Digital Agenda for Europe (DAE) (41). In this matter, regulatory barriers shall be eliminated to facilitate cross-border use of commercial and cultural digital content and services and to enable citizens and businesses to fully benefit from the European Single Market.

Therefore, e-SENS operates within the complex framework of EU law, as well as the national legal frameworks of its participants (42).

The cooperation with different beneficiaries and partners by eSENS Consortium Agreement (CA), which transposes the terms and conditions from the General Agreement between the European Commission to National Consortium Agreements and Guidelines (31).

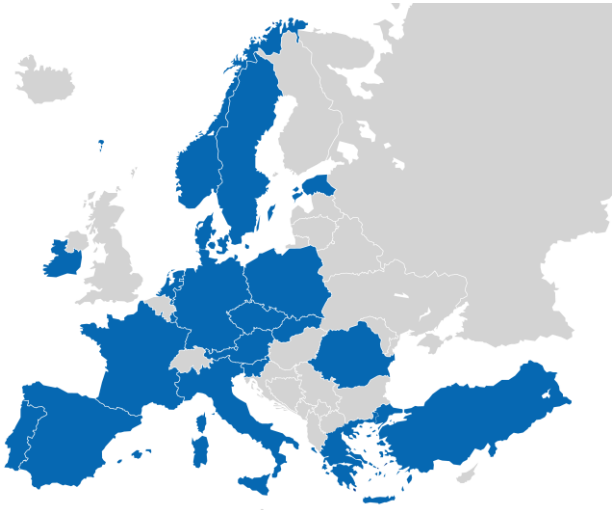


Figure 7 - European countries involved in eSENS (30)

Hence, an Advisory Policy Board (APB) was created to address specific policy related issues within domains and clusters, but also advise on cross-domain needs and requirements. It is an eHealth Portuguese representative who has the current Chair for this Board.

5.2.2 Semantic and technical interoperability

Building on previous LSP experiences, eSENS focuses on existing building blocks (BB) to provide seamless cross border services. Building blocks represent a (potentially re-usable) component of business, IT, or architectural capability that can be combined with other building blocks to deliver architectures and solutions (43).

eSENS technical solutions are based on the following modules for electronic communication (31):

- e-Documents: enable public administrations to understand any file format, appearance and content. The goal is to provide a method to create documents and electronic messages aimed at the exchange of information for cross border procedures, through the development of a stable set of Reusable Generic Tools. Metadata, data about data, are a means to structure documents — both structured and unstructured. Metadata can be developed and applied for each separate process of information exchange.

- e-Delivery: to facilitate electronic document exchange across borders. The goal is to establish a common transport infrastructure for the requirements of cross-border communication between e-Government applications in different domains, by an extended set of open specifications – Common Framework for e-Delivery. Major inputs are the transport protocols defined by PEPPOL and SPOCS that foresee end user authentication based on the SAML standard and STORK project results. The e-CODEX project is defining and implementing a transport infrastructure based on ebMS3.

- e-ID: to enable the use of citizens' digital identity in any EU country. An integrated framework will be developed in order to design modular solutions for usage of e-ID in modern environments (such as the mobile and cloud-based ones). STORK developed an infrastructure for cross-border use of government-endorsed electronic identities and STORK 2.0 is extending this to the exchange of attributes, including roles and mandates as needed by various on-line services.

- e-Signatures: to enable electronic signature and verification of any document. The most mature solutions come from the European Commission (Services Directive Digital Signature Service tool, SDDSS) and the PEPPOL project. Both solutions provide generic support for creation, validation, and risk assessment to enable decisions for acceptance or rejection. The SDDSS tool provides full-fledged software to create electronic signatures and validate them based on the European TSL system (EU TSL and Member States TSL), whereas the PEPPOL e-signature validation infrastructure is a server-and-service based approach, integrating TSL information and enhancing validation results with quality criteria.

- Semantics: to promote cross border understanding in public administration. The harmonization of metadata for specific domains or, where possible, cross-domain is a main goal. Examples of such standardized data definitions are the core vocabularies Person, Business, and Location as developed through the ISA Program and named the Asset Description Metadata Schema (ADMS). Building conceptual models for semantics is possible by exploiting the expertise of previous LSP. Use case centric approach, and Business rules documentation and Schemas and some of the methodologies currently available, whereas VCD/OCD, Metadata workbench (XSD-generator from controlled vocabularies), and epSOS terminology server are some of the instruments.

These prospectively consolidated and improved building blocks aim to provide the foundation for the platform of 'core services' for the e-Government cross-border digital infrastructure foreseen in the draft regulation for implementing the Connecting Europe Facility (CEF) (44).

Section 5.3 About Trillium Bridge

Figure 8 – Trillium Bridge: Bridging Patient Summaries across the Atlantic (45)

Trillium Bridge is a transatlantic eHealth interoperability project co-funded by the European Commission (EC) for 20 months (launched in July 2013) with a budget of approximately 400.000 €. It has 13 organizations in both Europe and United States (US), health care providers, industry, Ministries of Health, and Standardization Bodies and Associations promoting interoperability standards. It extends the European Patient Summaries (PS) and Meaningful Use Stage 2 (MU-2) Transitions of Care in the United States to establish an interoperability bridge that will benefit EU and US citizens alike, advancing eHealth innovation and contributing to the triple win: quality care, health system sustainability and economic growth (45).

This process encompasses the CDA-based epSOS enlargement scenarios in the EU and the Meaningful Use Stage 2 use cases under the Transitions of Care Initiative (using HL7/IHE/Health Story Consolidated CDA (C-CDA) Implementation Guide) in the US (27).

The following tables are placed side to side in order to compare the minimum data sets for PS used in Europe (epSOS) and US (MU-2).

Table 3 - epSOS Patient Summary minimum data set (27)

Information/dataset	Contains
Patient Identification	Unique identification for the patient in that country.
Patient Personal Information	Full name. Date of birth Gender
Allergies	Allergy description and agent
Medical Alerts	Other alerts not included in allergies
List of current problems	Problems/diagnosis that need treatment and/or follow up by a Health Professional
Medication Summary	Current medications
Country	Name of Country of origin of the patient (country A)
Date of Creation	Data on which PS was generated
Date of last update	Data on which PS was updated
Author organization	At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed.

Table 4 - MU-2 Patient Summary minimum data set (27)

Common Meaningful Use Data Set	
Patient name	Sex
Date of birth	Race
Ethnicity	Preferred language
Smoking status	Problems
Medications	Medication allergies
Laboratory test(s)	Laboratory value(s)/result(s)
Vital signs (Height, weight, BP, BMI)	Care plan field(s), including goals and instructions
Procedures	Care team members

5.3.1 Legal and organizational interoperability

Motivated by the Transatlantic eHealth/health IT Cooperation Memorandum of Understanding (EC-HHS MoU) (46) and Roadmap (47) and the Digital Agenda for Europe (41), in achieving a triple win for eHealth, it intends to create the foundation for the meaningful exchange of Electronic Health Records (EHR) in a transatlantic context.

Figure 9 – Trillium Bridge supports the Digital Agenda for Europe (DAE) in achieving the triple win for health (27)

The EC-HHS MoU highlights the importance of global collaboration in the area of health-related information and communication technologies, promoting more effective collaboration in health care delivery, disease prevention and health promotion. The scope of the EC-HHS MoU is 'cooperation on topics directly pertaining to the use and advancement of eHealth/health IT, in pursuit of improved health and health care delivery as well as economic growth and innovation' (46).

The exchange of patient summaries between the EU and US, through patient- and provider-mediated user scenarios, will address several aspects of interoperability and explore possible extensions of the eHealth Action Plan 2012-2020 (48) and the ISA European Interoperability Framework (EIF) (7) .

Meaningful Use (MU) promotes the spread of electronic health records to improve health care in the United States (49). The Health Information Technology for Economic and Clinical Health (HITECH) Act supports the MU with incentive programs as well as standards and certification criteria for EHR. Transitions of Care (ToC) initiative aims to improve the exchange of core clinical information among providers, patients and other authorized entities electronically in support of Meaningful Use. It goes beyond MU to define specific C-CDA document fit to a particular clinical context. A companion guide was developed to provide clear guidance on the usage of the core clinical elements and provide supplemental guidance, assisting the HL7 CDA Consolidation Implementation Guide (C-CDA), which is the initiative's recommended standard. The US Nationwide Health Information Network (NwHIN) comprises a set of services, standards and policies that enable secure health information exchange over the internet. A testable

portfolio of specifications widely adopted by the industry (for secure transport, content and vocabulary) support MU criteria and government priorities (27).

A Value Set Authority Center (VSAC) was established with the collaboration of the National Library of Medicine (NLM) and the Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) (50). It serves as the authority and central repository for the official versions of value sets that support the MU 2014 Clinical Quality Measures (CQMs), in which the Sharing Value Sets (VS) Technical Framework was created for broader distribution (51).

5.3.2 Semantic interoperability

epSOS semantic assets include terms and their mapping in different European languages and will be used with best-effort mapping to MU-2 value sets as part of Common Terminology Service (CTS2) infrastructure. These include Master Value Sets Catalogue (MVC), Master Translation/Transcoding Catalogue (MTC), Semantic Signifiers and Services. The first two ones were already exploited in the first section of this review. Semantic Signifiers are used to capture the semantics and behavior of information artifacts to be shared transnationally; Semantic Services provide functionalities needed to perform semantically accurate translation and transcoding of coded elements in epSOS pivot documents (27).Proposed standards for patient summaries in MU-2 include Consolidated CDA (C-CDA), ICD-10, SNOMED-CT, LOINC and RxNORM (52).

Table 5 - Comparison of terminologies in Meaningful Use and epSOS. Adapted from (27)

Elements	Meaningful Use	epSOS
Problem list	SNOMED-CT© (July 2012)	ICD-10 subset (moving to WHO ICD-10)
Medication list	RxNorm	ATC++, EDQM
Allergies	RxNorm, SNOMED	ATC, SNOMED
Surgical Procedures	ICD-9-CM, CPT	SNOMED
Blood group	LOINC	LOINC limited set

5.3.3 Technical interoperability

The main challenge is to transform patient summaries produced in the EU using the epSOS pivot document (CDA based) to a C-CDA form that can be safely used and correctly interpreted by the US health providers, and vice-versa. A key challenge is mapping between epSOS and Meaningful Use value Sets using a Common Terminology Service (CTS2) infrastructure as the foundation for the Trillium Bridge.

Both the epSOS pivot document and MU Transitions of Care are based in HL7 CDA release 2. However, only the Transitions of Care have the Consolidated CDA (C-CDA) project as the basic level of implementation guide (53), balloted within a Standards Development Organization (SDO). It constitutes a joint effort to represent harmonization of Health Story guides, HITSP C32 (Patient Care Coordination), and HL7 Continuity Care Document (CCD). It includes several document types as consultation notes, discharge summaries, imaging integrations, DICOM Diagnostic Imaging reports, history and physical notes, operative notes, progress notes, procedure notes, and also unstructured documents.

The epSOS document is expressed in HL7 CDA R2 standard and includes different sections (27): medication summary, allergies and other adverse reactions, immunizations, history of past illness, list of surgeries, active problems, history of present illness, medical devices, procedures and interventions, health maintenance care plan, functional status, coded social history, pregnancy history, vital signs, results, and the allergy and intolerance entry content module. Patient summary documents in epSOS are delivered through the National Contact Points (NCP) at the country of affiliation (A). When a patient summary is transmitted from a patient's home country to a country where treatment takes place, it's transformed to fit the purpose of destination.

Functional standards for MU-2 patient summaries include Web Content Accessibility Guidelines (WCAG) 2.0 Level A. For the transport, XDR/XDM and SOAP Secure messaging protocols are proposed (27).

Section 5.4 About EXPAND

Figure 10- EXPAND: Expanding Health Data Interoperability Services (54)

EXPAND is a recently launched (February 2014) European thematic network (TN), coordinated by the SPMS – *Serviços Partilhados do Ministério da Saúde, E.P.E.* from the Portuguese Ministry of Health, for a period of 24 months, co-funded by the Competitiveness and Innovation Program within the ICT Policy Support Program (EC CIP/PSP Program) (14), Public Health and FP7 Programs (54). It brings together with 20 national and regional health authorities and competence centers for semantic interoperability, Standards Development Organizations (SDO), and some EU-supported initiatives with the goal of exploiting, validating and organizing eHealth assets from different projects (epSOS, eSENS and Trillium Bridge) towards a large-scale deployment of cross-border facilities that support MS in delivering their services (55).

Taking other health related ICT projects in Europe as starting point, the TN finds its legal ground in the Directive 2011/24/EU on Patient's rights on cross-border health care, but also in e-ID, Data Protection and Standardization Regulations. As mentioned above, fulfilling the proposed goals will involve a range of clinical and public health communities across MS, obviously synchronized with the EU political and strategic premises, through eHealth Network (eHN) and eHealth Global Initiative (eHGI) (56).

Based on epSOS experience, further development of open source components by new partners and cooperation with SDO is envisioned to mature the exchange of PS information and appropriate standards for e-Prescriptions. There is a significant input coming from epSOS clinical and semantic agreements (MVC, MTC), regulatory frameworks, recommendation, policies, service models, and others. In addition, eSENS pilot shall provide reference for the desired cross-sectoral approach.

Nevertheless, EXPAND foresees a hand over of specifications for a web-based distribution channel for interoperability assets to the Connecting Europe Facility (CEF), which is planned to be operational in 2014 (57).

Chapter 6. Discussion

Interoperability is a dynamic concept that contributes for a smooth interaction among different health information systems, regardless of their origin. The present review synthesized different European point-solution pilots that strive for cross-border ICT cooperation in health through creation, reutilization and maturation of interoperability assets.

The following project findings are important to emphasize according to the four domains of interoperability proposed by the European Interoperability Framework (EIF):

- **Legal interoperability:** the Data Protection Directive 95/46/EC and the Patient's Rights in cross-border health care Directive 2011/24/EU are the major instruments to comply with by all initiatives, notwithstanding the existence of national legislations. The epSOS Framework Agreement (FA) establishes National Contact Points (NCP), within Participating Nations (PN), entities legally competent to link the national and regional health IT infrastructures. Other EU landmarks are described in eSENS, such as the European e-Government Action Plan 2011-2015 and the Europe 2020 Strategy. They promote a single market with seamless e-Government services through the establishment of a Digital Agenda for Europe. In addition to these, a meaningful collaboration in a transatlantic context is supported by the Transatlantic eHealth/health IT Cooperation Memorandum of Understanding (EC-HHS MoU) and Roadmap, as stated by the Trillium Bridge.

- **Organizational interoperability:** the introduction of new health information systems is often challenging for health care providers. This interoperability layer is closely dependent on the enforcement of consistent legal policies and possible extensions to national and regional jurisdictions that enable appropriate interoperation among organizations and enterprises. Established workflows within heath organizations need to be adapted and optimized according to these new architectures, but users are ultimately responsible for integrating them in their own systems, procedures and working cultures. The celebration of the eSENS Consortium Agreement (CA) denotes the transposition of this type of commitment from the European Commission levels to local implementation guidelines.

- **Semantic interoperability:** a universal interpretation of health data regardless of its source is essential for its meaningful use. This can be achieved with mutually accepted terminologies, coding systems and creation of metadata. Among different projects, the Health Level Seven Release 2 (HL 7 R2) mapping assures equivalency and coherence of

clinical information exchanged among heterogeneous health IT applications. Both epSOS and Trillium Bridge also explore value sets (MVC) and translation/transcoding catalogues (MTC), with relevant international classifications such as ICD-10, SNOMED-CT, and LOINC that settle a common scientific background for medical data. The RxNORM code list is proposed by Trillium Bridge for medications available in the US market.

- **Technical interoperability:** can be achieved by harmonized communication standards and interaction protocols, and implementation of processing and transaction mechanisms across systems. The Clinical Document Architecture (CDA) standard contributes for a uniform model used in Europe and establishes structure consistency for IT systems and for end-users. In the US, Consolidated CDA (C-CDA), with a basic level implementation guide, is used by the MU-2. Transitioning from PS pivot documents produced in Europe to fit the US reality requires the Common Terminology Service (CTS2) mapping infrastructure is indicated by Trillium Bridge. epSOS describes a well-defined NCP-NCP interaction protocol, based on Integrating the Healthcare Enterprise (IHE) profiles on the web, where communication can only be initiated by service consumers and follows a network of Open Source components. Nevertheless, eSENS introduces the concept of Building Blocks (BB), components that can be combined to deliver IT solutions, such as e-Documents, e-ID and e-Signatures.

Some common denominators were identified between these projects. Both epSOS, eSENS and Trillium Bridge remain operational until the present time, which allowed the synthesis of current and updated information and speculation of possible endeavors. They all count with the seal of several European MS, strong industry teams and the eHealth market, ranging from small enterprises to large multinationals, contributing with their knowledge, expertise and help moving eHealth forward in Europe.

Particularly with epSOS, a significant investment was made far beyond European Commission funding and the involvement of numerous beneficiaries. Its period length, including extension, is twice the proposed for eSENS, and even more when compared with Trillium Bridge and EXPAND. In consequence, it is not surprising that Smart Open Services for European Patients is a pioneer health LSP, and its recommendations are reference for the following Electronic Simple European Networked Services (eSENS), Bridging Patient Summaries across the Atlantic (Trillium Bridge) and Expanding Health Data Interoperability Services (EXPAND).

On the other hand, eSENS tackles other generic e-Government domains in order to deal with challenges not restricted to health sector that entail a more holistic perspective. There is no doubt that eHealth has a plenty to learn from other sectors' technological achievements, such as e-Justice and e-Procurement.

With EXPAND thematic network in specific, the most recent initiative, maturation of interoperability assets from epSOS, eSENS and Trillium Bridge and expansion efforts for the future are possible to anticipate. Despite the earliness of any conjecture at the moment, EXPAND is expected to serve as a platform that facilitates sharing of guidelines and recommendations from different EU projects and demonstrates their replicability.

However, some concerns arose when analyzing these projects in the light of suppositional real-life implications. Robustness of the described pilots might be affected by the diverse multilingual nature of European MS, disparate levels of engagement of PN and integration capacity in the multiple existing nationwide EHR systems.

In addition to the high costs of implementation and maintenance of health IT services, the complexity of health data itself and proposed architectures might represent obstacles for proper assimilation especially for PN with fewer resources. Therefore, further tailor-made guidance, training materials and long-term follow-up plans are essential.

Exchanged Patient Summaries might still have to handle ambiguities resulting from the lack of complete understanding of original contexts and subjective assessments, regardless of all technical efforts of standardization.

In terms of e-Prescription, having the same medication hypothetically available at different prices in different countries might possibly create alternative routes for pharmaceutical markets across countries, if common legal frameworks are not adopted.

Privacy and safety of patient's autonomy has to be a priority. Extremely strict security and protection standards are embedded in the architecture of the different pilots studied, with medical data being processed to the minimum and solely accessed with explicit patient's consent and traced.

Even further interoperability challenges for cross-border Patient Summaries are expected in a transatlantic setting, in consequence of several law, organizational, and terminology disparities between European and American settings.

Regardless the difficulties of implementation of interoperability in health ICT systems, benefits for all the involved parties are unquestionable.

For health care professionals, the major advantage is based on the availability of accurate and comprehensible information from patients' home countries, using tools integrated in existing working stations, for a better decision making in the clinical process. As a result, appropriate and secure treatment to foreign patients is, consequently, provided while improving efficacy and of the expected outcomes. A successful management of data is feasible with encoded and validated systems, standard forms of presentation, ready-to-use algorithms, and assistance throughout the whole paperless electronic process.

On the patients' turn, a high-quality interoperable network of health services beyond borders enhances the sense of safety and empowerment. Either unexpected or planned medical care, such as retrieving medications in case of lost or momentarily unavailability is possible when travelling abroad, through e-Prescription features.

European MS experience a first-hand opportunity to leverage eHealth in Europe, and also simplify and modernize their administrations, reducing the amount of bureaucracy by an easy access to public services by electronic means. By this, a better use of existing resources (efficiency) might be achieved in a long term scale, while supporting a bigger EU cause.

Chapter 7. Conclusions and future work

Affecting the economy of the countries and the quality of its citizens, high-quality standards for health services are central indicators of human progress and civilization (4). While citizens' demands towards health care increase, excellence is expected, with safe and equitable access to its services.

Drastic demographic changes are causing the rise of radical costs and staff shortages in the health care systems of many countries. Now and more than ever, citizens and businesses are moving across borders and call the attention of Governments for a more global approach, without physical nor intellectual boundaries. Investing on prevention instead of treatment and 'delivering consumer-centric and information-rich health care' (58) are key steps for an effective and efficient public management and administration.

The new digital era is probably the solution for these and other numerous challenges faced by the European public entities. Services available at any time and any place might shift the mindset of institutions from 'how to treat people' to 'how to keep people healthy and prevent illnesses' regardless of their location.

Shared open source system components, ontology driven and based on the comprehensible web data models, seem to be the way in handling relevant heterogeneous information from different sources. To make this possible, interoperability standards, quality, security, scalability, and reliability must be followed.

In order to tackle this problematic, Large-Scale Pilots have been launched by the European Commission to develop basic solutions for several domains such as justice and health. From their analysis, the following lessons were learned:

- Technology and skills to achieve a high level of interoperability and data integration are available today;
- It's unfeasible to address different layers of interoperability independently as they are interconnected;
- Technical and semantic assets and interdependent and therefore should be developed in closer cooperation;
- Reliability is a central concept as decision support rules are imperfect, and have specificity and sensitivity characteristics;

- Further agreements on common codes and terminologies will bring interoperability even closer.

There are still numerous barriers in effective delivery of public services in a pan-European setting. When it comes to electronic proceedings, even more obstacles arise in relation to law, organization, semantics, organization and technology. Although a certain level of complexity is still present in health information systems, several advantages can still be highlighted such as rapid and secure access to health data relevant for the decision-making at the care point, confidentiality promotion, centralization and structuring according with medical standards and the promotion of statistical control and performance optimization (12). Interoperability is not an ending or a question of being present or absent, but rather a process that can be improved over time just as the human's ability to communicate improves from childhood to adulthood (59). More studies are needed to understand how we can better connect our IT systems towards a sustainable exchange route of richer and even more intricate data, as sensitive as health information.

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