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# 1. Policy context

To efficiently meet the rising needs of European citizens, patients and health services providers, its often fragmented, disparate and “dis”connected eHealth infrastructures, systems and solutions must not only become connected, but also interoperable and collaborative so that independent of a citizen’s location he or she will receive optimal, seamless care based on all relevant health information wherever they may be stored. Member States’ interoperability initiatives must come together and become coordinated, and they must respond to the increasing need to link clinical data also to information from basic biological sciences and evidence of best clinical practice.

Considering the need for interoperability at the Member State and cross-border level of the European Union – as expressed in the EU eHealth Action Plan – and for global interoperability – as represented by WHO – *it is necessary to embark on a process that will prompt the divergent initiatives to join forces for the benefit of all citizens.*

The *SemanticHEALTH* study develops a European and global roadmap for RTD in health-ICT, focusing on semantic interoperability issues of eHealth systems and infrastructures. The roadmap will be based on consensus of the RTD community, and validated by stakeholders, industry and Member State health authorities.

In this chapter, we will first briefly review the wider context for such activities and the forces driving European health system policies, and then outline some recent eHealth policy initiatives and planned actions to better understand the overall context within which this roadmap has to be reflected.

## 1.1 Health system values, policies and priorities

### 1.1.1 European Union health systems values

In a very succinct way the "Council Conclusions on Common values and principles in European Union Health Systems"<sup>1</sup> summarise the goals and priorities of Member States in the field of healthcare. *Universality, access to good quality care, equity, and solidarity* constitute a set of overarching values that are shared across Europe. Universality refers to the universal, i.e. for everyone, access to healthcare; solidarity relates to the financial dimension of ensuring accessibility to all; equity emphasises that access should be according to needs, regardless of ethnicity, gender, age, social status or ability to pay. Member States are also concerned by differences in the quality of health services across the Union, as well as issues of prevention through promotion of healthy lifestyles.

The health systems of the European Union are a “fundamental part of Europe’s social infrastructure”<sup>2</sup>. EU health systems aim at ensuring healthcare provision, which is “patient-centred and responsive to individual need”<sup>3</sup>. However, Member States follow different approaches towards that aim, which creates a risk of the common values not being adequately respected outside the borders of a citizen’s home country, due to system incompatibility. Establishing European-wide interoperability, particularly including semantic interoperability, as well as the proposed large scale pilot on patient summary and ePrescription are important steps towards minimising that risk.

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<sup>1</sup> Document (2006/C 146/01), published in the Official Journal of the European Union on 22 June 2006, pp. 1 - 5

<sup>2</sup> *ibid.*

<sup>3</sup> *ibid.*

### 1.1.2 Quality, access and sustainability

All across Europe national health services are faced with similar challenges and issues, such as:

- Improving the **quality of services and outcomes**, both with respect to medical objectives and the quality-of-life perception of patients. Knowledge creation through basic and clinical research, knowledge translation - taking into account the needs of professionals, staff and patients -, continuing professional development (CPD), quality assurance including transparent measurement processes and result presentations, and public health surveillance are all part of this area of concern. Healthcare systems thus need to cope both with a rising demand (partially due to an ageing population) and increased expectations of citizens, who want the best care available.
- Policy pressure and citizen demands for **better and more equal access** across social strata and at-risk groups, older people, regions of countries and the Union
- Cost containment and **optimal allocation of scarce resources**
- **Public health** concerns like disease control, surveillance, preventive measures and protection against bio-terrorism and other new threads are gaining in public attention and have become global concerns.
- Health system **structural issues** will gain in relevance. The growth of private service providers, international hospital chains and private equity investors, cross-border cooperation, the free movement of professionals, outsourcing and (international) specialisation all will fundamentally alter health system structures and the way health care services will be delivered during the next decades.
- Finally, **research**, technological development, innovation and diffusion of medical, bio-medical, pharmaceutical, medico-technical, bio-informatics and ICT knowledge will continue to accelerate and create new opportunities, but also new stress for health systems.

## 1.2 European eHealth activities

### 1.2.1 eHealth and interoperability as key enablers

eHealth systems and solutions are widely regarded as a key means to cope with the above outlined challenges and meet the increasing demand for health services by European citizens. Information and communication technologies (ICT) are deployed on broad scale in healthcare in many, if not most Member States (MSs). In view of its key priorities - citizen mobility and borderless healthcare - a supportive approach by the European Commission as outlined in its eHealth Action Plan<sup>4</sup> will help to ensure a seamless pan-European flow of information between interoperable national systems for the benefit of patients. There are multiple factors driving the utilization of eHealth all over Europe: aging societies, increasing prevalence of chronic diseases, and financial strain on social security organisations. As a result medicine is going to be more and more information technology-based, relevant for both patients and health care professionals. This development is accompanied by increasing mobility, also of chronically ill citizens.

But it is not only the positive vision of a common European eHealth space that has been driving interoperability initiatives, but also the imminent risk that eHealth might stop at borders. It is well possible that future mobility of patients falls behind of what is currently

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

practiced: paper documents can be simply read (translated), laboratory values follow international standards, and pictures or x-rays speak for themselves. With electronic patient records and electronically stored data on cards the cross-border readability could worsen dramatically due to technical access obstacles.

In view of the complexity and diversity of national eHealth applications and the tremendous resources invested, only little attention has been given so far to international interoperability. The strategic approach of the European Commission is to focus on the core applications of electronic prescription and patient summary to serve as “gate-openers” to achieve interoperability on a wider European scale.

### 1.2.2 The interoperability challenge

It is against this background that European policy, initiatives and activities to foster interoperability must be seen. The interoperability of information and communication technology (ICT) systems is indispensable for efficient health service processes. However, interoperability of ICT systems in the health sector is a serious challenge. Health service providers use ICT from different manufacturers, from different technology generations, and, in a European context, from countries with different health systems and different languages.<sup>5</sup> In short: they use ICT systems operating with different and often conflicting technical and semantic standards. The consequence is that information systems in the health sector are very often fragmented and unable to exchange data. Seamless electronic communication between systems and between health professionals is not the rule but rather the exception. This lack of interoperability is everyday reality within single organisations such as hospitals, between different health care providers such as hospitals and general practitioners, within regional and national health systems, and last but not least also in international healthcare. For example, the computerised exchange of laboratory data of a particular patient between two hospitals may be impossible because the systems operate with conflicting ICT standards. To the extent that EU Member States seek cross-border health services and, in the long run, an internal market for health services,<sup>6</sup> such interoperability problems need to be solved on a European and international level.

### 1.2.3 European Commission Recommendation on Interoperability

Having in mind this situation, the EC is for quite some time now preparing for the publication of a Recommendation on eHealth Interoperability. In September 2006, an initial paper on “Connected Health: Quality and Safety for European Citizens”, a “Report of the Unit ICT for Health in collaboration with the i2010 sub-group on eHealth (formerly known as the eHealth working group) and the eHealth stakeholders’ group” was published.<sup>7</sup> This paper recognises that “among this decade’s major challenges are many that affect the provision, continuity and safety of health care. Europe’s peoples are ageing. At the same time, Europeans are increasingly moving around the Union for purposes of travel, study, work and retirement. Citizens and patients are demanding healthier lifestyles in combination with the provision of better, higher quality, and economic healthcare. Not only do these demands place considerable pressures on our nations’ health authorities and policy-makers, but they also offer unparalleled opportunities to European industry to help in the creation of a prosperous, professional, Europe-wide market for health applications and health technologies.

Such substantial social and economic developments – and the need to provide good, effective, and sustainable health care – mean that we are moving rapidly to a need to

<sup>5</sup> See European Commission (2005), “e-Business Interoperability and Standards: A Cross-Sector Perspective and Outlook”, for current background information on the subject.

<sup>6</sup> See the related declaration in eHealth 2007 Conference (2007).

<sup>7</sup> See [http://ec.europa.eu/information\\_society/activities/health/docs/policy/connected-health\\_final-covers18092006.pdf](http://ec.europa.eu/information_society/activities/health/docs/policy/connected-health_final-covers18092006.pdf)

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

The very beginnings of the eHealth interoperability map have now been drawn and the journey towards this exciting destination has been started.”<sup>8</sup>

In its recent follow-up to this, a draft paper on an Interoperability Recommendation<sup>9</sup> was presented, where the intentions were stated as follows: “An initiative – a European Commission Recommendation ... [will be presented] that supports the premise that connecting people, systems, and services is vital for the provision of good healthcare in Europe. The lack of interoperability in systems and services has long been identified as one of the major challenges to the wider implementation of the Union's eHealth applications. The opportunities and positive benefits of achieving interoperability are ultimately considerable, whereas various barriers and challenges act as impediments.

This Recommendation outlines a set of recommended guidelines for good practice on eHealth interoperability. The Recommendation is addressed to all the Member States, but it also has relevance for the European Economic Area (EEA) countries, and for the appropriate industries and stakeholder associations that work in the eHealth field.”

It is expected that a final “Recommendation of the Commission on cross-border Union-wide interoperability of Electronic Health Record Systems” will be published during 2008, a paper in which semantic interoperability will play a prominent role. In order to coordinate efforts towards semantic interoperability activities it will be essential for Member States (and also the global community) agreeing on common priorities, to share results and experiences, and to identify and use suitable eHealth standards that apply to the representation and communication of clinical meaning.

#### 1.2.4 eHealth Large Scale Pilot

Another key European activity in this respect is the Large Scale Pilot proposed by 12 Member States on the ‘EU wide implementation of patients’ summaries/ ePrescription solutions to support continuity of care<sup>10</sup> which is expected to become funded by the Competitiveness and Innovation Programme's (CIP) ICT Policy Support Programme (ICT PSP).

As defined by the text of the work programme of the Commission<sup>11</sup>, patients’ summaries including all their associated components, such as identifiers, authentication and security mechanisms, are important parts of electronic health records and therefore are essential to achieve interoperable national and European-wide health services.

EU funding support will go to the piloting of a large-scale deployment of patients’ summaries. It will involve Members States that are ready to implement and test a common approach to achieve interoperability of patients’ summaries.

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<sup>8</sup> Ibidem, p. 5

<sup>9</sup> EC: DRAFT REVISED DOCUMENT IN PREPARATION OF DRAFT RECOMMENDATION OF THE COMMISSION ON eHealth interoperability. Brussels, Brussels, 16.07.2007, p. 7. For download see: [www.ec.europa.eu/information\\_society/newsroom/cf/document.cfm?action=display&doc\\_id=369](http://www.ec.europa.eu/information_society/newsroom/cf/document.cfm?action=display&doc_id=369)

<sup>10</sup> See the description of this proposed Large Scale Pilot in the Competitiveness and Innovation Programme Policy Support Programme documents: [http://ec.europa.eu/information\\_society/activities/ict\\_psp/index.en.htm](http://ec.europa.eu/information_society/activities/ict_psp/index.en.htm)

<sup>11</sup> [http://ec.europa.eu/information\\_society/activities/ict\\_psp/library/ref\\_docs/docs/cip\\_ictsp\\_wp.pdf](http://ec.europa.eu/information_society/activities/ict_psp/library/ref_docs/docs/cip_ictsp_wp.pdf)

The second objective is the implementation of an EU-wide interoperable system for ePrescription that will improve patient care and patient safety in Member States and make available essential administrative, clinical and economic data relevant to medicines (i.e. adherence to therapies, medication history, prescription patterns, health economic information). By enhancing availability of accurate information related to medicines throughout Europe, the implementation of this objective will facilitate mobility of citizens and support public authorities in responding to the continuous increase of pharmaceutical expenditure. It will also provide an important contribution to the development of the Internal Market for pharmaceuticals.

As a result to the above mentioned call for proposals (Call 1 CIP PSP) a Pilot A called *Smart Open Services S.O.S.* was selected. The proposal for this pilot was submitted by 12 Member States and other stakeholders as well as an industrial association.

According to the project description "the national regulatory authorities and competence centres for eHealth that are cooperating in this large scale pilot to implement interoperability for the two proposed focal applications aim to test them out in pilot applications in a range of Member States. The approach, which is based on well-developed and distinct use cases, and associated infrastructural components, aims to deliver both a methodological process and durable implementations (termed 'building blocks'). These will form the basis for a longer term, pan-European approach to building interoperable service solutions."

The project is now in its negotiation phase and the start of the project is expected towards the summer of 2008.

The semantic aspect is outlined in the project description and will be developed in a specific work package.

The pilot is focussing on two applications and several components, a joint approach will be followed to agree on a common architecture and modular building blocks such as

- overall architecture
- semantic services, e.g. translation, terminologies, classifications
- identity management (persons/patients, health care professionals, health provider organisations like hospitals, pharmacies, ...)
- Security services, acknowledgement of certification authorities, ...

At the semantic level, links will be sought to standards organisations responsible for classifications like WHO-ICD, WHO-ATC, IHTSDO (formerly SNOMED) or International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and other activities in these fields.

### **1.2.5 Overview of Member States eHealth interoperability activities**

The deliverable D 1.2 of Semantic Health reviewed key relevant Member States and international experience regarding infrastructure, connectivity and interoperability in the eHealth sector. Taken together, these activities show some distinct commonalities but also differences specific to the unique national policy framework:

- All interoperability activities define a variety of layers or levels, which usually correspond to a rough division between technical, organisational and political aspects. However, the exact way in which these domains and their interactions are envisioned differs considerably.
- All countries have already or are planning to establish a temporary or, more often, permanent eHealth body in a governmental or quasi governmental setting.
- All countries apply a longer term approach which points to the growing realisation in the international community that interoperable eHealth solutions cannot be

implemented over night but require years to set up - and, perhaps even more important, need to be continuously sustained, further developed and adapted.

- Countries have focused on different aspects of interoperability. Some countries have done considerable work on standardisation management; others have focused on concrete applications, like ePrescription and/or a Patient Summary as drivers for interoperability. Open Source solutions have also received some attention.

A common denominator is the growing realisation that interoperability is about continuous change management, implying that successfully establishing and maintaining eHealth interoperability is a long-term endeavour requiring both a (permanent) structure of institutions or bodies charged with this responsibility, and the organisation of processes for consensus-building and cooperation among all stakeholders involved. *In a dynamic, constantly changing and highly complex environment like a health system achieving interoperability is a permanent task which will never be fully accomplished.* Some further general observations are:

- The review of activities shows limited progress as far as full (level 3) semantic interoperability, or co-operability, is concerned.
- Achievements across the initiatives are numerous. There is therefore a rich and varied mix of experiences for cross-national cooperation and for unlocking synergies. The commonality of Canadian and Australian initiatives also provides a unique opportunity to learn from.

Some issues appear to deserve special attention in the European context, e.g., the level of centralisation and decentralisation in different Member States, the impact of diverse overall health policy goals, varying levels of experience in eHealth policy making, infrastructure, investment policy, planning and implementing IT in healthcare as well as accompanying cost-benefit assessment and evaluation.

The following table summarises the findings of this inventory. It shows the issues relevant for the *SemanticHEALTH* project that have been addressed by the literature and assessed by the project partners and other experts. Because of the constantly changing environment the information should be used with caution. The fact that an issue is, or is not, in the list of priorities for a particular country now does not guarantee that this will be the case in six or twelve months time. Thus, the validity of these results will be continuously tested, for example during the upcoming workshops and interviews. The summary table below gives insights on the current trends in the field of interoperability as a whole and semantic interoperability in particular.

**TABLE 1: SEMANTICHEALTH INTEROPERABILITY ISSUES – COUNTRY OVERVIEW**

Dimension	SemanticHEALTH relevant issues addressed	Indicator	No. of countries
Analytical Dimension	<b>Technological Interoperability Issues</b>		
	Information Model	At 1	9
	Architecture and Messages	At 2	11
	Archetype-template-interface with clinical terminology	At 3	2
	Clinical terminology, ontology	At 4	7
	Multilingual approach (encoding, language generation)	At 5	
	Standards (incl. de facto standards; actors in standard development: ISO, WHO, CEN; W3C; user groups – e.g. HL7)	At 6	11

Dimension	SemanticHEALTH relevant issues addressed	Indicator	No. of countries
	Imaging	At 7	9
	Security-integrity-availability	At 8	11
	Open source	At 9	2
	<b>Socio-economic issues</b>		
	Health policy	As 1	10
	Legal, regulatory issues	As 2	12
	Economic issues (costs, benefits)	As 3	5
	Management: planning, organisation (structures, processes), controlling, including change management	As 4	5
	Stakeholder involvement	As 5	11
	Professional culture	As 6	3
<b>Application dimension</b>	<b>Clinical Settings</b>		
	EHR, pat. summary, interface w. DSS, CPOE	Ap 1	11
	<b>Public Health</b>		
	Classifications	Ap 2	2
	Demography (birth registration, mortality, morbidity, disability, risk factors,	Ap 3	2
	Health indicators, etc.	Ap 4	2
	<b>Secondary uses</b> epidemiology, preparedness, patient safety, bioterrorism, healthcare management, financing, research, education	Ap 5	4

The outcome of this desk research was reviewed by all partners as well as invited experts from Australia, Germany, Sweden, USA, and the UK, at the first *SemanticHEALTH* workshop in Copenhagen on 2006/09/30. The workshop identified a number of issues towards semantic interoperability. Among these issues is the necessity of defining specific use cases or scenarios how to integrate eHealth systems in a particular context. This means for the standards harmonisation process that it should start with clearly defined use cases. Further issues identified are the importance of developing and integrating appropriate services for secondary uses (for public health, population research, clinical research, etc.) of health-related information collected in direct patient care; different approaches to terminology and ontology development and integration in eHealth systems as well as the urgent need to address multi-lingual issues.

### 1.2.6 Healthcare terminologies in selected Member States

**Nordic countries situation:** The Nordic countries have a tradition of cooperation in healthcare and welfare terminology work. This has been based on detailed definition work of key concepts in the field and has yielded only a low number of well defined concepts. The people working in this area have had collaboration which has almost ceased due to lack of resources.

The Nordic Centre for Classifications in Healthcare had the terminology work on its work list for a number of years. However, almost no resources have been given to this work and thus the role of the centre has been restricted to observe the situation in the field.

The original pathology-centred SNOMED system has been used in all Nordic countries to code findings in pathology. There has been also interest to the more advanced versions of SNOMED (SNOMED international) but they have not been translated to any Nordic language before the advent of SNOMED CT.

### **Denmark**

Based on the *National Strategy for Information Technology in Hospitals* (1999) and the *National Strategy for Information Technology in Health Care Systems* (2003) Denmark started the development of a Electronic Patient Journal (EPJ) which is to be based on SNOMED CT. For this purpose Denmark has had a testing license for SNOMED CT till they joined the IHTSDO collaboration in 2007. The Danish SNOMED CT translation is to be completed by mid 2008 whilst the EPJ is being developed in parallel to the translation process.

Despite the high investments in this work, no decision about the implementation of the EPJ system has been taken. The plans of pilot studies have been postponed. Currently we do not have any information about such plans. The key person of this work, Arne Kvaerneland, has recently resigned from the National Board of Health and is no longer working with SNOMED CT related matters. He is still responsible for the Danish post in the IHTSDO work.

### **Sweden**

Sweden was using a SNOMED CT testing licence but the work has been discontinued. As an initiative of different individuals, it was mainly centred on the county level. However, in 2006 a national report on potential use of terminological systems was published (*Nationell terminologi- och klassifikationsresurs med SNOMED CT*). Based on this report a national strategy has been developed and yearly budget provided for the years 2007-2010. As a part of this strategy Sweden also joined the IHTSDO as one of the 9 starting members. The plans included the translation of SNOMED CT to Swedish, the mapping and harmonisation with existing systems (in international collaboration) and its linkage to common Swedish language. The project does not include the implementation in the health care systems, which is expected to be part of a subsequent national health strategy.

### **Finland**

Finland has passed a law for electronic health care record standardisation through a nationwide archive which all patient record systems have to be able to communicate with by April 2011. This means in practice that all health record systems will be able to communicate with each other either directly or through the national archive. The demand for paper based backup of the electronic patient records will be waived with this archive. All data and information will be categorized based on open medical classification systems and free text. This system will therefore be strictly national. Individual patient information may be transferred to other health care facilities on demand by the patient and with the permission of the unit that has been treating the patient. This permission of the patient is always necessary and as the authorization management will be part of this system. Neither SNOMED CT nor any other international terminological system will be used. It is assumed that the broadly used national classification systems will best fit for indexing and retrieving crucial elements of patient information.

### **Norway**

Although Norway has earlier had a test license of SNOMED, it is currently not interested in SNOMED CT. There is no direct development work in this direction, but there is definite interest and need for further development of health care information systems.

### **Iceland**

There is no current development work in Iceland aiming at the use of SNOMED CT or any other terminological system. Categorised information is collected using existing classifications mainly ICD-10 and NCSP (Nomesco Classification of Surgical Procedures) in the extended version adapted for use with NordDRG. There is some local interest for SNOMED CT but resources for extensive projects like translation are not available.

### **United Kingdom**

In the UK, the Read Codes were developed. Although not explicitly based on ICD and containing much clinical information needed for UK general practice not included in ICD, their overall structure followed the main ICD headings and many of the rubrics can be traced directly to ICD. The success of the original “four digit” Read codes (now known as Read I) in UK primary care led to a major effort to develop a much larger set to include secondary care. This major effort consumed several millions of pounds without producing anything used outside of general practice, although a subset of Read 2 (“five digit read”) remains the standard in UK primary care. Subsequent to this an effort to develop a more “compositional” system, Clinical Terms Version 3 (CTv3) was progressing when it was decided that the cost of developing the system by the UK NHS on its own was prohibitive, and a decision was made to collaborate with the College of American Pathologists to produce what is now SNOMED-CT.

SNOMED was fundamentally different from ICD and Read in that it had multiple axes and composed codes out of their several parts. This gave rise to the first compositional systems, followed first by a major effort by the College of American Pathologists to develop SNOMED-RT, and then the collaboration with the UK NHS to produce SNOMED-CT. Both SNOMED RT/CT, and a major EU initiative, GALEN, was based on new “description logics” that allowed new terms to be composed out of old and had the potential for greater computer support for the development process.

In the UK SNOMED-CT is mandated, but Clinical Terms (Read Codes) Version 2 continues to be used in primary care.

The Office of Population Census and Statistics 4 (OPCS4) operated, in effect, cooperatively by the OPCS and the NHS.

### **France**

France is mainly following the ICD stream (since its initial start) and for the DRG/GHM systems for hospitals. For findings in pathology France is mainly using a French brand system ADICAP and not SNOMED. For biology the use of LOINC is increasing but a French brand system named NABM is broadly used: The parliament passed an act in 2004 for a life long individual electronic record accessible to the patient named DMP starting in 2007.

A recent audit has decided to postpone “sine die” the implementation which was unable to start. Within this program in 2006 the organisation GIP DMP has bought the rights of French speaking SNOMED 3.5 international from the French speaking Canadian co-founding father of SNOP and SNOMED. On the other hand the French department of health has decided not to participate in SNOMED IHTSDO. Contacted by the Canadian team in charge of translating SNOMED CT in French GIP DMP has decided to make the French version of SNOMED 3.5 available to them. In primary care there are some punctual implementations of ICPC and a French brand coding system developed by a scientific organisation of G. It is difficult to forecast the future but the implementations of either SNOMED 3.5 or SNOMED CT in the real world have a low probability considering the resistances of health care

professionals to use any mandatory terminology as ICD 10, preferring instead their own point of care terminology or their specific college terminology.

### 1.3 Global perspective

Besides Denmark, the United States, the United Kingdom and Australia were the driving forces that had brought forward the foundation of the SNOMED SDO. In the UK, the NHS Connecting for Health had already heavily invested into the development of SNOMED CT, bringing into it the legacy of NHS Clinical Terms (former Read codes) that had become increasingly obsolete. Through NHS Connecting for Health's membership of the IHTSDO, the UK Terminology Centre (UKTC) acts as an affiliate of the IHTSDO and provides a central point for managing, distributing, supporting and controlling the use of SNOMED CT and related assets throughout the UK.

In the United States, SNOMED CT has been available on a free-of-charge basis since 2003, when several agencies reached agreement with the CAP on a nationwide license negotiated by the National Library of Medicine (NLM). In the meanwhile, SNOMED CT has become a U.S. standard in several interoperability specifications identified by the Health Information Technology Standards Panel, which are anticipated to be recognized by the HHS Secretary at the end of 2007. The NLM is distributing the SNOMED CT sources through its Unified Medical Language System (UMLS).

In Australia, the National eHealth Transition Authority (NEHTA), representing the Federal and the State governments, is member of the IHTSDO and driving force of the introduction of SNOMED CT, with a strong focus on primary health care (PHC) and the mapping of PHC legacy terminologies to SNOMED CT.

## 2. Semantic interoperability - goals and vision

Clinicians of all disciplines require access to detailed and complete health records in order to manage the safe and effective delivery of health care. These records need to be linked to salient knowledge and guidance, and to be shared in real time within and between care teams across geographical boundaries. Patients nowadays also require access to their own EHR, coupled with suitable educational materials, to a full extent that permits them to play an active role in their health management.

The clinical interoperability requirement from health IT is for clinical meaning to be expressed consistently within electronic health records, in particular where computers in addition to humans need to be able to process EHR data safely. This goal is known as semantic interoperability, and is needed if computational services are to be able to interpret safely clinical data that has been integrated from diverse sources. In terms of EHR semantic interoperability requirements, we need:

- to enable the safe, meaningful sharing and combining of health record data between heterogeneous systems;
- to enable the consistent use of modern terminology systems and medical knowledge resources;
- to enable the integration and safe use of computerised protocols, alerts and care pathways by EHR systems;
- to link EHR data to explanatory and educational materials to support patient and family engagement and professional development;
- to ensure the necessary data quality and consistency to enable rigorous secondary uses of longitudinal and heterogeneous data: public health, research, health service management.

Interoperability requires agreement on meanings and labels for those meanings – on ontology and lexicons, which together we label as terminology. The primary goal of ontologies and terminologies for interoperability is to enable the faithful exchange of meaning between machines and between machines and people.

### 2.1 Defining interoperability

SemanticHEALTH applies the following IOp definition:

*Health system interoperability is the ability, facilitated by ICT applications and systems,*

- *to exchange, understand and act on citizens/patient and other health-related information and knowledge*
- *among linguistically and culturally disparate clinicians, patients and other actors and organisations*
- *within and across health system jurisdictions in a collaborative manner.*

In this view, semantic interoperability (SIOP) addresses the **transmission and use of meaning within the framework of seamless healthcare services**, between providers, patients, citizens and authorities. In essence the SemanticHEALTH goal is to work towards and support collaboration among human actors and stakeholders, rather than only interoperability among computers.

As this Support Action is based on real existing implementations, or implementations planned for the near future, it distinguishes four levels, two of them allow for semantic interoperability:

<b>Level 0:</b>	no interoperability at all
<b>Level 1:</b>	technical and syntactical interoperability (no semantic interoperability)
<b>Level 2:</b>	two orthogonal levels of partial semantic interoperability Level 2a (quality): Unidirectional semantic interoperability Level 2b (quantity): Semantic interoperability of meaningful fragments
<b>Level 3:</b>	full semantic interoperability, sharable context, seamless co-operability

To explain and distinguish the 4 different levels, consider the following scenario: 56 year old Pádraig recently moved from Ireland to Spain to take up his new job in a multinational IT company. A few weeks after arriving, he falls ill, consults his local (Spanish) GP and his being transferred to the next hospital for further tests.

**Level 0 (*no interoperability at all*)** Pádraig has to undergo a full set of lengthy investigations to find out the cause of his severe pain. Unfortunately, results from the local GP as well as from his Irish GP are not available at the point of care within the hospital due to the missing technical equipment.

**Level 1 (*technical and syntactical interoperability*)** Pádraig's doctor in the hospital is able to receive electronic documents that were released from the Irish GP as well as his local GP upon request. Widely available applications supporting syntactical interoperability (such as web browsers and email clients) allow the download and provide immediate access. Unfortunately, none of the available doctors in the hospital is able to translate the Irish document, and only human intervention allows interpreting the information submitted by the local GP for adding into the hospital's information system.

**Level 2 (*partial semantic interoperability*)** The Spanish hospital doctor is able to securely access via the Internet parts of Pádraig's Electronic Health Record released by his Irish GP as well as the local GP that he visited just hours earlier. Although both documents contain mostly free text, fragments of high importance (such as demographics, allergies, diagnoses, and parts of medical history) are encoded using international coding schemes, which the hospital information system can automatically detect, interpret and meaningfully present to the attending physician.

**Level 3 (*full semantic interoperability, co-operability*)** In this ideal situation and after thorough authentication took place, the Spanish hospital information system is able to automatically access, interpret and present all necessary medical information about Pádraig to the physician at the point of care. Neither language nor technological differences prevent the system to seamlessly integrate the received information into the local record and provide a complete picture of Pádraig's health as if it would have been collected locally. Further, the anonymised data feeds directly into the tools of public health authorities and researchers.

It is desirable among all levels to achieve symmetrical SIOp, i.e. two or more systems semantically interoperate in a bidirectional way, rather than asymmetrical SIOp where one participant can use the others data but can not provide data usable by the other systems.

The partial nature could be expressed in terms of part-total ratio. For example, there may be SIOp within a number of institutions, but lack of SIOp across them.

In other words, **SIOp might not exist as an all-pervasive state, but rather be a description of the relationship between specified systems or services.**

It must be kept in mind that *SIOp implementation also depends on social, cultural and human factors within each country, each system and each time period.* Full SIOp is not necessarily a consensual goal in every place at any fixed time. This was confirmed at the Copenhagen workshop. One of the four most important conclusions of the event was that: „Full semantic interoperability SHALL NOT BE a generic characteristic of eHealth initiatives: it shall be restricted to the smaller number of problems creating the most trouble” (partial SIOp).

There may be **different approaches** to semantic interoperability:

1. Everyone adopts a *single, core model*. This – more than likely – becomes a long and tedious, probably even unsuccessful process due to disagreement on key aspects of such a central model (see also standardisation process for standards in the health sector).
2. Everyone has its *own model* but follows *interchange standards* (communication, messaging) between the models. An essential prerequisite for this scenario includes bilateral and/or multilateral agreements between the participating parties.
3. Everyone agrees on *common data elements* with systematic unambiguous formats e.g. data descriptions (data types, terminologies, coding), meta data and information models.
4. Everyone uses a predefined *knowledge representation framework* (classes, attributes, definitions, identification principles) and *inference mechanisms* (inclusions, exceptions, constraints, reasoning etc)
5. Other

It quickly becomes clear that SIOp is part of a bigger challenge.

## 2.2 Visions for the future

### 2.2.1 A hopeful outcome

#### 2.2.1.1 Technical evolution

- Semantic operability will be achieved gradually beginning with applications with high benefit and modest cost. Given appropriate incentives, there will be a series of bottom up and top down measures that will achieve a level of interoperability that protects patient safety and supports common undertakings in public health, clinical research, and dissemination of best practice. Material for dissemination of best clinical practice will increasingly be linked to the structures and terminologies used for clinical care.
- Semantic interoperability will not be complete. Much care will continue to be delivered locally using idiosyncratic systems or with minimal, or no, IT support
- Nor will there be complete harmonisation of either EHR models or terminologies. There will continue to be a major requirement for mappings and transformation services based on technologies analogous (or identical) to current data warehousing and mediation technologies.
- For terminologies, this will best be achieved by starting with areas where there is a high degree of consensus on both the content and the need. Key areas are likely to

be sensitivities and adverse drug reactions, translational medicine, and large scale public health and population research initiatives such as “biobanking”.

- The mechanisms that are successful will be open, collaborative and Web enabled, and specialised communities will contribute to much of the effort by standardising vocabularies for local purposes. These communities will “own” and take responsibility for their terminologies, helped by central servers and technologies which they will think of as part of their environment, just as much of the population today thinks of the Web, Google, Facebook, Flickr and related applications as just “there”.
- The methods will become increasingly formal. The conflict between the scaling problems presented by pre-coordinated terminologies and the difficulty of maintaining consistency with post-coordinated terminologies will be overcome. To this end, the formal structure of SNOMED-CT and will be radically revised to take advantage of its purported underpinnings in description logic. HL7 v3 and/or Archetypes will likewise be reformulated to take advantage of modern technologies to ensure their mutual consistency and consistent binding to the new terminologies. Common links to terminologies from OBO and others used in molecular biology will be forged.
- Because of obvious usefulness, there will be serious involvement by clinical staff in medical terminologies as there is in bioinformatics and molecular biology in bio-ontologies.

#### **2.2.1.2 Evolution with respect to use cases**

- *Patient care* will improve dramatically with a significant reduction in avoidable errors and improvements in patient safety. Distributed care will become the dominant paradigm, with a rapid shift of care both to the community and to highly specialised centres expert in applying the latest techniques arising from accelerated clinical and translational research. Care in remote areas will be particularly affected. Patient’s will take increasing responsibility for their own care with the help of Web-enabled tools that link directly both to their own records and to the records held in the various institutions in which they seek care. The elapsed time to translate new findings into practice will be drastically reduced. The rise in the overall cost of care will be mitigated.
- *Public Health* will be facilitated by much faster and less costly collection of international statistics, as most statistics will be derived from data collected during patient care, although there will remain a need for experts to monitor and check data for critical measures. Surveillance for the emergence of new epidemic diseases and major health problems will become more effective, and most outbreaks will be recognised early enough to be contained, although the increasing population and rate of travel will result in more small outbreaks.
- *Clinical and translational research* will advance very rapidly. Information sharing amongst researchers will be the norm. The lines between patient care and translational research, and between translational research and basic research in molecular biology will become increasingly blurred. Most studies will be large scale, international. Many will re-use data from earlier studies to triage hypotheses and minimise the number of patients exposed to unsuccessful therapies. Research will depend increasingly on BioBanks and tissue banks which will have access to rich information on the lifelong outcome of large cohorts of patients collected in the course of their routine care. A uniform structure of privacy, consent and governance will manage data sharing for research in ways that are accepted by the vast majority of the population.
- *A balanced market will develop* with large suppliers managing hospitals as a whole but with innovative SMEs and specialist vendors supplying systems to address

special functions and niche markets. The evolution between large and small, institutional and personal suppliers will be fluid, and European companies will play a major part in the overall commercial market. The time required to integrate a new specialised module or system into a hospital's infrastructure will drop from person years to person weeks, in some cases to person-hours. The difficulty of integrating systems will cease to be a barrier to adoption of best-of-breed solutions, and they will be embraced by central administrations and central IT directorates.

## 2.2.2 Inevitable outcomes

### 2.2.2.1 Technical evolution

- *Statistical text and Web mining technologies* will advance rapidly, and Google-like technologies will take over much of the burden of coarse grained search for navigation information discovery. This will probably include linking of EHRs to text material for decision support such as the Map of Medicine<sup>12</sup>. The balance between semantic and statistical technologies will eventually be established, but where the balance will be remains to be seen. Cross language searching will improve rapidly, driven by general commercial imperatives, but is unlikely to eliminate the need for multilingual systems. Research on how best to use the two in concert is a major priority.
- *Direct encoding of free text into formal vocabularies* and EHR structures will improve radically, partly driven by voice recognition.
- Personal medical systems will proliferate. Whether they interact effectively with the local health care systems will depend on a combination of technical and commercial pressures. They may become a key driver for interoperability or may operate entirely outside it.
- Concerns about privacy and confidentiality will continue to be key limiting factors in interoperability, and may impede developments that would be technically feasible and beneficial.

### 2.2.2.2 Evolution with respect to use cases

- Patients will increasingly use web resources and take responsibility for their own care, with or without coordination with professional carers.
- Clinical medicine will advance and new treatments will inevitably be more expensive.

## 2.2.3 Outcomes to be avoided

### 2.2.3.1 Technical evolution

- Little will be done and the status quo will be allowed to evolve without incentives to interoperability.
- Semantic interoperability will remain confined to special cases, with little advance on the current state where. National and specialist terminologies and EHR formats will remain silos. Virtually all records for patient care will remain in free text.
- Alternatively, enormous resources will be spent on over-ambitious plans for semantic interoperability which inevitably fail. In either case communication will take place by

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<sup>12</sup>[http://demo.mapofmedicine.com/demo/1/login\\_page.html?next=http%3A%2F%2Fdemo.mapofmedicine.com%2Fdemo%2F1%2Findex.html](http://demo.mapofmedicine.com/demo/1/login_page.html?next=http%3A%2F%2Fdemo.mapofmedicine.com%2Fdemo%2F1%2Findex.html)

going around rather than via the clinical information systems. In countries where it is mandated, SNOMED and HL7 V3 will become taxes on healthcare, absorbing significant resources while returning no, or in some cases negative, benefits.

- Terminologies will remain closed or partly closed. Most of the developing world and much of Europe will be excluded from their development, so they will neither fit their purposes nor be owned by them.
- The revision time for major terminologies will remain years. The release time for “mandated” terminologies will remain months.
- Technologies will continue to be based on (often ill understood) techniques from the late `80s and early `90s, without formal validation and support. Tools will remain primitive. The resultant defects in the systems will make them unreliable and untrustworthy.
- Large amount of resources will be expended on developing expertise to overcome these defects making the legacy increasingly difficult to change.
- The profession will remain alienated from informatics in general and `coding’ in particular.

### **2.2.3.2 Evolution with respect to use cases**

- *There will be tardy progress in patient safety improvement* and reduction in clinical errors will (continue to) be slow and sporadic. The current death toll of hundreds of thousands per annum will continue. Best practice will (continue to) require up to twenty years to be adopted by the profession as a whole, even when evidence in its favour is unequivocal. Care will continue to be fragmented institutionally. Errors resulting from miscommunication will (continue to) occur and account for significant morbidity. Well educated and informed patients may take matters into their own hands, but those with fewer resources or in marginalized areas will be left at the mercy of chance and hazard.
- *Public health* will (continue to) depend on specialist encoders and be limited by the cost and accuracy of capturing information post-hoc. Biosurveillance will remain a specialist activity divorced from mainstream clinical practice.
- Clinical and translational research will continue to be conducted in silos. The cost of mounting multi-centre trials will become the dominant barrier in the application of basic biological knowledge to medical care.
- The market will (continue to) be dominated by a few large suppliers who supply `complete’, one-size-fits-all solutions to entire hospitals or even countries. Innovation will become nearly impossible. Niche systems will be rare and will not interact with the main systems. Integration related difficulties will be the major barrier to the procurement of specialist systems which will be resisted vigorously by administrative and central IT directorates.

### 3. Action plan and recommendations for selected application fields

#### 3.1 Electronic Health Record (EHR)

Clinicians of all disciplines require access to detailed and complete health records in order to manage the safe and effective delivery of health care. These records need to be linked to salient knowledge and guidance, and to be shared in real time within and between care teams across geographical boundaries. Nowadays, patients also require access to their own EHR, along with suitable educational materials, to an extent that permits them to play an active role in their health management. These requirements are becoming urgent as the focus of health care delivery shifts progressively from specialist centres to community settings and to the patient's personal environment. Lack of informatics solutions to support these needs is widely recognised to be a major obstacle to the safe and effective delivery of health services<sup>13,14,15,16,17</sup>.

Existing computer-based patient record systems comprise unconnected bundles of data and are designed to mirror the current, manual way of using and exchanging clinical data<sup>18,19</sup>. The diversity and complexity of clinical data is difficult to capture fully and faithfully on current computerised systems<sup>20,21</sup>. The lack of agreed and implemented standards has made it virtually impossible to transfer detailed healthcare information in a way that supports data integration within the receiving system.

The adoption and use of interoperable electronic information systems within healthcare is currently less developed than in other public service sectors or industries, at least in part because the overall percentage of the healthcare budget spent on information and communication technologies is relatively low. There exists an international momentum to establish the means by which patient health record information can be shared between healthcare providers and follow patients as they move between the healthcare providers. Realising the Electronic Health Record is a core target of, for example, the UK National Health Service IM&T strategy<sup>22,23</sup>. The NHS approach is considered a 'big bang' developmental programme, in contrast to equivalent health infrastructure projects in, for example, Canada's Infoway<sup>24</sup> and Australia's HealthConnect<sup>25</sup>. In these countries the intent

<sup>13</sup> Smith R. What clinical information do doctors need? *BMJ* 1996 Oct; 313:1062-1068.

<sup>14</sup> Patterson D, Ingram D, Kalra D. Information for Clinical Governance, In: *Clinical Governance: Making it Happen*. The Royal Society of Medicine Press Ltd. 1999. ISBN 1-85315-383-4.

<sup>15</sup> Waegemann CP. Medical Record Institute's survey of electronic health record trends and usage. *Toward an Electronic Health Record Europe '99*. Nov 1999; 147-158.

<sup>16</sup> Kohn, L.T.; Corrigan, J.M., and Donaldson, M.S. *To err is human: Building a safer health system*. National Academy Press. Washington DC; 2000 Apr. ISBN: 0309068371.

<sup>17</sup> Audit Commission UK. *A Spoonful of Sugar - Medicines Management in NHS Hospitals*; 2001.

<sup>18</sup> Hammond W.E., Pollard D.L., and Straube M.J. *Managing healthcare: a view of tomorrow*. *Medinfo* 9. 1998; 1:26-30.

<sup>19</sup> Rothschild AS, Dietrich L, Ball MJ, Wurtz H, Farish-Hunt H, Cortes-Comerer N. Leveraging systems thinking to design patient-centered clinical documentation systems. *International Journal of Medical Informatics* 2005 74, 395-398.

<sup>20</sup> Rector A.L., Nowlan W.A., and Kay S. Foundations for an electronic medical record. *Methods of Information in Medicine*. Aug 1991; 30(3):179-86.

<sup>21</sup> van Ginneken A.M., Stam H., and Moorman P.W. A multi-strategy approach for medical records of specialists. *Greenes, R. A. and others, eds. Medinfo* 8. 1995; 290-294.

<sup>22</sup> Burns F. NHS Executive. *Information For Health - An Information Strategy For The Modern NHS 1998-2005*. HMSO Ltd, London; 1998. ISBN: 0 95327190 2.

<sup>23</sup> Department of Health UK. *Delivering 21st Century IT Support for the NHS - National Strategic Programme*. The Stationery Office; 2002.

<sup>24</sup> Alvares R. Integrating Telehealth – Infoway perspective. In: *Proceedings of the 7th Annual Meeting of the Canadian Society for Telehealth*; 2004 Oct 3-5; Quebec City, Canada. Available from: URL: [http://www.infoway-inforoute.ca/pdf/CST\\_TelehealthV8\\_E.pdf](http://www.infoway-inforoute.ca/pdf/CST_TelehealthV8_E.pdf).

<sup>25</sup> Australian Department of Health and Ageing. *HealthConnect – an overview*; 2004; Available from: URL: [http://www7.health.gov.au/healthconnect/pdf/HealthConnect\\_overview\\_May2004.pdf](http://www7.health.gov.au/healthconnect/pdf/HealthConnect_overview_May2004.pdf).

is to foster a network of regional projects, encouraged towards strategic alignment and interoperability through national co-ordinators and selected key infrastructure elements.

In achieving this vision of an integrated health information environment, the clinical, technical, managerial and citizen perspectives on hitherto unmet information needs have to be acknowledged and solutions developed through co-evolution. This process must inevitably begin with a focus on requirements.

Considerable research has been undertaken over the past fifteen years to explore the user requirements for adopting EHRs, for example published by the Good European Health Record project<sup>26,27,28,29,30</sup> and the EHCR Support Action<sup>31</sup>. These have formed the basis of architecture formalisms and standards to represent and communicate personal health data comprehensively and in a manner that is medico-legally rigorous and preserves the clinical meaning. Much of this work has now been taken forward as international standards, for EHR architecture requirements: ISO TS 18308<sup>32</sup>, and interoperability: EN13606<sup>33</sup>, through open source initiatives such as the *openEHR* Foundation<sup>34</sup>, and formalisms such as the use of archetypes.

There are several clinical and health service drivers for integrated electronic health records, in which a patient's cumulative health information can be virtually accessed from any new point of care delivery<sup>35</sup>. The following, to some extent, contribute to the business case for the present international investment in e-Health:

- Manage increasingly complex clinical care
- Connect multiple locations of care delivery
- Support team-based care
- Deliver evidence-based health care
- Improve patient safety
  - reduce errors and inequalities
  - reduce duplication and delay
- Empower and involve citizens
- Underpin population health and research
- Protect patient privacy

<sup>26</sup> Ingram D., Southgate L., Kalra D., Griffith S., Heard S. and others. The GEHR Requirements for Clinical Comprehensiveness. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 4. (19 chapters, 144 pages).

<sup>27</sup> Ingram D., Hap B., Lloyd D., Grubb P. and others. The GEHR Requirements for Portability. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 5.

<sup>28</sup> Ingram D., Lloyd D., Baille O., Grubb P. and others. The GEHR Requirements for Communication Capacity. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 6.

<sup>29</sup> Ingram D., Murphy J., Griffith S., Machado H. and others. GEHR Educational Requirements. European Commission, Brussels; 1993; The Good European Health Record Project: Deliverable 9

<sup>30</sup> Heard S, Doyle L. and others. The GEHR Requirements for Ethical and Legal Acceptability. European Commission, Brussels; 1993; The Good European Health Record Project: Deliverable 8. 9 Chapters, 68 pages. Available from <http://www.chime.ucl.ac.uk/work-areas/ehrs/GEHR/EUCEN/del8.pdf>. Last accessed 22 July 2004.

<sup>31</sup> Dixon R., Grubb P.A., Lloyd D., and Kalra D. Consolidated List of Requirements. EHCR Support Action Deliverable 1.4. European Commission DGXIII, Brussels; May 2001. 59pp. Available from [http://www.chime.ucl.ac.uk/Health/EHCR-SupA/del1-4v1\\_3.pdf](http://www.chime.ucl.ac.uk/Health/EHCR-SupA/del1-4v1_3.pdf).

<sup>32</sup> Schloeffel P (ed). Requirements for an Electronic Health Record Reference Architecture. ISO/TS 18308: 2002.

<sup>33</sup> Kalra D, Lloyd D. EN13606 Electronic Health Record Communication Part 1: Reference Model. CEN TC/251, Brussels. February 2007.

<sup>34</sup> Ingram, D, Beale, T, Heard, S, Kalra, D. The openEHR Foundation [Web Page]. Accessed Nov 2007. Available at: <http://www.openehr.org>.

<sup>35</sup> Kalra D. Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service. PhD Thesis. University of London. 2002. Available from <http://eprints.ucl.ac.uk/archive/00001584/> (Last accessed Nov 2008)

In today's health care, some of these, such as sharing of care within a local health care team, could be served by providing access to human readable documents, such as Adobe PDF files accessed via a secure network. Indeed, a number of clinicians, sceptical of national ICT programmes, who assert that even meeting this basic need seems (to date) to have defeated the multi-million Euro/Dollar programmes. At the same time, it is now widely acknowledged that assimilating the sheer volumes of data in a patient's record, and cross-referencing it to the ever expanding medical knowledge in a timely manner, is beyond the realistic expectations of unassisted clinical professionals. Clinicians will need to work in partnership with systems that monitor unusual patterns, interactions and overdue care interventions.

The morbidity associated with managing patients without adequate health record and guideline information has been well documented<sup>36,37</sup>. The US Institute of Medicine report 'To Err is Human' has estimated that 100,000 US citizens die each year through medical errors<sup>38</sup>. These possibly rank as the eighth leading cause of death in the US, and contribute 4% (\$37.6 billion) to the cost of US healthcare<sup>39</sup>. High rates of missing or erroneous information have been confirmed in a number of other studies. For example, in two London hospitals, Vincent *et al* found that adverse events occurred in around 10% of patients, a third of which were moderate, severe or fatal and around half of which were preventable<sup>40</sup>. Haughton identified over 20% of patients with potential misdiagnoses, possible drug interactions, lack of follow-up or missed screening tests<sup>41</sup>.

The wide scale use of 'decision support' and 'alerting systems' that interact with patient records is an essential contribution to the prevention of errors<sup>42</sup>. Weed has argued that the expanding wealth of medical knowledge now exceeds the ability of healthcare professionals to retain and retrieve it appropriately or safely<sup>43</sup>. Straus & Sackett argue that consolidating this array of knowledge within evidence-based guidelines, developed by trusted organisations, is the only way in which individual clinicians can remain safe and optimally effective<sup>44</sup>.

Remote monitoring systems (tele-monitoring) permit clinicians to assess their patients' condition on a frequent basis and provide valuable means to patients to play an active role in tailoring their own health care. This is provided that feedback on the acquired data is offered to the patients.

Educated, technically literate and well-motivated patients can make good use of their EHR web portals, for example, to view test results and access linked educational materials. Patients are keen to learn and should know about problems and complications arising within their health care, and should be encouraged to access EHRs.

Web-based Personal Health Record systems targeted specifically at patients are becoming popular but continue to exhibit limited functionality and almost no interoperability with clinical record systems. A major drawback to most contemporary tele-monitoring and PHR systems is their use of a proprietary data structure to represent these records. Patients frequently

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<sup>36</sup> Audit Commission UK. A Spoonful of Sugar - Medicines Management in NHS Hospitals; 2001.

<sup>37</sup> The Audit Commission (UK). For Your Information - A Study of Information Management and Systems in Acute Hospitals. HMSO Publications, London; 1995; ISBN: 011 886 4165.

<sup>38</sup> Kohn, L.T.; Corrigan, J.M., and Donaldson, M.S. To err is human: Building a safer health system. National Academy Press. Washington DC; 2000 Apr. ISBN: 0309068371.

<sup>39</sup> Anderson J.G. Evaluating clinical information systems: a step towards reducing medical errors. MD Computing. May 2000c-Jun 2000 17(3):21-3.

<sup>40</sup> Vincent C., Neale G., and Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. Mar 2001; 322(7285):517-9.

<sup>41</sup> Haughton J. A paradigm shift in healthcare. From disease management to patient-centered systems. MD Computing. Jul 2000-Aug 2000; 17(4):34-8.

<sup>42</sup> Bates D.W., Cohen M., Leape L.L., Overhage J.M., Shabot M.M., and Sheridan T. Reducing the frequency of errors in medicine using information technology. J Am Med Inform Assoc. Jul 2001-Aug 2001; 8(4):299-308.

<sup>43</sup> Weed L.L. Clinical judgement revisited. Methods of Information in Medicine. Dec 1999; 38:279-86.

<sup>44</sup> Straus S.E. and Sackett D.L. Using research findings in clinical practice. BMJ. Aug 1998; 317(7154):339-42.

suffer multiple health problems, and it would be unfortunate if their health record(s) are inharmonious due to the diversity of incompatible information resources.

If the EHR is to serve as a tool to engage patients (citizens) more actively in their health care decisions in partnership with professionals, they need to work from a single shared record.

**The findings of this project suggest that full semantic interoperability (Level 3, as defined by SemanticHEALTH) is required across heterogeneous EHRs in order to gain the benefits of computerised support for reminders, alerts, decision support, workflow management and evidence-based health care i.e. to improve effectiveness and reduce clinical risk. However, it is recognised that achieving Level 3 across the entirety of healthcare would be a lengthy, expensive and possibly unattainable goal. It is instead recommended that Level 3 quality is sought in specific areas of clinical practice that are known to be of high patient safety risk, and in priority areas for which the evidence is strongest for a gap to be bridged between current and best practice. In effect, these are the cases for which computerised decision support and care pathway support are most needed.**

### 3.1.1 Short, mid and long term goals

The following chapter identifies tasks on the road to enable Semantic Interoperability in the future. The tasks are categorised into short, medium and long term and have involved actors defined by numbers:

- [1] Policy makers and health authorities
- [2] Health professionals and professional organisations
- [3] Academic organisations and research fund supporters
- [4] Standards Development Organisations
- [5] Industry (primarily healthcare ICT)

#### 3.1.1.1 Long term vision for EHR semantic interoperability

- To enable the safe, meaningful sharing and combining of health record data between heterogeneous systems.
- To enable the consistent use of modern terminology systems and medical knowledge resources.
- To enable the integration and safe use of computerised protocols, alerts and care pathways by EHR systems;
- To link EHR data to explanatory and educational materials to support patient and family engagement and professional development;
- To ensure the necessary data quality and consistency to enable rigorous secondary uses of longitudinal and heterogeneous data: public health, research, health service management

#### 3.1.1.2 Target EHR system capabilities

- clinical applications that can capture complete and real-time health record information from different kinds of direct care actor in different settings and with different physical and logistical challenges
- EHR systems underpinned by architectural and knowledge representation capability to systematise diverse kinds of clinical input to enable co-operability without imposing constraints on conformity upon clinical practice beyond that which is necessary to enable safe interpretation of the information

- analytic tools to be able to process integrated health data in order to improve patient safety, to help deliver evidence based care and to enable clinical audit and to conduct research
- basic functions such as viewing and searching within a single patient record will increasingly rely upon filters and queries that in turn need to know what every data item means clinically in order to determine if it should be presented to the user in a given context
- workflow support linked to notification and alerting components to monitor for patient safety situations and to ensure that shared care is optimised for patients and professionals

### **3.1.1.3 Areas needing adoption or short term action (short term)**

[by national e-Health programmes, and therefore by industry, and ideally internationally]

- Agree on a generic model for EHR communications: consider seriously the adoption and promotion of EN13606 [1,5]
- Adopt a standardised approach for representing and sharing of clinical data structure specifications: agree to use archetypes, in relationship with the categorial structures published by CEN/TC 251 and ISO/TC 215 [1,2,5]
- Collaborate on key use cases for shared care and patient safety, and on defining and tidying the corresponding SNOMED-CT sub-sets [1,2,3,4]
- Develop and share policies on SNOMED CT term co-ordination [2,3,4,5]
- Seed clinical fora to develop care pathways and archetypes to meet the needs of safe and evidence based care in different medical domains and disciplines [1,2,3]
- Strengthen clinical user training in the use of EHRs, terminology and structured records [1,2,3]

### **3.1.1.4 Areas needing wide-scale evaluations (medium term)**

[results exist, but need refinement and real clinical use, to determine best practice]

- Develop best practice in archetype design [2,3,4]
- Establish useful exemplars of SNOMED-CT sub-sets being adopted within EHR systems and delivered in meaningful ways to clinical users [2,3]
- Develop the business rules and validation processes to support term co-ordination (pre- and post-coordination) [2,3,4,5]

### **3.1.1.5 Areas needing investment (medium term)**

[the business cases are not yet strong enough for industry, but products are needed: maybe sponsored open source]

- Archetype & template authoring and validation tools [1,2,3,5]
- Terminology servers and term browsers for SNOMED CT, including support for term co-ordination [1,2,3,4,5]
- Consider seriously the global multi-cultural dimension - not just term translation but catering better for internationalisation across health care paradigms and cultural differences in how health and illness are perceived [1,2,5]

### 3.1.1.6 Areas needing further (focussed) research (long term)

[e.g. for consideration in future EU Framework programmes]

- Quality assurance and certification of archetypes [1,2,3,4]
- Archetype indexing (including ontology resources) and archetype/template repository services [2,3]
- Term binding to archetypes and record structures [2,3,4]
- EHR visualisation applications that can support search and navigation within large and complex health records electronically [2,3,5]
- Linking EHR data to educational materials and clinical evidence, to enable consumer engagement and support health professional training [2,3,5]
- Evaluations of citizen and clinical acceptance of shared EHRs [1,2,3]
- Semantic interoperability goals and solutions for Personal Health Records and near patient e-Health [1,2,3]
- Adaptable clinical applications that can reflect evidence-based data structures [2,3,5]
- Test the HL7 Terminology Standard for consistent implementation and usage [2,3,4,5]
- Further test SNOMED for more global experience [2,3,4]
- Investigate the knowledge management resources necessary to foster records in which all entries are fully computable [2,3]

### 3.1.2 Key actors and their role

The following actors play an important role and have to become involved as indicated in the roadmap matrix below:

- Policy makers and health authorities
- Health professionals and professional organisations
- Academic organisations and research funders
- Standards Development Organisations
- Industry (primarily healthcare ICT)

**TABLE 2: ROADMAP MATRIX ON EHR**

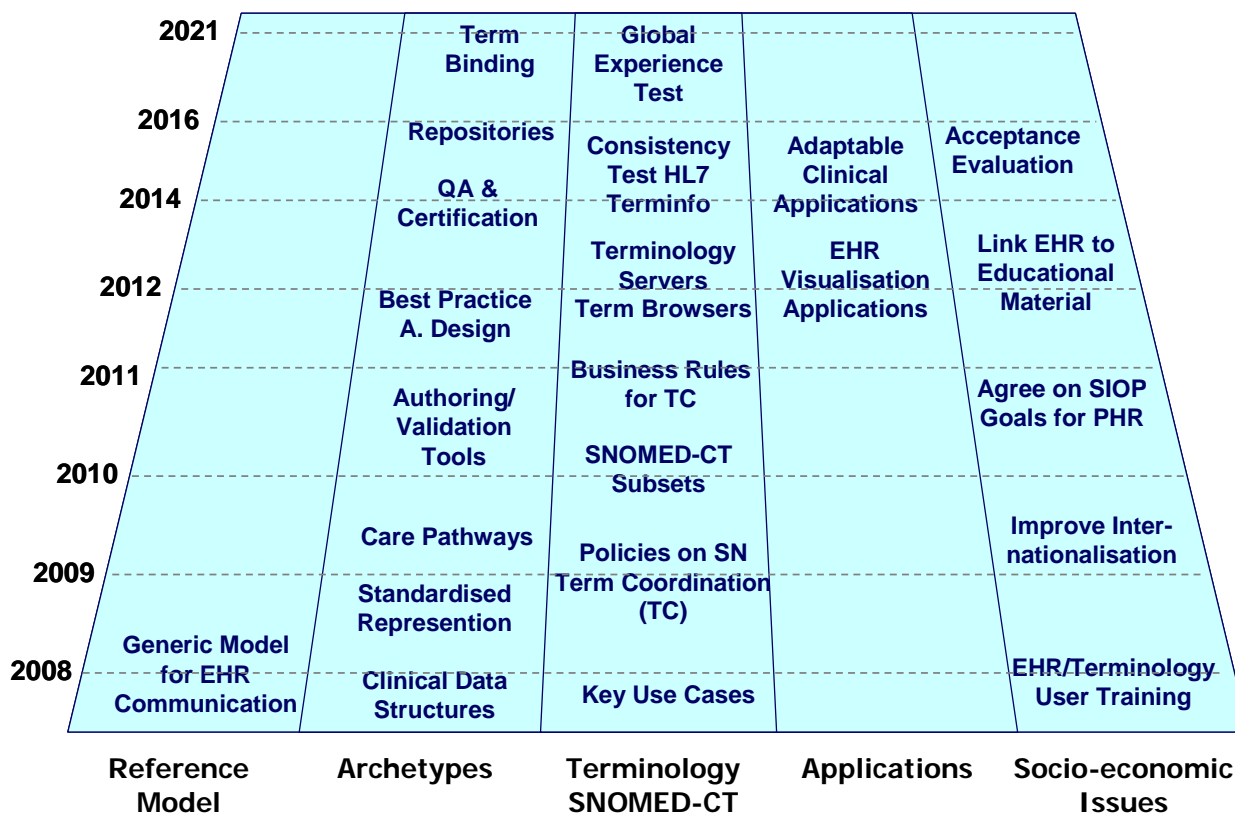
	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
R1	<b>Reference Model</b>	Agree on a generic model for EHR communications: consider seriously the adoption and promotion of EN13606	X			X				X	
R2											
A1	<b>Archetypes</b>	Adopt a standardised approach for representing and sharing of clinical data structure specifications: agree to use	X			X				X	R1

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
		archetypes, in relationship with the categorial structures published by CEN/TC 251 and ISO/TC 215									
A2		Seed clinical fora to develop care pathways and archetypes to meet the needs of safe and evidence based care in different medical domains and disciplines	X			X	X	X			
A3		Develop best practice in archetype design		X			X	X	X		A1, A2
A4		Develop Archetype & template authoring and validation tools		X		X	X	X		X	A1
A5		Consider quality assurance and certification of archetypes			X	X	X	X	X		A1, A3
A6		Archetype indexing (including ontology resources) and archetype/template repository services			X		X	X			A1
A6		Term binding to archetypes and record structures			X		X	X	X		R1, A1
A7											
T1	<b>Terminology Systems</b>	Collaborate on key use cases for shared care and patient safety, and on defining and tidy the corresponding SNOMED-CT sub-sets	X			X	X	X	X		
T2		Develop and share policies on SNOMED CT term co-ordination	X				X	X	X	X	
T3		Establish useful exemplars of SNOMED-CT sub-sets being adopted within EHR systems and delivered in meaningful ways to clinical users		X			X	X			T1
T4		Develop the business rules and validation processes to support term co-ordination (pre- and post-coordination)		X			X	X	X	X	T2
T5		Develop Terminology servers and term browsers for SNOMED CT, including support for term co-ordination		X		X	X	X	X	X	T4
T6		Test the HL7 Terminology Trial Standard for consistent implementation and usage			X		X	X	X	X	T1, T2

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
T7		Further test SNOMED for more global experience			X		X	X	X		T1, T2, T5
T8											
S1	<b>Socio-economic issues</b>	Strengthen clinical user training in the use of EHRs, terminology and structured records	X			X	X	X			R1, A2, A3, T1, T3
S2		Consider seriously the global multi-cultural dimension - not just term translation but catering better for internationalisation across health care paradigms and cultural differences in how health and illness are perceived		X		X	X			X	
S3		Agree semantic interoperability goals and solutions for Personal Health Records and near patient e-Health			X	X	X	X			
S4		Linking EHR data to educational materials and clinical evidence, to enable consumer engagement and support health professional training			X		X	X		X	S1, S3
S5		Evaluations of citizen and clinical acceptance of shared EHRs			X	X	X	X			S3
S6		Investigate the knowledge management resources necessary to foster records in which all entries are fully computable			X		X	X			R1, T1-T7
S7											
I1	<b>Implementation</b>	EHR visualisation applications that can support search and navigation within large and complex health records electronically			X		X	X		X	R1, A1-A6, T1-T7
I2		Adaptable clinical applications that can reflect evidence-based data structures			X		X	X		X	R1, A1-A6
I3											

The recommendations set out in the matrix above can be summarised along a timeline presented in Figure 1 below:

FIGURE 1: EHR TIMELINE



### 3.2 Biomedical ontologies, terminologies, and classification systems

#### 3.2.1 Vocabulary

The vocabulary surrounding terminologies and ontologies is confusing, and different authors use the same words differently. We first borrow a list of common definitions from DD6.1 as they will be used throughout this deliverable.

- *Controlled Vocabulary* – a list of specified items to be used for some purpose, usually in an information system to reduce ambiguity, mis-spellings, etc.
- *System of identifiers (“codes”)* – Controlled vocabularies, and many lexicons, ontologies, and thesauri, are usually accompanied by systems of identifiers for their units, e.g. Typically, identifiers act as the primary unambiguous means of referring to the entities in the system for computational purposes with the text form being used for communication with users. Examples the “Concept Unique Identifiers (CUIs) from the UMLS, SNOMED Identifiers, etc. In many contexts, identifiers are known as “codes.”
- *Lexicon* – A list of linguistic units that may be attached to a controlled vocabulary or ontology, in a specific language or sublanguage, often including linguistic information such as synonyms, preferred terms, parts of speech, inflections and other grammatical material. Example: Term terms and lexical material in UMLS identified by Lexical Unique Identifiers LUIs)
- *Ontology (sensu information system)* – a symbolic logical model of some part of the meanings of the notions used in a field, i.e. those things which are universally true or true by definition.<sup>45</sup> The

<sup>45</sup> Different authors refer to the meanings as “concepts”, “universals,” “categories”. Note that the word “ontology” was borrowed from philosophy, and that there remain controversies concerning the extent to which the symbolic models referred

key relationship in an ontology is “subsumption” or “kind-of”. Every instance of a subkind must be an instance of the kind, without exception. Typically ontologies are implemented in logic languages such as Ontolog or OWL or frame systems such as Protégé-Frames. Examples: The GALEN Core Model, the stated form of SNOMED.

- *Classification* – an organisation of entities into classes for a specific purpose such as international reporting or remuneration. Examples ICD and Diagnosis Related Groups.
- *Thesaurus* – a system of terms organised for navigation with the primary relationship being “broader than”/“narrower than”. The “broader than”/“Narrower than” relation is explicitly not limited to subsumption/kind of relation. It is a general form of linguistic hyper/hyponymy aimed at assisting human navigation. However, it is explicitly not intended that it be used as the basis for logical inferences, e.g. in decision support. Examples MeSH, WordNet.
- *Background knowledge base* – or “*Knowledge Representation System*” – the common knowledge to be assumed by the system, including both the ontology – what is universally true – and generalisations about what is typically true.
- *Terminology* – Any or all of the above in various combinations. Most health terminologies consist, at a minimum, of a controlled vocabulary and a system of identifiers. They may include extended lexicons, ontologies, thesauri or background knowledge base. This definition is deliberately broader and less specific than that in most of the standard references and intended to approximate common usage.
- *Coding system* – A terminology with attached identifiers or “codes”.

We further point out the importance of distinguishing.

- *Ontology (Sensu philosophy)*: The study of what there is. Formal ontologies are theories that attempt to give precise formulations of the types of entities in reality, of their properties and of the relations between them. [Quine, 1948]
- *Ontology (Sensu Informatics)*: First defined as by Gruber as: “The conceptualisation of the entities in a domain”.<sup>46</sup> (The ancestor to the more precise definition given above.)

The difference is important, because the term “ontology” was “borrowed” from philosophy, but the two meanings are quite different. In philosophy, ontology is the study of what is; in informatics, ontology is the study of what is to be represented – and by extension the means of representation. The test of an informatics ontology is whether or not it is useful in information systems. This may, or may not, correspond to what any given school of philosophy considers to exist “in reality”.

There is continuing controversy concerning which principles from philosophical ontology it is appropriate to apply to ontologies as used in informatics. On the one hand, the fruits of thousands of years of thought since Aristotle often throw light on difficult issues; on the other hand, the distinctions and restrictions advocated by philosophical ontologists often seem at best irrelevant and on occasion actively counterproductive to the use of ontologies in information systems. (The most vociferous advocate of the philosophical approach is Smith<sup>47</sup>)

### 3.2.2 Claims for Ontology and Terminology in Interoperability

The issue of semantic interoperability has been intensively discussed in recent years and it was often claimed that it could be addressed simply by insisting on the application of shared clinical terminologies. More recently the use of the term ‘ontology’ has been steadily growing, and the question arises whether this constitutes any real advance or advantage? There is indeed good reason to cast at least some doubt on the claims made on ontology’s

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to as ontologies used in information systems should conform to principles laid down by philosophers for ontologies understood as part of the philosophical study of being.

<sup>46</sup> Gruber TR. Toward Principles for the Design of Ontologies Used for Knowledge Sharing. *Journal of Human-Computer Studies*. 1993;43:907-928.

<sup>47</sup> <http://ontology.buffalo.edu/smith/>

behalf: Too many recent publications, calls for research proposals and project descriptions have embodied what are in our view (and have sometimes already proven themselves to be) insupportable expectations. It is thus understandable that some have been tempted to see in ontology just one more new and flashy buzzword.

### **3.2.3 Goals for Ontologies and Terminologies within information systems**

The primary goal of ontologies and terminologies for interoperability is to enable the faithful exchange of meaning between machines and between machines and people to achieve the vision outlined in Chapter 3. The test of whether or not they are successful is whether or not they perform this task effectively.

A second major goal of standard ontologies and terminologies is to make it easier to build systems that successfully exchange meanings. Currently, agreeing meanings is one of the most time consuming and resource intensive tasks in setting up clinical systems. Agreeing meanings between systems is a major barrier to system interoperability. The goal of improved standard terminologies is to reduce that barrier – to reduce the effort required to establish effective exchange of meaningful information between two systems.

### **3.2.4 Short-, mid- and long-term technical objectives**

The long term goals are relatively easy to articulate. Immediate short term objectives are more difficult. Whether or not all long term objectives are achievable remains speculative. The objectives are phrased in a sufficiently specific way to reduce risk.

#### **3.2.4.1 Long term goals to achieve desirable outcomes**

The desirable outcomes can be divided into content – what is actually in the terminologies and resources – tools – what software is needed to make it possible to work with them – and process – what is required to sustain them.

#### **Content**

- (i) a set of interoperable and computable biomedical terminologies responsive to the needs of the communities that need them.
- (ii) inclusion of unambiguous formal and natural language definitions for all terms in
- (iii) availability of lexical and linguistic to support the use of (i) and (ii) in all important European languages.
- (iv) availability of knowledge representation resources and formalisms using (i-iii) sufficient to support the needs of patient care, public health, clinical research, and health service management.
- (v) Comprehensive maps between (i-iv) and major classification systems, including the successors to the ICD.
- (vi) Availability of a library of adaptable information models along with bindings to (i-v).
- (vii) Availability of multilingual language generation based on above
- (viii) Availability of multilingual automatic encoding from text to support above.(to be coupled with voice recognition which is expected to be available from independent sources.)

## Tools

- (viii) Widespread availability of methodologies and tools for implementing the content into practical applications at less cost than developing new content from scratch coupled with
- tools that use the content to generate applications quickly and at far less cost than currently.
- (ix) Wide spread availability and use of tools exploiting the Web for collaborative development and maintenance of (i-vi) by the communities involved.
- (x) Widespread availability of tools, often based on Web technologies, for deploying and disseminating (i-vi) including mediators and repositories so that specialist ontologies and terminologies can exchange information wherever possible.
- (xi) Widespread availability of tools for systematic open quality assurance and feedback on all content
- Tools to allow above to synergise with Web Mining and Text mining approaches

## Process

- (xii) A highly responsive sustainable process for maintaining and updating the content by clinical experts. This process will need to be radically different from current standardisation processes if it is to succeed. It should be world-wide and engage with the developing world.
- Sustainable development of tools and central repositories and distribution resources. This almost certainly requires government involvement analogous to the resources devoted in the US to MeSH, PubMed, and the other common resources provided by the National Library of Medicine.
- (xiii) Clear scoping statements limiting the scope of terminologies and ontologies to be interoperable and when investment in interoperability has a positive cost/benefit ratio.
- (xiv) Existence of sustainable mechanisms that engage communities and result in effective QA
- (xv) Close integration of Clinical, Research, Best Practice and Management communities in their relevant areas of content.

## Target capabilities of new-generation ontologies and terminologies

- Clear articulation of purpose, scope, limitations and criteria for quality assurance.
- Clear technical specifications formal foundations coupled to clear text based resources
- Integration with other Web Resources and Digital Libraries.
- Reliable recognition of semantic equivalence between pre-coordinated and post-coordinated forms
- Methods and tools for formal specification and automatic validation of the binding of terminologies to EHRs and Decision Support Systems.
- Flexibility, rapid adaptation, and responsiveness
- Scalability – the terminologies, ontologies, and knowledge representations themselves should not grow exponentially, and they should contribute to controlling the combinatorial explosion of special cases and special functionality in the software that uses them.
- Collaborative development – which requires that they be understandable and transparent. to the clinicians and scientists who must build and maintain them.

## Areas needing adoption or short term action (short term)

- Demonstration of a semantically sound and well quality assured reformulation of one or more suitable subsets of SNOMED using modern tools including multilingual lexicons and extensions.
  - This is required both in its own right and to provide evidence for long term decisions on the role of SNOMED in semantic interoperability in Europe.
  - The VA/KP<sup>48</sup> subset is one possible target, Various European subsets are others. The action should be undertaken in cooperation with the IHTSDO but should *not* be under its control or limited by its strictures. It is implausible that the IHTSDO will undertake a suitable revision of SNOMED from within. This should include identification of subsets of SNOMED actually in use. The criteria for success should be that using the reformulated version to create subsets is a) less resource intensive and b) more repeatable and reliable than existing methods.
- Development of one or more freely available, preferably open-source, authoring environments and toolsets to support the above. These should be capable of handling compositional terminologies in general and SNOMED in particular. A combination of the capabilities of the SNOB<sup>49</sup> browser growing out of GALEN and Protégé-OWL<sup>50</sup> environment linked to UK projects and the US National Center for Biointologies should be encouraged.
- Development of a coordinated authoring environment for EHR models and Terminologies. *This is the natural follow-on from the development of terminology authoring tools, and can, in fact, proceed in parallel with it. This is a high priority for both EHRs and Terminologies/Ontologies (See Deliverables 4.1 and 6.1)*
- An honest and public evaluation by independent evaluators of what SNOMED-CT can and cannot be used for safely.
- Open Collaborative development of ICD-11 using Web based technologies, which could serve as a demonstration for other open collaborative developments. Where possible this should be mapped to the semantically sound subset of SNOMED, or if necessary, to SNOMED itself. (Mapping it to the existing structure may be necessary as a political exercise but will squander resources in terms of technical achievement)<sup>51</sup>
- Adoption of a clear policy that, insofar as possible, aims to map all terminologies to UMLS CUIs and LUIs, either by their originators or in collaboration with the US National Library of Medicine.
- Establishment of a European centre of expertise for collaboration with the National Cancer Institute on the use of its ontology and terminology resources, with the goal that groups should be able to build on this platform with only modest cost. (Currently, the cost of 'getting to grips with' the platform is prohibitive for all but the largest European projects.)
- Adaptation of Web2.0
- Widespread engagement with both vendors and providers on requirements, gaps, and irrelevancies. Engagement of vendor and provider groups in any effort should be a pre-requisite for further funding.

### Areas needing wide-scale evaluations (medium term)

- The use of SNOMED with Archetypes and HL7 v3

<sup>48</sup> [http://www.nlm.nih.gov/research/umls/Snomed/snomed\\_problem\\_list.html](http://www.nlm.nih.gov/research/umls/Snomed/snomed_problem_list.html)

<sup>49</sup> <http://snob.eggbird.eu/>

<sup>50</sup> <http://protege.stanford.edu/>; <http://www.co-ode.org>

<sup>51</sup> sometimes called "aggregation logic", but this phrase is avoided here because of its possible confusion of aggregations of codes with aggregation of patients.

- The use of SNOMED to map to ICD 10/11
- Use of social computing mechanisms to QA and provide feedback on ontologies and terminologies
- Use of social computing mechanisms to assist with translation of terminologies
- Identification and cataloguing of the terminologies actually used in the various European states, including, and in particular, the terminologies for drugs, adverse reactions, and sensitivities, as a preliminary for harmonisation.

#### **Areas needing investment (medium term)**

- Establishment or support for a major network of tool providers and terminology service provider for Europe
- Development of human capacity and skills in terminology, ontologies,
- Development of methodologies and tools for binding of Archetypes and HL7 v3 Messages to Terminologies and Ontologies.
- Engagement with the SNOMED IHTSDO and HL7 with sufficient focused resources to have a major impact. This is a moment of opportunity. It should not be missed.

#### **Areas needing further (focussed) research (long term)**

- Integration of Ontologies, Terminologies, and Knowledge Representations focused on practical applications in clinical medicine.
- Optimal balance between “Google-like” and semantic techniques for interoperability
- Ontology driven architectures for clinical medicine
- Evaluation metrics for ontologies and terminologies for use in Healthcare IT, including the relevance of “good ontological practice” to practical software success.

### **3.2.5 Milestones (Implementation, Deployment, Research)**

- Semantically sound SNOMED Fragment supported by tools and organisation
- Social/Collaboratively built ICD-11 with widespread support
- Mapping of ICD-11 to Semantically Sound subset of SNOMED
- Establishment of a set of widely used Web Based terminology services for access to, quality assurance, and feedback on clinical ontologies

### **3.2.6 Research priorities**

- Integration of Ontologies, Terminologies, and Knowledge Representations focused on practical applications in clinical medicine
- Ontology driven architectures for clinical medicine
- Evaluation metrics for ontologies and terminologies for use in Healthcare IT, including the relevance of “good ontological practice” to practical software success.

### **3.2.7 Key actors and their role**

Engagement with players is a major gap in current development. Key players – as indicated in the roadmap matrix - are

- 1 = Policy makers and health authorities including actual service providers
- 2 = Health professionals and professional organisations
- 3 = Academic organisations and research funders
- 4 = Standards Development Organisations
- 5 = Industry (primarily healthcare ICT)

The importance of engagement with industry and with health professionals cannot be overstated. This has been a major point of failure in most existing work.

TABLE 3: ROADMAP MATRIX ON ONTOLOGIES

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
C1	<b>Content SNOMED</b>	Feasibility study and semantically sound reformulation hierarchies and relations for a of subset of SOMED	X				X	X	X	X	T1
C2		Multilingual multicultural versions of semantically sound subset	X	X					X	X	
C3		Formal QA of Subset of SNOMED		X				X	X	X	
C4		Statistical extension of QA to all of SNOMED		X	X				X	x	
C5		Policy in conjunction with member states on future of use of SNOMED hierarchies and relations				x					X
C6	<b>Content Other</b>	Consultation on issues related to LOINC & DICOM	X					X	X	X	
C7		Consultation on issues related to Adverse reaction reporting and Drug Reporting	X				X	X		X <sup>52</sup>	
C8		Actions arising from consultations		X	X		X	X	X	X	
E1	<b>Terminologies and EHRs</b>	Tools and methods for preliminary implementation of Terminfo guidelines including gap analysis	X								
E2		Generic toolkits for HL7 messages and Archetypes binding to Terminologies using Description logic technologies to ensure reproducibility and consistency		X	X			X	X	X	T1
E3											
O1	<b>Ontologies</b>	Research on consequences of different ontological patterns and commitments as they effect deliverable IT systems	X					X	X	X	
O2		Research on mapping and interface between ontologies	X	X				X	X	X	
O3											
T1	<b>Tools</b>	Initial toolset for feasibility study	X					X	X	X	
T2		Web 2.0 / social computing based terminology service	X	X			X	X	X	X	T1?

<sup>52</sup> Incl. Pharma

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
T3		Large scale collaborative ontology environment		X	X		X	X	X	X	T1-T2
T4		Central web based reference terminology services			X			X		X	T1-T3 <sup>53</sup>
T5											
P1	Process	Establish policy that all local terminologies will map to UMLS CUIs & LUIs	X			X			X		
P2		Establish centres for multilingual multicultural adaptation of international classifications including SNOMED		X							
P3		Establish sustainable centres for selected ontologies on basis of studies		X							P2
G1	From Genomics to Public Health	Establish collaboration with EBI and US NCBO	X	X				X	X	X	
G2		Establishment of international BioBanking collaboration on terminologies	X	X			X	X		X <sup>54</sup>	
G3		Establishment of local European centres of expertise on NCI technologies <sup>55</sup>	X					X		X	
G4											
S1	Socio-Economic Issues	Establish with European industry sustainable framework for effective standards and terminology/ ontology development		X						X	
S2											

<sup>53</sup> Requires recheck on requirements with industry.

<sup>54</sup> Pharma

<sup>55</sup> Note that the CancerGrid study at Cambridge and Oxford have already established the nucleus for such a collaboration.

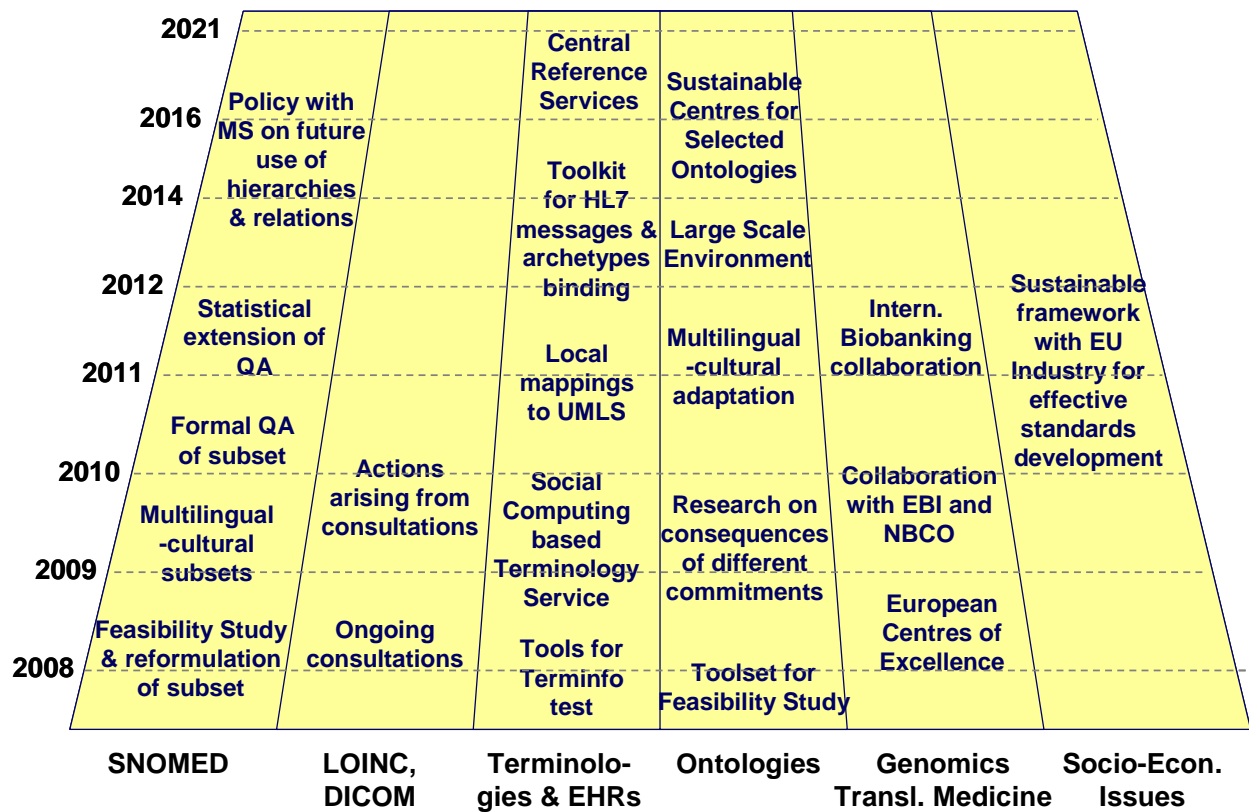
### 3.2.8 Roadmap Outline

**TABLE 4: ONTOLOGIES ACTION PLAN**

<b>Year</b>	<b>Content</b>	<b>Process</b>	<b>Tools</b>
<b>2008</b>	<ul style="list-style-type: none"> <li>• Open ICD 11 with SNOMED Mappings</li> <li>• Reformulation of SNOMED</li> </ul>	<ul style="list-style-type: none"> <li>▪ Establish Open collaborative framework for ICD11</li> <li>▪ Begin to establish mechanisms for industrial involvement</li> </ul>	<ul style="list-style-type: none"> <li>▪ Open tools for ontology development</li> <li>▪ Open Web 2.0 tools to support ICD 11</li> </ul>
<b>2009</b>	<ul style="list-style-type: none"> <li>▪ Quality assurance metrics for SNOMED Fragment</li> <li>▪ First translations of SNMED Fragment</li> </ul>	<ul style="list-style-type: none"> <li>▪ Extend industrial involvement</li> <li>▪ Establish formal collaboration with European BioBanking and EBI</li> </ul>	<ul style="list-style-type: none"> <li>▪ Develop tools for linking and binding terminologies and Archetypes</li> <li>▪ Establish open social site for clinical terminology</li> </ul>
<b>2010</b>	<ul style="list-style-type: none"> <li>▪ Continue</li> </ul>	<ul style="list-style-type: none"> <li>▪ Establish mechanisms for reformulation of SNOMED Fragment</li> </ul>	<ul style="list-style-type: none"> <li>▪ Extend and test open tools for terminology and Archetypes, possibly with inclusion of HL7</li> </ul>
<b>2011</b>	<ul style="list-style-type: none"> <li>▪ Reassess and create long term plan for selected terminologies including limits on scope</li> </ul>		<ul style="list-style-type: none"> <li>▪ Establish European Network of Terminology Servers</li> </ul>
<b>2012</b>			
<b>2013</b>	<ul style="list-style-type: none"> <li>▪ Review and reassess interoperability</li> </ul>		
<b>2014</b>			
<b>2016</b>			
<b>2021</b>			

The actions presented in Table 4 above are part of a wider set of actions in adjacent domains such as socio-economics and genomics. Key milestones for SNOMED, LOINC and Genomics as well as terminologies and EHRs are presented in Figure 2 below.

**FIGURE 2: ONTOLOGIES TIMELINE**



### 3.3 Public Health

This section of the roadmap is intended to inform policy and technical discussions about possible ways by which semantic interoperability and health information compilation at population levels could be achieved and operated on a sustainable basis for public health purposes.

Public Health, mainly focusing on population health, uses information aggregated from multiple sources. To monitor health events, evaluate interventions and assure quality of programmes linking and analysing data is critical for public health. The computerization of health information systems add unprecedented power for such interconnection and analysis based on aggregation population based data, however, this promise all depends on interoperability and mainly semantic interoperability. Semantic Interoperability is essential to benefit from the added value of digitalization of health information, such as:

- search functionality, text mining, data mining of same meaning across different records
- ability to exchange patient health information among different providers and other authorized bodies in real time,
- compute various indicators of care (e.g. quality and efficiency) in a setting, region or population,
- compiling the complete health record of an individual from multiple sources as personal health records (either based on episodes or lifelong)
- assisting providers to make fact-based decisions so better outcomes could be attained with reduced medical errors and redundant tests
- cost-effective and timely data collection for monitoring and evaluation, surveillance, clinical and service research, service.

For digital information to be merged at population level there must be specific formats that enable this amalgamation. In particular, common standards must exist for a clear description of the information content as well as information about the population characteristics. To achieve public health with digital means a coordinated set of strategic actions need to be taken over many years:

- a) **consistent use of electronic health records** as person-based health records in clinical settings - Existing computerized record systems mirror the manual way of using medical records. Each person in a given community should have similar electronic record structures so that the search and aggregation across personal records are possible for public health purposes based on identical key variables.
- b) **interconnecting health service providers** so health information can be exchanged through interoperable digital means in a standard fashion with identified formalisms - a systematic effort has to be in place with an enabling architecture (e.g. an information model, exchange and content standards) to integrate data from multiple sources and providers through with unique identifiers of individuals and other entities in the system. It should be possible to keep all data in a single digital record for each individual as a meaningful compilation of data. Similarly, each entity in the record (e.g. a diagnosis, drug, health care facility or geographical location) could be a unit of analysis provided that they can be uniquely and consistently identified.
- c) Information on **structure of populations** is available so that the methods to aggregate data across populations, health care settings or geographical units could be applied in a consistent manner. It is essential in population based statistics that the denominator population is well identified and indicators are representative of the population.

- d) **Research to prove the comparability of digital information** with analogue traditional measures used for monitoring and evaluation in various health information systems. This requires creating standards for digital processing of data and metadata to aggregate data across populations, settings or geographical units; adopting a standardized approach for representing and sharing of public health indicators (e.g. rates for mortality, morbidity, vaccinations to be expressed as public health archetypes)

The purposes of the data aggregation for public health may be manifold:

- demographic information about populations (such as birth and death rates, morbidity and disability rates and risk factors within a given population)
- statistics about health services (such as coverage of key interventions: immunization, antenatal care or patient safety: e.g. adverse reactions, errors, reporting...)
- financial (such as costs, insurance payments or resource allocations)

Given the traditional use of public health applications, such as surveillance, epidemiology and services research any function that has been performed in an analogue model could be replicated in a digital fashion. Feasibility of such replication depends on the availability of data, its accuracy, timeliness and source.

For public health purposes various use cases could be foreseen:

- 1) Digital Vital Statistics: Traditionally a major public health indicator has been the compilation of **cause of death statistics**<sup>56</sup>, based on death certificates. If electronic health records were available then this information would speed up information processing tremendously and provide public health authorities with information in real time. Death certificates, in turn, can be logically linked in many cases to patient records, from which causes of death are inferred. Similarly semi-automation, and subsequently full automation, of the processing would speed up procedures for extracting **morbidity information** straight from the patient record<sup>57</sup> itself or from the **patient discharge summary** which would itself be based on the patient record in health facilities.
- 2) Cost Analysis: Another major use case for aggregated population health data relates to administrative planning and cost analysis such as case-mix groupings, patient-flow statistics, billing etc<sup>58</sup>. Clearly, the quality and reliability of this information will depend on both the quality and usability of the source data and the quality and purposefulness of the analytical process captured in the aggregation logic. Most of this data is directly linked to coding of morbidity information in electronic health records. Having access to clinical information with adequate safeguards for protecting privacy and confidentiality would provide key information that would assist in making automated service statistics.
- 3) Surveillance systems and public health reporting: Another traditional public health function is the investigation of disease outbreaks and their reporting as well as health surveillance, monitoring and analysis<sup>59</sup>. Such systems would greatly benefit from an interconnected population based compilations in terms of screening and identifying risk groups as well as cases.
- 4) Patient Safety: Another use case is the compilation of data on patient safety events by setting or facility; or compilation of adverse drug reactions, etc further to the immediate relevance of this data for direct patient care<sup>60</sup>.

<sup>56</sup> Use case 1 in Public Health Informatics Key Informant Survey - added as an appendix. The Public Health Informatics Key Informant Survey is asking questions about the feasibility of different use cases and explores the barriers in this field. The survey results are expected to allow the users of the roadmap to better understand user needs and interpret demands regarding interoperability

<sup>57</sup> Use case 2 and 7 in Public Health Informatics Key Informant Survey

<sup>58</sup> Use case 2 in Public Health Informatics Key Informant Survey

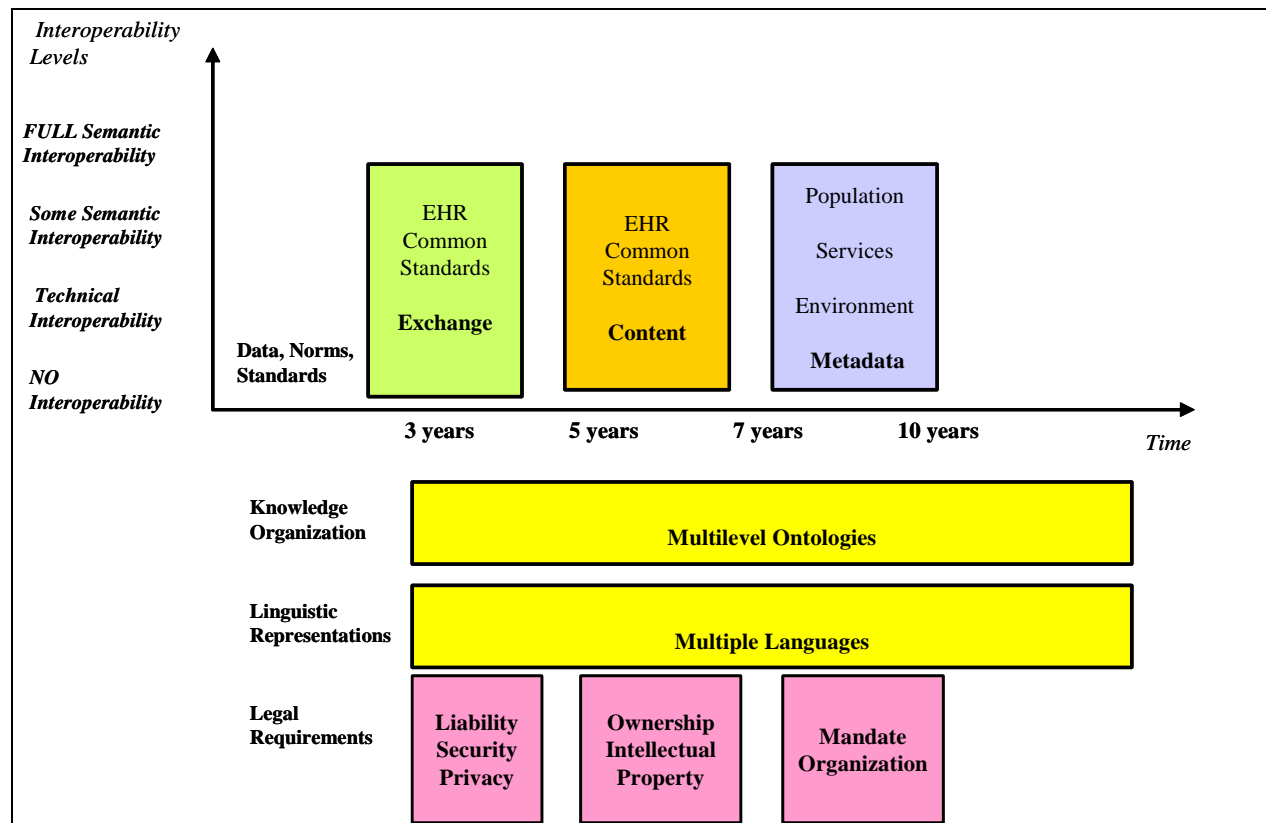
<sup>59</sup> Use case 3 in Public Health Informatics Key Informant Survey

<sup>60</sup> Use case 8 in Public Health Informatics Key Informant Survey

### 3.3.1 Short-, mid- and long-term goals

Long term vision for semantic interoperability for public health purposes relies on consistent use of common standards for electronic health records for both data exchange and content as well as identification of aggregation functions across different units such as populations, service settings or geographical units.

**GRAPH 1: GOALS FOR SEMANTIC INTEROPERABILITY IN PUBLIC HEALTH INFORMATICS**



**Requirements for semantic interoperability:** Many health information systems do not currently have meaningful health information interoperability capabilities. Moreover, the set of requirements for interoperability are not well-defined. It is known that interoperability requires a set of common standards that specify how information can be represented and communicated. On these issues, there have been considerable efforts and progress achieved by the International Standards Organization (ISO), the European Committee for Standardization (CEN) in setting the groundwork. Private sector organizations such as Health Level 7 (HL7) has developed important messaging standards, and recently by the International Health Care Terminology Standards Development Organization (IHTSDO) has converted the intellectual property of the privately owned clinical terminology standard into a multi-government owned model. Most of these efforts are consensus based standards setting organizations which have dealt with various aspects of a multi-faceted huge knowledge. However more remains to be done to achieve interoperability such as:

- interconnection tools,
- identification management,
- common web services,
- security technologies,

- mechanisms for ensuring the sustainable operation of these components on a widespread and publicly available basis.

There are potentially other requirements for semantic interoperability that may not have been identified at this time. Once the interoperability is achieved at technical level (i.e. a bit of information is exchanged) , it remains open whether the meaning of the information is similarly shared by all parties accessing the information in terms of quantity, quality and context. Semantic interoperability feature could be developed and operated in many ways. It could include state-of-the-art semantic web technologies as well as traditional controlled vocabularies and clearinghouse architectures. Operation of these elements could be centrally regulated however, given the heterogeneity of various health information systems developments, a collection of distributed regional services or a set of tools that conform to common standards is more likely to develop such as EHR common standards , common terminology and classifications and multilingual infrastructure based on ontological constructs .

**Legal Requirements:** Legal frameworks are important in terms of regulating the enabling environments through mandating public health benefits for the greater good of the populations while securing privacy and confidentiality of the individual. Intellectual property is an important asset for development of such products that could be overseen by public organizations, by private organizations, or by public-private consortia. Irrespective of its oversight or operation such standards, there is a compelling public interest for semantic interoperability. Therefore, this roadmap identified three main legal requirements how semantic interoperability could be deployed for widespread use as identified in the figure above and in the roadmap matrix.

### 3.3.1.1 Long term vision for Public Health semantic interoperability:

- To enable the common standards that will allow **data exchange on predefined key variables important for public health from individual health records**: these will conform to requirements for notification of reportable diseases (e.g. WHO list) and public health emergencies of international concern (e.g., international health regulations).
- To enable the common standards that will allow **compilation of content from individual health records**: for example disease groupings such as DRG's (diagnostic related groupings); hospital statistics; compilation of causes of death statistics
- To enable **compilation of data across populations** (e.g., number of diabetic patients in a given town); **across health care providers** (e.g., well treated diabetic patients of a clinic) or number of overweight population by geographical location.
- To enable multilevel ontologies and **linking of data across multiple care settings and link information from different sources** (e.g. linking genetic, biochemical, sign and symptom data as well as clinical and laboratory findings and general outcomes)
- To enable **comparisons of data across regions, time or populations** (e.g. international comparisons or epidemiological comparisons between age, sex and other socioeconomic variables)
- **Enabling environments to set up organizational and legal regulations** on liability, security, privacy, ownership, intellectual property as well as mandating the organization of public health informatics is operated in a **sustainable fashion**.

It is clearly up to each health information system to define their own goals, targets and priorities balancing expected outcomes and available resources. Coordination and synergy of efforts based on creation of common standards in messaging and information exchange, content and metadata standards to define populations, services and environmental variables, however, may generate significant economies of scale.

### 3.3.1.2 Target Public Health capabilities

- Standardization of **requirements** for each use case, in particular identifying key **aggregation logics** (e.g. grouping requirements for diagnosis or compilation of case-mix groups etc) and data, metadata standards and norms.
- Development, validation and adoption of unambiguous **information models**: delineation of clearly defined data categories, their ontological base and functional semantic relationships, arranged in minimum and optimum data sets within each use case specific information model.
- Verification of these information models in **multiple languages**, countries and a variety of jurisdictions, with a view to assess their relevance and practicability
- Optimizing synergies between **interconnection of key applications** (e.g. use of EHRs in clinical practice to produce international classification standards for statistical applications, as well as linkage to clinical guidelines and best practices).
- Evidence-based **documentation of underlying principles and processes**, including with a view to real-time adjustment to scientific progress and derived work hypotheses.
- **Validation of models** to convey information for meeting the expectations of all health information stakeholders, from researchers to citizens.
- **Portability / versatility of use**: Capability to use the information models across disciplines, platforms, preserving relevance and specificity allowing translational research from genetics to population parameters.
- **Development of global registries** of standardized information models and related metadata, implemented on distributed platforms ( e.g. global burden of diseases, cost effectiveness of key interventions, coverage of selected interventions such as vaccinations).
- **Appropriate metrics** for assessing reliability, validity, comparability, applicability, and cross-platform portability of proposed solutions.
- Definition of full-scale **quality assurance procedures and parameters**, to be used as global templates for any application products developed by both public and private sectors, as a reference model for national and international certification schemes.
- **Estimates of socio-economic benefits** derived from key applications (e.g. cost of key public health informatics applications and their cost-benefit ratios)

### 3.3.2 Milestones (Implementation, Deployment, Research)

#### 3.3.2.1 Base line platform

- Delineation of **interoperability requirements** for health information objects at different level of use (care facility, district level, national level, international level) that would serve aggregation of **key data across populations**. Characterization of essential features through use of multilevel ontologies, based on intended use cases as registered with reference public health authority.
- **Consensus building** between at least two levels (e.g. jurisdictions in non hierarchical relation) on proposed lists of required features (entities and relationships) for objects entering the interoperability universe, presented in a tiered manner and illustrated with concrete examples relating to at least two use case applications from local to global level.

- Establishment of distributed but fully integrated **registry system** for interoperable objects and applications for use in **public health informatics**. All registered object should have a minimum set of core features agreed by the respective constituencies at each jurisdictional level as common data structures, norms and standards. All registered applications should be based on recognized standards and preferably should be open source.
- Selection of **priority interoperability applications** for specific use cases of relevance to end users in other environments.
- **Enabling environments** and establishment of mechanisms and **legal regulations** for liability, security, privacy, ownership, intellectual property and mandates of **responsible authorities** and organizations/networks.

### 3.3.2.2 Deployment

- Validation of selected priority interoperability objects as **candidate public health informatics applications**. Quality assessment of key terminology elements and alignment on predefined characterization requirements. Elicitation of knowledge representation features matching the requirements of the registered use cases.
- Definition of priority segments of information system resources to be made interoperable. Definition of the intended levels of interoperability and adoption of the corresponding underlying information model. Awareness building concerning benefits and limits of choices made.
- Enactment on legal and organizational requirements

### 3.3.2.3 Research

- Appropriate metrics on reliability, validity, comparability of tools, instruments and indicators used in reference use-case-specific models
- Validation and quality assurance protocols on use-case specific information models,
- Identification of population norms and standards - data and metadata structures on populations, services and environmental variables.

### 3.3.3 Research priorities

- **Knowledge representation within multilevel ontologies** (cross-disciplinary, cross-language, cross-cultural meaning differentials) explicit formal inheritance rules, in a manner that is both domain specific and context sensitive
- **Operationalisation of Aggregation Logics**: Theoretical and practical development of algorithms for probabilistic management of inheritance and functional relationships such as co-morbidity, context-adjusted (similar to summary measures of population health e.g. Health Adjusted Life Years) weighing of data and their relations.
- Structuring application-specific **metadata registries** as a robust basis for multilingual instantiation of knowledge content, including through mobilization collaborative language-inference transforms. Where appropriate, development of context-sensitive context interchange mediators
- **Real-time large-scale parallel information processing** (e.g. grid technology populating distributed repositories and registries) including semantic graph processing and geo-coded data representations.

### 3.3.4 Key actors and their role

- Policymakers, health authorities and the Public: communities deciding for the greater good of the public
- Health care providers, organizations, insurance sector
- Standard Development Organizations ( e.g. HL7, IHTSDO, ISO, CEN, WHO and others)
- Industry (primarily health care ICT, e.g. W3C life sciences group, semantic web developers)
- Academic researchers, donors, foundations

**Adoption of Interoperable systems by private sector:** World wide implementation of interoperable health information technology in both the public sector and the private sectors. Use in public sector could be assured by government action whereas use in private health sector will pose problems in systems providing incentive and utility for both users and consumers. In many countries use of private sector is less regulated and there is a traditional lack of systematic health recording even in the analog health information systems. This issue has to be carefully attended in terms of regulatory measures.

What effect could the requirements for semantic interoperability have on the health information technology market at large? Could the ensuing market opportunities be significant enough to merit the investment in this area by the industry? To what entities could the benefits of these market opportunities accrue, and what implication (if any) does that have for the level of investment and/or role required from those beneficiaries in the establishment and perpetuation of a semantic interoperability?

What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

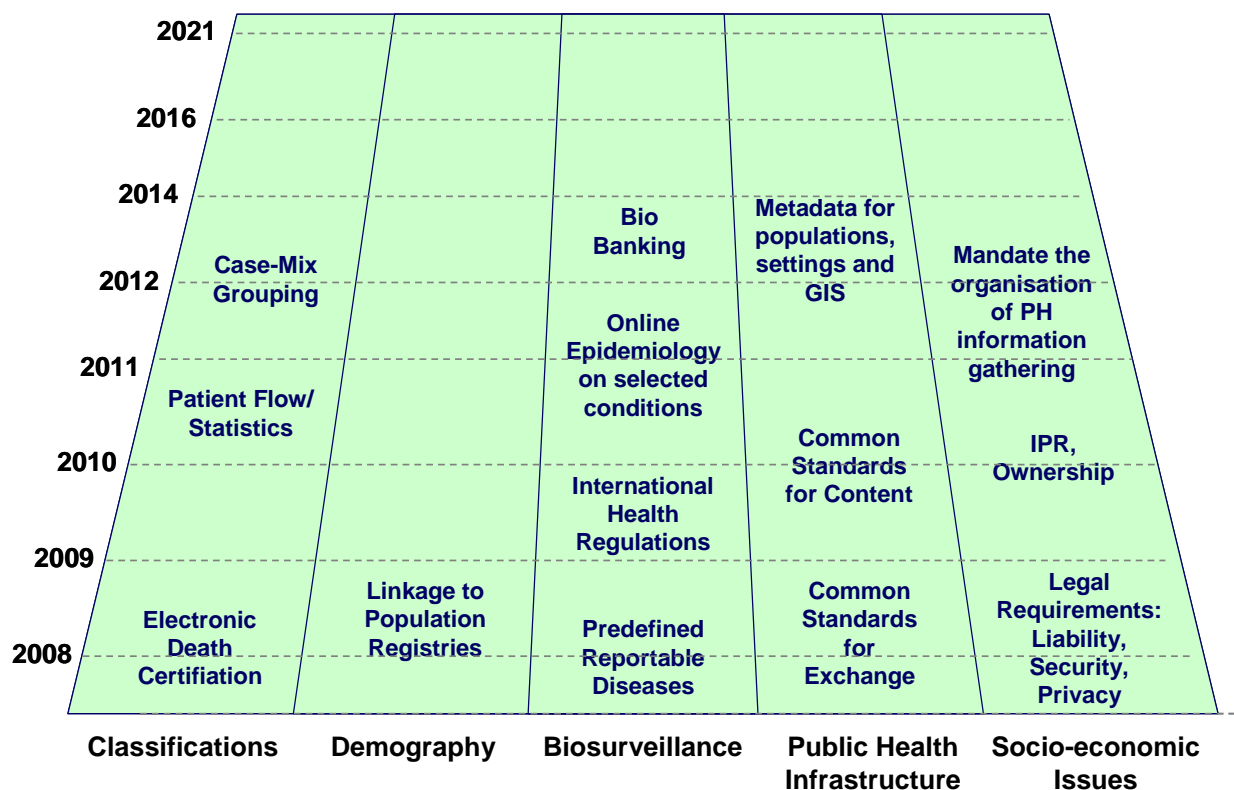
**TABLE 5: ROADMAP MATRIX ON PUBLIC HEALTH**

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
C1	Classifications	Electronic death certification	X	X		X	X	X			Country Implementation Legal framework arrangements
C2		Patient Flow Statistics		X			X	X		X	Large scale automation of individual EHR including e-prescriptions and lab data; Metadata on health facilities
C3		Case-mix Groupings		X	X	X	X	X	X	X	Large scale implementation of

	Content Tools Processes	ToDo	Time			Actors					Prereqs
			Short Term	Medium Term	Long term	Policy Makers	Health professionals	Researchers	SDOs	Industry	
											individual EHR1
D1	Demography	Linkage to population registries	X	X		X	X	X			Identity management, Legal requirements on privacy and security
D2											
B1	Bio Surveillance	Predefined Reportable Diseases	X			X	X	X			1, 2
		International Health Regulations		X							
B2		Online epidemiology on selected conditions (obesity, diabetes, depression)		X	X		X	X	X	X	Pilot applications, Quality metrics
B3		Biobanking			X	X		X	X	X	Setting standards (10, 11, 12) Legal requirements on privacy, genomics and mandate
P1	Public Health Informatics infrastructure	Common Standards for exchange	X				X	X	X	X	HL-7
P2		Common standards for content		X			X	X	X	X	WHO, IHT SDO
P3		Metadata for populations, settings and environment			X		X			X	Other information systems, registries,
P4		Geographic Information Systems	X	X	X		X	X	X	X	Other information systems
S1	Socio-Economic Issues	Legal Requirements on liability, security, privacy	X				X	X			
S2		Legal requirements on intellectual property, ownership		X					X	X	
S3		Mandate the organization of PH information gathering			X	X	X			X	

The Public Health priorities outlined in Table 5: Roadmap matrix on public health can be summarised in a timeline as in Figure 3 below.

**FIGURE 3: PUBLIC HEALTH TIMELINE**



Given the heterogeneity of multiple lines of developments and various stages of development towards an integrated health information environment, it may be useful to conceptualize the development of the semantic interoperability for public health in various stages. Most institutions and communities pass through various steps that evolve over time:

1. Most developments start with converting prescriptions to e-prescriptions, automating laboratory results and creating patient summaries.
2. At a second stage the population in a given community is organized to have electronic health records with proper identity management and possible geo coding.
3. Advanced stages include use of common standards for interconnecting services and use of messaging and content standards.
4. To achieve population and environment based data integration these records have to have a strong metadata about the population structure, services and the environmental variables (e.g., air, water, sanitation and other environmental health variables).

The developmental process across these stages depends on a number of factors that may include:

1. Cultural readiness:
  - a. Awareness - preparation - action - sustainability chain
  - b. Use of ICT in everyday life
  - c. Society adoption (availability and use of tools, locally relevant content)

2. Policy at institutional and government levels
  - a. liability, security and privacy issues
  - b. ownership and intellectual property issues
  - c. mandate and enforcement issues
3. Technological readiness
  - a. Common EHR standards - exchange: messaging
  - b. Common EHR standards - content: terminologies
  - c. Meta data about population, services and environment

eHealth Readiness refers to the degree to which users, health care organisations, and the health system itself, are prepared to participate and succeed with e-health implementation” (CANARIE report, 2002). This may involve necessary physical infrastructure; integration of current ICT’s throughout communities and government; strong telecommunications support; independent regulations with commitment to universal access, e-readiness tools available on [www.bridges.org](http://www.bridges.org). Currently no one incorporates semantic interoperability as a measurement dimension.

All of these results are collated in Table 6 below in a “Summary Roadmap for Semantic Interoperability Deployment and Research”.

This summary roadmap illustrates the interdependence of milestones in each domain, in particular between EHR development and ontologies and terminologies.

**TABLE 6: ROADMAP FOR SEMANTIC INTEROPERABILITY DEPLOYMENT AND RESEARCH**

Roadmap for Semantic Interoperability Deployment and Research										
Tools-Contents-Processes		2008	2009	2010	2011	2012	2014	2016	2021	
EHR	Reference Model	Generic Model for EHR Communication								
	Archetypes	Standardised Representation/ Sharing of clinical data structures		Care Pathways and Archetypes	Archetype/Template Authoring/Validation Tools	Best Practise Archetype Design	Quality Assurance and Certification	Archetype Repositories	Term Binding to Archetypes	
	Terminology Systems	Key Use Cases	Policies on SNOMED-CT Term coordination	SNOMED-CT subsets	Business Rules to support term coordination	Terminology Server/Term Browser for SNOMED-CT	Consistency Test HL7 Terminfo Trial Standard	SNOMED-CT global Experience Test		
	Technology/ Visualisation							EHR Visualisation Applications	Adaptable Clinical Applications	
	Socio Economic Issues	EHR/Terminology User Training	Improve Internationalisation across HC paradigm and cultural differences			Agree on Semantic Interoperability Goals for PHR		Link EHR data to educational material	Acceptance Evaluation	
Ontologies	SNOMED	Feasibility Study and re-formulation of SNOMED subset		Multilingual/ -cultural SNOMED subset	FORMAL QA of SNOMED subset	Statistical extension of QA to all SNOMED	Policy in conjunction with MS on future use of SNOMED hierarchies and relations			
	LOINC, DICOM	Consultations on issues related to LOINC & DICOM			Actions arising from consultations					
	Terminologies and EHRs	Tools/methods for Terminfo guidelines test implementation		Social Computing based Terminology Service	Policy: Local terminologies map to UMLS CUI & LUI	Generic Toolkit for HL7 messages and Archetypes binding to Terminologies		Central Reference Terminology Services		
	Ontologies	Toolset for Feasibility Study	Research: Consequences of different ontological patterns and commitments		Ontology Mapping Research	Multilingual/-cultural classification adaptation	Large Scale Collaborative Ontology Environment	Sustainable Centres for Selected Ontologies		
	Genomics/ Translational	Establish local European CoE on NCI technologies		Establish collaboration with EBI and US NBCO		Establish international Biobanking collaboration on terminologies				
	Socio Economic Issues	Establish sustainable framework with European Industry for effective standards and terminology/ontology development								
Public Health	Classifications	Electronic Death Certification			Patient Flow/ Statistics		Case-Mix Grouping			
	Demography	Linkage to Population Registries								
	Biosurveillance	Predefined Reportable Diseases			International Health Regulations	Online Epidemiology on selected conditions	Bio Banking			
	Public Health Infrastructure	Common Standards for Exchange			Common Standards for Content			Metadata for populations, settings and GIS		
	Socio Economic Issues	Legal Requirements on Liability, Security, Privacy				Legal Requirements on Intellectual Property, Ownership		Mandate the organisation of PH information gathering		

## 4. Key use cases

### 4.1 An overview

The following use cases in 5 major categories have been identified for further investigation:

#### 1) Patient Care

- Patient Safety
  - Reduce avoidable errors
  - Co-ordinate increasingly complex care ["Manage" --> "Co-ordinate"]
  - Foster evidence based care
  - Monitor good practice
  - Reduce duplication and delay
- Dissemination of best practice and integration of education and care
  - Link patient records to guidelines and care pathways
  - Link patient records to professional and patient educational resources
- Connect multiple carers locations of care delivery (at local, regional, national and international levels)
  - Support team-based care
  - Co-ordinate care between multiple specialist centres and primary care
- Empower and involve citizens - Patient centred healthcare

#### 2) Public Health

- International Statistics
- Assessment and Surveillance
- Pharmacovigilance
- Public Health Observatories
- Underpin population health research

#### 3) Research and translational medicine

- Multicentre studies and trials
- Repositories, Biobanking
- Development of personalised medicine based on genetic and genomic analyses

#### 4) Support for diverse markets

- Enabling plug-and-play best of breed
- Encouraging of European industry, especially SMEs
- Encouraging innovation

#### 5) Cost drivers (horizontal case)

- Reduce costs at all levels through improved efficiency and reduced duplication and delay

## 4.2 The use case of cross-border exchange of patient summaries: A scenario

Use cases have a well-developed rationale – they are purely examples that enable decision-makers and systems designers to design well-prepared and planned information systems<sup>61</sup>.

This use case scenario is based on the use cases developed by the Commission services in collaboration with the i2010 sub-group and will provide a practical example of the implementation of semantic services. The semantic aspect is added and discussed.

This case is relevant in the context of the Large Scale Pilot. The Pilot will propose a method of involving the users of the system/service and the health authorities in defining the use cases and the definition, the purpose of the Pilot based on the Pilot objectives, and on standards or existing recommendations at EU and international level for the two topics included in the Pilot 'EU wide implementation of eHealth services to support continuity of care: patients' summaries and ePrescription solutions.

In this LSP project a modular minimum dataset for a European Patient Summary will be defined by the participating member states in close collaboration with relevant stakeholders. The developed dataset would be made available from a national contact point in each participating country, making it possible for citizens to access from abroad.

An incremental approach will be adopted to define the content, starting with a common, agreed minimum set of data. It is noted that because data can only be held with the citizen's explicit consent, and further that the citizen can determine whether and which HCPs can see the data, it cannot be assumed that all the content of the Patient Summary will be present or be available to HCPs in all circumstances.

The current assumption of the SOS project is that the Patient Summary will hold key data such as current medications and existing clinical conditions (e.g. allergies) that will be important for HCPs attending in an emergency or unscheduled scenario to know. It does not hold detailed medical history or details of clinical condition.

The two use cases defined by the project are

- safe emergency treatment for the occasional visitor on holiday or attending a conference
- continuity of care for routine treatment for citizens living in one country and working in another<sup>62</sup>

A scenario combining elements of both use cases is presented below:

### **Use case: A patient with diabetes and chronic heart disease experiencing an acute condition which worsens while travelling abroad**

A 68 year old retired teacher visited his general practitioner (GP) to ask if it would be safe for him to travel to the Mediterranean for a four-week holiday. John had never been to the Mediterranean and planned to go on the trip with his wife who had just become a pensioner too.

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<sup>61</sup> In software engineering and system engineering, a use case is a technique for capturing functional requirements of systems and systems-of-systems. According to Bittner and Spence, "Use cases, stated simply, allow description of sequences of events that, taken together, lead to a system doing something useful". Each use case provides one or more scenarios that convey how the system should interact with the users called actors to achieve a specific business goal or function

<sup>62</sup> S.O.S. eHealth Project Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription; Project presentation by Daniel Forslund, Head of Section Swedish Ministry of Health at eHealth 2008 conference in Portoroz, Slovenia

John had been attending his GP regularly for many years. He developed diabetes 20 years ago, and was later also treated for hypertension and hypercholesterolemia. Two years ago John developed angina, and his GP made a referral for him to the local hospital to find out if heart surgery was indicated. The specialist concluded that there was no hurry for an operation. If treatment with the relevant medicine did not succeed, then John could get a new referral. However during the x-ray examination of John's heart, John developed an allergic reaction to the contrast fluid. He also experienced an atrial fibrillation for some minutes. The examination had to be cut off and therefore was not completed entirely.

The GP nevertheless encouraged John to go on holiday. He told him that the health care service where he was going was just as good as at home. The GP retrieved John's electronic health record and drug chart and gave him an ePrescription. John could then later get his drugs at the pharmacy that he needed to take along on holiday. The GP printed out a paper copy of his drug chart and gave it to him - just in case. He also explained to John what would be important for other doctors to know if he got ill. John was pleased to hear about that.

Patient summary \_\_\_\_\_

John gave the GP his approval for which categories of information were to be included in the patient summary. When the GP had completed the recording in John's electronic health record (EHR), a message containing all information needed to establish the patient summary was automatically sent to the national patient summary database. The patient summary was recorded using a reference information model, a template agreed between several countries including John's destination country. The terms recorded so as the drugs were automatically mapped against a reference terminology and following an ISO standardised structure. This will allow automatic translation, coding and integration in other national or regional Electronic Health Records. The patient summary was marked "automatic update", meaning that any new information of the relevant categories recorded in John's EHR would be automatically added to his patient summary. As a unique means of identification, John's passport number, driver licence number and national patient identifier were recorded. John chose a combination of his mother-in-law's name and his son's birthday as a password for his patient summary.

Unfortunately, when John arrived at his destination airport, his suitcase did not turn up. In his hand baggage, John had only the insulin and tablets he needed for that very day. Nor could John remember exactly the name or the dosage for all drugs that he needed. The paper copy he got from his GP was in his suitcase. It was Saturday and John could not reach his GP at home. Would the hospital back home know which medicines he was using these days? Could the local doctor or pharmacy get the information? John tried the local pharmacy first.

Patient summary \_\_\_\_\_

John was lucky. The local pharmacy at his holiday destination had access to the European patient summary network. The data stored in his Patient summary was automatically mapped on a single terminology and an automated translation was done in several languages. John gave the pharmacist his passport and the pharmacist entered John's nationality and his passport number into the patient summary system. She thereafter gave John the keyboard so that he could enter his password. Using John's patient summary, the pharmacist identified herself. As a pharmacist, she was allowed to request any active ePrescriptions issued for John. The pharmacist could read the ePrescription in local language and see the local equivalent of John's prescription that John's GP had 'written' earlier on. John got the medicine that he needed. John then obtained and paid for his medicine. Finally, the pharmacist entered information into John's patient summary about the medicine that she had dispatched. This information was also sent automatically to the ePrescription server where John's prescription was stored. The data entered was automatically mapped and translated into his Patient summary.

On the third week of his trip, however, John suddenly got a lasting chest pain that wouldn't go away even when John was resting. The hotel called the ambulance and he was brought to the hospital immediately. The examination showed that he had atrial fibrillation and ischemia. John told the specialist at the hospital that he had had an episode with an irregular pulse while he was at the hospital at home. He also said that when he was treated at his own hospital at home he had become critically ill. But John didn't know why he'd become ill or what had happened. Could it have been the drugs they had tried, the anaesthesia, or

something else? This was vital information to obtain in order to proceed effectively in trying to treat John's fibrillation and relieve his pain.

Patient summary \_\_\_\_\_

Since John had a patient summary, the holiday destination hospital specialist was able to call up the information she needed. To get the information, the specialist first had to enter her healthcare professional ID and her personal password. Then she entered John's passport number and nationality (just as John had selected at home) as the unique identifier to get access to his data. The view she saw was automatically adapted to the country of destination. The data has been mapped and translated into the local language. Moreover, the data was structured following a specific template ready to be integrated into the local Hospital Information System. The specialist created a local patient record based on the data integrated from the remote patient summary. After the possible examinations, analysis, diagnostic and treatment – all the related data were to be transferred and translated into his patient summary.

The specialist got John's fibrillation under control by medication. But there were still signs of serious ischemia. The specialist decided to send him home to his own country straightaway because John needed an immediate coronary heart operation. John was referred to a hospital with a heart surgery unit close to the destination airport in his home country. John's own local hospital could not perform this kind of service.

Preparing for the operation, the heart surgeon needed all the relevant information about what had happened to John while abroad. Had the hospital staff started with anticoagulation or another new medicine, and what "episode" was it that they were referring to two years ago at John's local hospital? They were planning an initial x-ray examination.

Patient summary \_\_\_\_\_

The surgeon logged on to John's patient summary system using his professional ID and his personal password. To access John's patient summary, he entered John's national patient identifier. He also had to state the reason for his access request. Using the patient summary he got access both to the information recorded by the specialist who had treated John on holiday, and also the information originally recorded by the GP. He could also see precisely what hospital had performed the heart examination on John two years ago, and he made a request to get access to the results from that examination. All the necessary information was integrated in the Hospital Information System when John arrived at the hospital due to the coding and unique terminology broker and the shared reference information model used by several countries.

The operation went well and John was transferred to his local hospital for rehabilitation. Two weeks after the operation he showed up again at his GP's office. The GP was already informed about John's discharge notes and patient summary and he prepared a full program of follow-up and training as well as home-monitoring. The home-monitoring platform will include wireless scale, blood-pressure, glucometer, pulse and ECG. All these monitoring devices will provide inputs into John's Electronic Health Record and will be automatically interpreted by an alert system in order to ensure compliance with the treatment and prevent future acute episodes.

## 4.3 The Use Case of Electronic Transfers of Prescriptions

### 4.3.1 Definition and rationale

The electronic transmission of prescriptions is considered to form a central 'building block' on the path towards a systematic electronic data interchange within European healthcare systems. However, like the term EHR (system), ePrescribing and the related electronic transfers of Prescriptions (system) is not a well-defined fixed term, but rather covers a wide variety of eHealth solutions all related to drugs and administering of medications.

Back in 2004, the eHealth Initiative (EHI) defined electronic prescribing as “the use of computing devices to enter, modify, review, and output or communicate drug prescriptions”. Because prescriptions are a form of transaction that very frequently interlink different health and organisational sectors many member states are opting for ICT-enabled systems of transmission as a means to reduce paper flow and make reimbursement more efficient. Given the potential benefits associated with this process, it is often placed at the beginning of a longer policy towards full deployment of national EHR solutions.

In the current large scale pilot project on patient summary and ePrescription, the two use cases for ePrescription are the following<sup>63</sup>:

- Medicine that is already prescribed in the home country will be available for dispense in another country.

characteristics: prescribing thru regular national system, notification to home country after dispense.

- A healthcare provider can prescribe a new drug to a visiting patient from another country.

characteristics: medical and pharmaceutical history from home country available, copy of the prescription included in the national medication summary.

#### 4.3.2 State of play

The current focus of ETP programmes across Europe is to provide for the electronic communication of one or more medication items that a licensed practitioner wishes to be dispensed to their patient, to a suitable community pharmacist nominated by the patient.

The Nordic countries, in particular Sweden and Denmark are frontrunners in e-Prescription activities. In Denmark ePrescriptions are today used by almost all general practitioners and more than 80% of all prescriptions are electronic. All citizens may access both ePrescription and the selected patient data using the website [www.sundhed.dk](http://www.sundhed.dk). In Sweden, a national ePrescribing system has operated for 5 years. The Swedish Pharmacy (Apoteket AB) operates a national database for all drugs dispensed to patients over the counter. From this database authorised care providers and the patients themselves can see all drugs dispensed to the patient for the last 18 months.

Countries such as France and Germany are both working currently on a dedicated eHealth infrastructure. In the German case, electronic prescriptions will use a qualified, legally authorized signature of the healthcare professional as a means of authentication. They may be transmitted to the party providing the prescribed objects by storage on a card or on an online service. Italian regulations foresee that all regions – autonomously or by using a tool of the Ministry of Economy – will electronically communicate prescriptions to the Ministry’s Agency of Income. In the Czech Republic, a frontrunner in the use of web-based patient records, the implementation of ePrescription has been widely discussed and is a distinguished part of a national eHealth roadmap.

In sum, ePrescription activities are all high on national agendas but only few countries in Europe have actually moved towards large scale implementation. Despite much rhetoric, most ETP programmes are, at this stage in their maturity, largely the electrification of existing paper systems, with little value-add.

<sup>63</sup> S.O.S. eHealth Project Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription; Project presentation by Daniel Forslund, Head of Section Swedish Ministry of Health at eHealth 2008 conference in Portoroz, Slovenia

### 4.3.3 ETP benefits and challenges

The workflow underpinning ETP resembles closely that followed currently by paper prescriptions: the paper prescription is issued by the prescriber and its life-cycle then passes to the patient to manage. It identifies the patient and prescriber, defines the medication items, incorporates any relevant pharmacy or patient instructions, acts as authorisation to dispense (i.e. it has legal weight) and provides part of the evidence used by the pharmacist to claim reimbursement.

With paper prescriptions, the patient (or a carer on behalf of the patient) can select the pharmacist they wish to dispense their medication by choosing which pharmacy they take it to. ETP programmes also incorporate mechanisms to replicate that patient choice, and in the future this is expected to be Europe wide choice. Patients are of course free not to get one or more medication items dispensed, and the original prescriber does not always know of this.

As with the paper systems, ETP messages are limited in scope to the specification of new medication items. In order to provide Europe wide semantic interoperability we need a common nomenclature for medicinal (proprietary and generic) products and packages (or, a robust mapping between those nomenclatures in use). Standard administration instructions need also to be capable of being specified in an interoperable way and to be printed onto medication packaging in the language of the patient's choice (as opposed to the language in prevalent use at the pharmacy's location). Non-standard patient instructions are often written in free text, and it is not easy to envisage how this can usefully change to something multi-lingual since such instructions are often written using words and phrases deliberately tailored to the patient.

However, the role of the pharmacist in modern health care is much richer than a simple dispenser, and is extending. In many countries the pharmacist is properly regarded as a member of the multi-professional care team. ETP would provide a series of important benefits to pharmacists and enhance their overall role and standing in the healthcare system.

Firstly, a distributed prescription service has the possibility to offer each pharmacist access to a longitudinal medication record. This enables any new prescription to be cross-checked for consistency and safety against recent and regular medications. As patients are now being encouraged to see each pharmacy more as a utility, and to "shop around", a distributed prescription service can offset the risk that this continuity and this safety value will not be lost. This does not in itself pose significant additional semantic interoperability challenges to those already addressed by making single prescriptions interoperable, other than the need for a richer privacy management architecture.

Secondly, if coupled with a real-time medical summary which includes a list of conditions and allergies, ePrescription can enhance the pharmacists role as a second line of safety to the doctor as he or she verifies the suitability of prescriptions, checking for contraindications and other risk scenarios. There are privacy concerns about this, as the relationship of trust between patients and pharmacists varies hugely (as indeed does the relationship of trust between doctors and pharmacists). However, given the desire across eHealth programmes to enhance patient choice, it would seem reasonable to permit patients to grant nominated pharmacists access to their medical summary if they wish.

Thirdly, in order to continue with and grow their role as long term care managers for their clients in diabetes and warfarin therapy, pharmacists need access to greater portions of the EHR and to be able to add to it in real time. Early evaluations suggest that these services underpinned by common care pathways and on-line clinical applications work well for patients and complements the role of the family practitioner.

In effect, the short term semantic interoperability challenges for electronic prescriptions are focussed on the common representation of medication items and dispensing/administration instructions across countries and languages. These are already in progress given the early intended deployment of ETP systems across Europe.

The medium and longer term challenges for pharmacy health records are identical to those for the EHR in general, coupled with a need for this professional group to be recognised as a key part of the multi-professional care team and empowered, with consent, to interact with the holistic longitudinal EHR.

#### 4.4 Use case for Translational Medicine and Clinical Trials

The key long-term goal is to achieve a step-change in the speed and effectiveness of clinical, experimental and pharmacogenomic research whilst respecting patients' rights to privacy and informed consent. Consider the following scenario:

*A clinical researcher is attempting to confirm suggestions both that part of the variation in response to a treatment protocol may be related to genetic markers and patterns of genomic expression, and that the risk of certain adverse events can be predicted from comparison of processed pre- and post- treatment radiographs.*

*The researcher is registered with the one of more international repositories and portals and through their authority has automatic access to fully anonymised pooled information derived from pseudonymised records. All information has been either reported directly in standard EHR and terminologies, or has been extracted from text into these standards, so that it can be communicated easily. Where differences in information models and terminology persist, mediation services make the conversions transparently without the clinical scientist needing to be aware of them unless he or she wishes to "drill down" to examine the data in more detail.*

*Query results are presented in generated outline-style natural language that the researcher finds easy to read and use. Filtered links to Pubmed, Cancer Net, NICE and Cochrane, along with links to the genomic literature provided by specialist tools, Google Scholar, and national library resources are found automatically. Scientific workbench software dynamically builds a browsable dossier of current mainstream and grey literature linked to the electronic healthcare records of the patients under review.*

*Not all data is strictly comparable, but standard ontology management tools allows decisions to be made concerning which items can be safely aggregated for preliminary analysis — the clinical equivalent of an "in-silico" experiment. The researcher applies to the Repository Oversight Authority for more detailed access to individual pseudonymised records for selected cases. In parallel the researcher contacts networks of clinical and molecular biologist colleagues involved in relevant virtual e-Science communities.*

*A study is quickly formulated, largely from existing protocols, possibly using existing workflows from social sites such as myExperiment<sup>64</sup>, and is sent to the ethical committees for fast track approval. Eligible patients are quickly identified and recruited via the repository and quickly traced to their originating institution and clinician who may then contact them for possible recruitment to the proposed trial.*

*The geneticists, meanwhile, note that a related effect is known in an animal model, and link to the resource other web resources to follow up the detailed molecular biology across the range of genomic and proteomic resources.*

*The early results of the clinical study indicate that these radiographic and genetic markers are relevant, and the information is added to routine clinical guidelines which are widely*

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<sup>64</sup> <http://www.myexperiment.org>

*disseminated through the links to NICE, the Cochrane Collaboration, and the Cancer Networks. It is also arranged that the relevant image processing and information extraction from the radiology reports be available in real time for clinic use — an application which requires more computing resources than NHS hospitals would normally have at their disposal — and which is therefore arranged to be performed via the an international HealthGRID, which uses the same standards for semantic interoperability as the other resources.*

## 5. Horizontal issues

### 5.1 General socio-economic issues

Full SIOp cannot be captured in binary, either/or conditions. We can have partial SIOp with (here simplistic) parameter values such as ‘a little’, ‘some more’ and ‘a lot of’. In this setting, and given the already identified challenges in achieving higher levels of SIOp, the horizontal issue of socio-economic aspects related to SIOp can be summarised by the questions: “What is the optimal, or desired, level and degree of SIOp?” “How much SIOp do we need?”

The answers very much depend on the point of view of the person answering. A researcher, desperately searching for vast quantity of data will probably plead for maximum SIOp, regardless of any side effects. Someone who has the job of data input, and whose task would become more demanding without any extra personal benefit will have an incentive to ask for as little change as possible, even if this means no SIOp at all. For the purposes of the SemanticHEALTH project, we have to consider all possible perspectives together. In economics, this is called the perspective of the ‘social planner’, usually represented by a government or another policy making body.

The model for analysing the socio-economic impact of SIOp developed in WP3 allows researchers and decision makers to address exactly these issues. It provides a framework for identifying the ‘optimal’ level and degree of SIOp from the point of view of society at large, as well as facilitators and barriers to individual stakeholders. The model is suited to include relevant regulatory, legal, and ethical issues into the analysis, thus accounting for these non-trivial aspects of health services and utilisation of semantically interoperable solutions in particular.

In the following sub-sections, we first provide a brief summary of the model itself, and then focus on specific issues and recommendations at the high, policy and organisational level, as well as the critical implementation level, including stakeholder involvement and change management issues.

### 5.2 Costs and benefits of SIOp

The costs of improving SIOp among technical solutions and, more importantly, among the people involved health services including treatment, research, and public health, relate to analysing and addressing the following issues and questions. The first five themes relate to the implementation of SIOp, whereas the rest of the issues concern the utilisation of SIOp. Utilisation of SIOp, by which we mean the actual collaboration between professionals from different disciplines, organisations, and countries, is critical to the realisation of benefits from SIOp and thus deserves particular attention.

- To begin with, we need to know where we are on the money versus SIOp chart. Similar to the fact that SIOp is a matter of degree (at least at the present moment), to what degree have existing terminologies, classifications and ontologies been integrated to allow for the envisaged degree of SIOp? Working this out requires certain analyses that come at a certain cost.
- What options are available to strengthen (even enforce) political cooperation, especially on the health policy layer? Most ministries have a small team of people and commit resources without a coherent framework. Coordination of these often disparate activities requires appropriate allocation of working time, which is a cost measured in Full Time Equivalents.

- The translation and localisation of terminologies (such as SNOMED) are key to adoption in all countries. Who is paying for the initial service? Terminologies are a dynamic, constantly changing environment; who will take care of the continuing maintenance processes and costs? How large will that contribution have to be, initially and on an ongoing basis? Translation and localisation thus comprise another cost item deserving a prominent place in the cost function.
- To allow SIOp, technical standards and detailed specifications have to be created, implemented and maintained. These are the pre-requisites of SIOp levels L0 and L1. Who pays for these additional costs to allow for seamless connectivity? And again, how much is to be paid?
- Industry involvement is crucial to the deployment of SIOp capable products in health. SIOp and market shares can't bind the customer. There are too many competing initiatives and whoever manages to deploy his standard first gets the big cake. This competition soon becomes a source of unproductive waste, so an effort is required to minimise this waste. This effort will be a cost factor.
- One of the key aspects in enabling SIOp is change management. How can we influence and support this matter, especially provide system thinking and optimise the care process? Additionally, changing the culture of healthcare is necessary to make the interoperable EHRs and other shared resources part of that culture. Training and education has to be adapted to meet the new challenges in providing SIOp. Evidence suggest that change management can comprise up to 40% of total eHealth investment costs<sup>65</sup>, most of which related to assuring utilisation conform to SIOp requirements.
- What are possible (and in particular the right) incentives to those who will have to do the additional work? How much additional work is involved to allow for partial (full) SIOp? And who will most likely do the additional work: industry to implement SIOp, medical staff to provide metadata to allow SIOp and later use SIOp solutions, researchers to define SIOp? The additional work will have to enter the SIOp cost function in a complex way, accounting for all these possibilities.
- All participants in healthcare services have diverse responsibilities and interests. Currently, data collection is goal dependent, which restricts the opportunity for re-use and associated synergies. Typical examples of this aspect include the collection of clinical treatment data that is often different from treatment data for invoicing. The harmonisation of data collection practices will accordingly be a notable cost factor.
- What does SIOp mean for practitioners? Initially, it means that they (or their staff) have to do a lot of data entry for the benefit of others. Will a registration dividend affect the business models within healthcare? There is no immediate benefit for the local doctor to spend extra time, costs and effort to support SIOp. Only if the medical community as a whole embraces the idea of SIOp and collaborative working practices, and agree to take on the additional work, will SIOp become a success for the individual. Overcoming this barrier does not necessarily involve (although it can) direct expenditure, but necessarily comes at a cost – even educational work, explaining the situation and the size of benefits to come involves effort that can and must be measured.

The benefits expected from SIOp relate mainly to the speed and consistency of, and timeliness of access to meaningful data. Thus, these are the themes determining the success of SIOp and the benefit curve in a benefit-to-SIOp diagram. The following is a list of issues that should be included in the benefit function that defines the SIOp benefits curve:

- The usability of SIOp systems is a key aspect in assuring acceptance by medical staff. SIOp has to facilitate transparency. Ideally, the users do not explicitly notice the

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<sup>65</sup> based on the eHealth IMPACT study: <http://www.ehealth-impact.org/>

extra effort needed to comply with the SIOp guidelines and have the feeling that they have **less work and maybe more time to spend** with patients or family.

- The use of SIOp applications has to lead to a **decrease in reaction time to global threats such as pandemics**. Global pandemics are considered a valid threat anytime soon and only by utilising SIOp based collaboration can we successfully fight the coming challenges.
- SIOp ensures that each doctor, or other medical personnel across discipline boundaries, reads and interprets patient information as well as clinical findings, treatment directives etc. in exactly the same and consistent way. This explicitly includes the conversion of information between different systems and countries (language) and the associated **efficiency and access gains**.
- The collaboration between different treating institutions is largely improved due to the availability of semantically relevant information. Doctors are able to share their results seamlessly and **avoid duplicate investigations**.
- The integration of the individual patient into the care&cure process is of utmost importance in reaping the full advantages of SIOp. Homecare, responsibility, ubiquitous access to health values need the help of the informed patient and close communication with the medical staff. SIOp aimed at the patients improves the doctor-patient relationship and is critical in strengthening the role of the patient in improving health services.
- Applying SIOp concepts to the daily tasks of medical staff will ultimately lead to faster implementation and adoption of new treatment guidelines. Although this is needed immediately, results will only be visible once SIOp applications are used and applied for some time.
- Further benefits from SIOp are derived from being able to use richer clinical detail in electronic records for the purposes of classification, leading to improvement and greater confidence in information used for audit, planning, and performance management. Here too, the shape of the benefits curve will be affected by the speed of uptake of SIOp and the scale effects that result from this.<sup>66</sup>

The above presented issues and considerations provide a starting point to an assessment model based on Cost Benefit Analysis. The consensus in the eHealth community, and practitioners do not seem to oppose it, is that the benefits from properly utilised SIOp will exceed the costs, at least on a society, or system level. Thus, we are looking at a benefit function that is eventually above the cost curve on a money-against-SIOp diagram.

The following table summarises the expected benefits and costs for the three different areas of application analysed by this project, elaborated into the four purposes of information use described above, which correspond to work packages 4 to 6.

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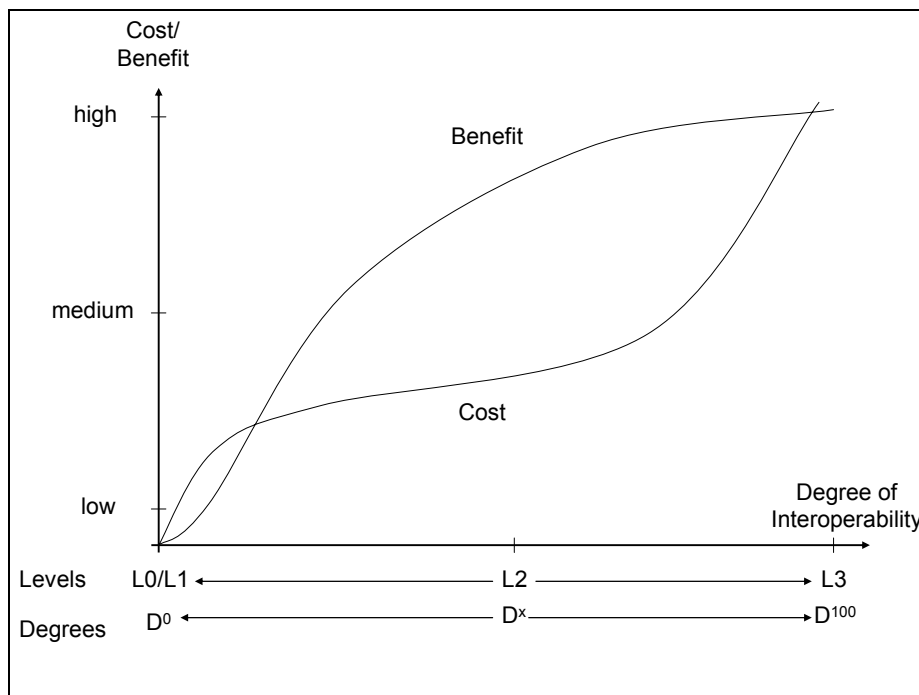
<sup>66</sup> A more comprehensive list of the benefits of semantic interoperability is presented in chapter 3 of the Canada Health Infoway 2005 report: EHR Semantic Interoperability Benefits.

**TABLE 7: SUMMARY OF COSTS AND BENEFITS FOR VARIOUS LEVELS AND PURPOSES**

Information Reuse for	Purpose 1: minimal data set purposes	Purpose 2: direct patient care purposes	Purpose 3: public health purposes	Purpose 4: research and knowledge sharing purposes
<b>Level 0</b> No SIOp ( $D^0$ )	n/a	n/a	n/a	n/a
<b>Level 1</b> No SIOp but Technical IOp ( $D^0$ )	Initial Cost: <b>L</b> Initial Benefit: <b>L</b>	Initial Cost: <b>L</b> Initial Benefit: <b>L</b>	Initial Cost: <b>L</b> Initial Benefit: <b>L</b>	Initial Cost: <b>L</b> Initial Benefit: <b>L</b>
<b>Level 2</b> Partial SIOp with varying degree of SIOp ( $D^x$ )	Added Cost: <b>M</b> Added Benefit: <b>H</b>	Added Cost: <b>M</b> Added Benefit: <b>M</b>	Added Cost: <b>M</b> Added Benefit: <b>H</b>	Added Cost: <b>M</b> Added Benefit: <b>M</b>
<b>Level 3</b> Full SIOp ( $D^{100}$ )	Added Cost: <b>H</b> Added Benefit: <b>M</b>	Added Cost: <b>H</b> Added Benefit: <b>H</b>	Added Cost: <b>H</b> Added Benefit: <b>M</b>	Added Cost: <b>H</b> Added Benefit: <b>H</b>

The specific shape of the curves is essential for constructing a complete picture. Different shapes have different consequences regarding recommendations for further activities. Given the assumptions made, the resulting benefit and cost curves will be shaped as illustrated in Graph 2 below. It clearly shows that very low levels of SIOp are associated with costs that are higher than the benefits, making it very unattractive for consideration. However, the more SIOp is being achieved at slowly rising costs, the higher the benefits are until we reach a stage where the cost increase dramatically and the benefits changes are negligible.

**GRAPH 2: COSTS AND BENEFITS OF SIOp**

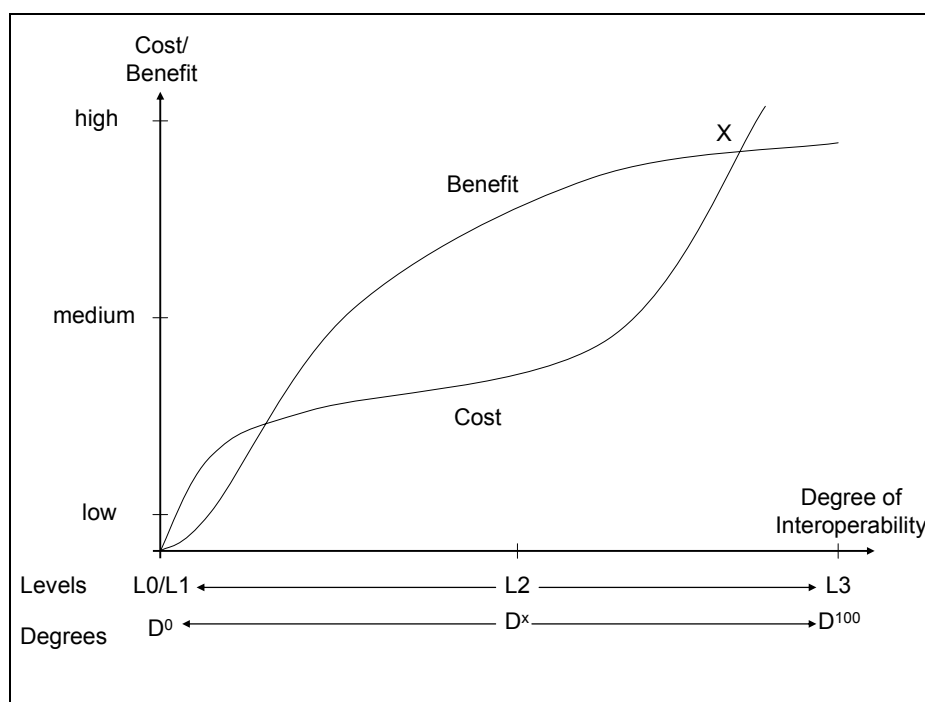


A distinct and very important potential feature of SIOp becomes apparent – until a certain degree of SIOp is reached, the costs are higher than the benefits. This would have four implications:

- a) If the degree of SIOp at which benefits exceed costs cannot be reached, there is no case for working towards SIOp at all;
- b) The mathematically calculated optimal degree of SIOp must be higher than the point of intersection of the two curves in order to be an optimal point from an economics point of view;
- c) Every effort should be made to reach the optimal point as quickly as possible, in order to minimise the time during which a negative net benefit is accumulated, i.e. the time during which costs exceed benefits;
- d) As soon as the optimal point is being reached, the increase of costs to provide significant benefit changes is economically not desirable.

All numbers and curves in the previous diagrams are purely theoretical and lack any thorough foundation due to the many unknown factors and influences which need further research. As a result, a picture depicted in Graph 3 below is another hypothesis, where the costs and benefits curve cross before they reach the highest degree of interoperability. In such a case it is economically not feasible to further force an increase in SIOp as the costs would outweigh the benefits.

**GRAPH 3: COSTS AND BENEFITS OF SIOp – OPTIMAL DEGREE (1)**



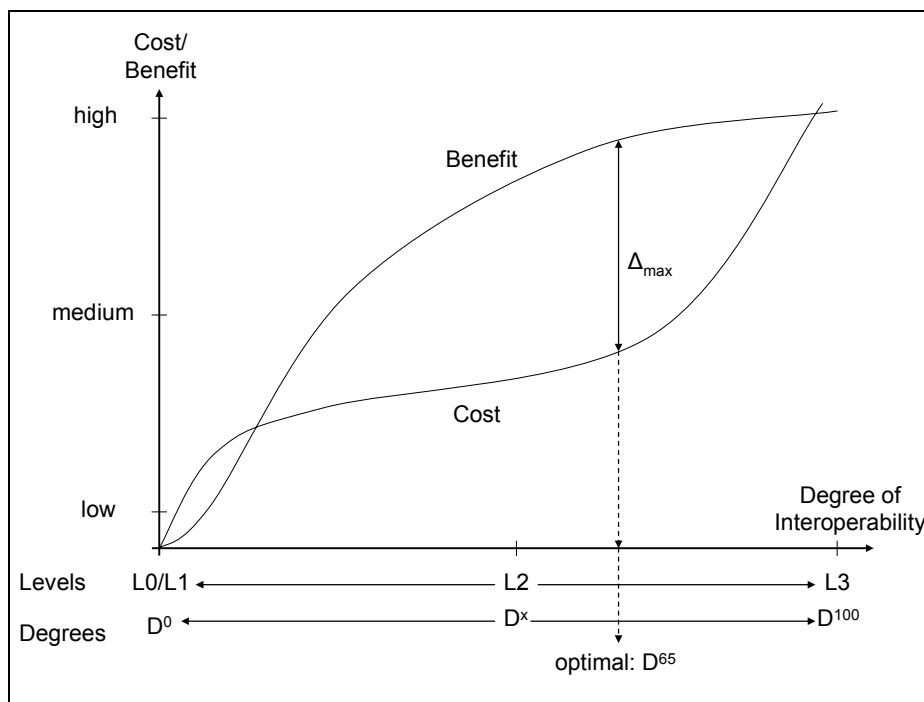
**The optimal degree of SIOp**

Given the model presented above, we are now in a position to give some insights on the optimal, or desired, level of SIOp that we should aim for. As already indicated, the optimal degree is not simply where benefits are largest. Neither is the case that we should want more and more SIOp as long as the total benefits exceed the total costs. It is the marginal

costs and benefits that are decisive. That is, the additional costs and benefits associated with one extra 'unit' of SIOp. Using the above assumed graphs for costs and benefits, we can clearly identify the optimal degree of interoperability. In the case of Graph 4 (see below), this would be the point where the difference between the costs and benefits graph is highest, in our example at around 65%.

**(Important Note:** It is important to note again that the given numbers are exemplarily in order to demonstrate the above given analysis. The specific number of 65% is in no way accurate, meaningful or even validated.)

**GRAPH 4: COSTS AND BENEFITS OF SIOp – OPTIMAL DEGREE (2)**



The rationale behind the idea is that as long as it costs less to increase the provision of a service, in this case SIOp, by one 'unit' than is the value of the gain from that same 'unit' extra service, it makes sense to provide it. If the marginal cost exceeds the marginal benefit, then the money is better spent elsewhere.

In economics, "the margin" is a guiding concept of solving optimisation problems. The marginal cost is the change in total cost resulting from increasing output by one unit. In other words, it is the cost of providing one more unit of output. Similarly, marginal benefit is the change in total benefits from increasing output by one unit. The rationale behind marginal costs and marginal benefits is that they define the optimal level of output.

Imagine the following example that illustrates the concepts of marginal cost and marginal benefit:

**Example:**

A local pottery produces 100 coffee cups every month. The marginal costs are the extra costs to increase the output to 101 cups. Let us assume that these additional costs are 3 euros. Once the output is 101 cups, the marginal cost of production will be the extra cost to increase the output to 102 cups. This time, the marginal cost may be 4 euros, because the firm has to buy an extra box of paint. The 103<sup>rd</sup> cup will cost an extra 5 euros.

Output	100 cups	101 cups	102 cups	103 cups
Marginal Costs		€3	€4	€5
Total Costs	€100	€103	€107	€112

Similarly, there is an extra benefit by increasing the output from 100 cups to 101 cups, or from 101 cups to 102 cups. Let us assume that the marginal benefit from the 101<sup>st</sup> cup is 5 euros (e.g. the price for which it can be sold). The 102<sup>nd</sup> cup can only be sold for 4 euros, the 103<sup>rd</sup> for 3 euros.

Output	100 cups	101 cups	102 cups	103 cups
Marginal Benefit		€5	€4	€3
Total Benefit	€250	€255	€259	€262

If the company produces the 101<sup>st</sup> cup, it will gain an extra benefit of 5 at an extra cost of 3 euro. This leads to a net benefit of 2 euro, so it is worth increasing the output to 101 cups. The company should increase output for as long as the extra benefits exceed the extra costs of doing so. If the company produces the 102<sup>nd</sup> cup, it will gain 4 euros at a cost of 4 euros. This is where the company is indifferent to changing the output, i.e. it does not make a net gain, but it does not make a loss either. The 103<sup>rd</sup> cup will generate a net loss – it creates additional costs of 5 and a benefit of only 3 euros.

Output	100 cups	101 cups	102 cups	103 cups
Total Benefit	€250	€255	€259	€262
Total Costs	€100	€103	€107	€112
Marginal net gain		€ 2	€ 0	€ -2
Net Benefit	€150	€152	€152	€150

An output of 102 cups in this case is optimal because: If reduced to 101, the extra benefits exceed the extra costs, so it will be beneficial to increase output. If increased to 103 the extra benefits are less than the extra costs, so it is beneficial to reduce the output.

Mathematically, the marginal cost and benefit curves (functions) are the derivatives of the total cost and total benefit curves (functions) respectively. On a money-against-output chart, the optimal output is defined by the crossing of the marginal curves. This is where the difference between total costs and total benefits is largest. If the output is less, the total net benefit (benefits minus costs) will be less because the lost benefit from producing one unit less is more than the costs saved. If the output is increased, the total net benefit decreases again, because the extra costs exceed the extra benefits.

On the basis of the presented analysis, we now turn to specific roadmap recommendations concerning the horizontal issues of socio-economic aspects, including organisational, cultural, legal, regulatory, ethical, and other barriers.

### 5.3 Policy and organisational issues

Policy and organisational issues include two broad categories:

- Recommendations on further work to convert this Cost Benefit Analysis (CBA) model into a realistic and pragmatic tool facilitating policy and other decision making.
- Recommendations stemming from first generic observations based on the presented model.

#### 5.3.1 Recommendations for development of the CBA model

The foremost task in establishing a roadmap for semantically enabled collaboration between professionals in the field of medical treatment, surveillance, and research is the thorough definition and detailed set up and description of a dynamic model for analysing the costs and benefits from SIOp. As mentioned in this document, the earlier given cost and benefit curves are solely for demonstration purposes and are not based on any statistical data. It is strongly recommended to address and include the following issues in the process of model creation. The following issues shall be also considered for the final roadmap:

- The shape and position of both, the cost and the benefit curves, should be analysed after sufficient data on the factors affecting them is gathered. Ideally, the mathematical functions defining the curves will be calculated on the basis of a sufficiently large data set processed by econometric techniques.
- The model has to be further developed to account for the dynamic nature of SIOp. Introducing a time dimension is a challenge, yet not impossible.

Health Information Systems – and in particular Electronic Health Records – are a highly dynamic system in a constantly changing environment. This should be reflected in the CBA model.

As part of the process, the following issues need to be addressed:

- The size of investment and potential return on investments (as presently assumed) are solely based on imprecise estimates. A more thorough investigation is recommended to provide an empirical basis and rigour to the CBA model.
- The current problem space is not sufficiently detailed in many aspects including objectives, timelines, language/cultures and dissimilar health systems. Especially the issue of highly heterogeneous language/cultures and varying health systems among the EU Member States is of utmost importance and needs to be discussed in order to be included in the model. This affects mainly the cost curve.
- The issues around legal liabilities, imprecise representation of terminological knowledge are currently unknown and need further investigation. On the one hand, legal and regulatory uncertainty poses a risk, which affects the cost curve. On the other hand, SIOp may help reduce the risk of unsafe expression and/or derivation, which will have a positive impact on the benefits curve.

#### 5.3.2 Recommendations on the basis of the CBA model

The successful definition of the CBA model is the basis to find the optimal degree of SIOp as described in this document. It is important to mention that it is expected that the optimal degree of SIOp is not equivalent to the maximum level of SIOp. Although maximum

interoperability is often considered to be the ideal situation, initial considerations do not support this idealistic view. **The future technical and organisational developments should be guided by the results of the CBA, and in particular the estimation of optimal degree of SIOp.** The following issues are important in this context and should be addressed in the final roadmap recommendations, at least as issues to be further investigated with the support of the CBA model:

- What impact do the initial observations on the basis of the CBA model have on the desired end-point of the SIOp roadmap? Is the proposed path viable and achievable within the given timeframes? Where do we have to adapt and correct in order to make semantic interoperability possible within the given boundaries?
- The synchronisation of implementations and maintenance of SIOp solutions, initially within institutions, but subsequently within regions and nations, is complex but necessary. Semantic interoperability comes at a cost, initial as well as continuous. This cost has to be covered by the various stakeholders. The CBA framework allows allocating this burden in an efficient way.
- There has been a long standing argument whether SIOp is better achieved by a single (centralised) national centre or developing institute or a network of (decentralised) collaborating centres. Solutions and recommendations will be better justified with the help of the above mentioned CBA model and results thereof. The CBA analyses allow direct comparison of these and other options.

## 5.4 Stakeholder involvement, change management

Stakeholder involvement and change management are critical to the success of the activities towards SIOp. It is understood that developing the CBA model and providing recommendations on the basis of it are only initial, but highly important steps on the way to defining the SIOp roadmap. The above described CBA model can help to provide a basic cost benefit analysis for each stakeholder, which can be used as a foundation for further more-in-depth investigations and analysis of private (individual) incentive structures. Looking further into the future, it is important to understand and take into consideration the workflow and daily routine of medical personnel and to suggest incentives for a successful and sustainable deployment of the roadmap. **The core of the recommendation is to undertake a thorough investigation of incentives for development, implementation, maintenance, and utilisation of SIOp based collaborative practices.** The following questions illustrate the issues to be considered in such an investigation:

- What are the legal restrictions on recording/exchanging certain types of information?
- What are the incentives for the person who enters the data? When are these incentives visible to the person? Are these personal, institutional and or moral/ethical incentives?
- What are the short and/or long term impacts on the existing business/clinical/working practices affecting the stakeholder in question?
- Are effective data entry technologies available to support the techniques described in the roadmap? Are such technologies user-friendly? How do the acceptance and learning curves among the medical community affect the potential and actual further development and uptake in the field of SIOp?
- What effects might the various languages and cultures among the Member States have on the sustainability of SIOp based practices?

In order to ensure sustainability of the SIOp developments, continuous cooperation among stakeholders, and thus realisation of benefits over time, individual (private) incentives have to be understood and if necessary adjusted.

## 5.5 Legal issues

### 5.5.1 Semantic Interoperability for Privacy Management

In addition to the structural and semantic interoperability challenges discussed throughout this report, citizens' rights to privacy and clinical obligations to respect confidentiality must be managed well in order to grow public confidence that the wide-scale sharing of EHRs and the re-use of EHR data for quality management, public health, research and educational purposes can be trusted and welcomed.

There are many technical security standards that have been implemented, commercialised and adopted to provide good protection of information assets and of various communication modalities. These include keys and certificates, PKI, encryption algorithms, disk and database protection to give but a few examples, and have made e-commerce, e-banking, online retail and digital music purchase an everyday reality.

Almost every national eHealth programme incorporates a security architecture that resembles those used across industry, including demographic registries of patients and healthcare staff, digital certificates for authentication and authorisation, encrypted communications and security policies to manage information assets. The programmes each propose some kind of role based access control, mechanisms for selectively labelling health record information with some marker of sensitivity, and a means for providing citizens or patients with a decision making influence on the access rules pertaining to their data, occasionally going as far as consent directives.

However, unlike the other examples from industry, the greatest challenge for managing confidentiality in e-health at a national scale is the complexity of defining which individuals and systems ought to be permitted to access and perform what operations on the personal health data of each citizen or on populations of records. Expressed in terms of roles, for example, the problem is not how to implement the architecture (ISO TS 22600 defines this) but what roles to define, how to map staff to roles, how to classify EHR data from a confidentiality perspective and how to map that classification to the defined roles. EN 13606-4 provides a basic framework, but this is only a starting point for any national solution.

So far, no health record permissions framework has been demonstrated at a large scale. Although small pilots have worked, the classifications and their granularity have each been different. In effect, the eHealth privacy management challenge is now primarily a semantic one: how to define a suitable and scalable set of person, role and sensitivity categories that can be adopted universally - i.e. semantic interoperability for privacy management.

Regrettably, this problem is too poorly understood, only naively specified in most national programmes, and can draw on too little evidenced success to be solved quickly. Best practice is most likely to emerge piecemeal from across the national eHealth programmes.

### 5.5.2 European Data Protection regulations

The key principles relevant to the processing of personal data were first established by the Council of Europe and further developed in Directive 95/46/CE of the European Union – the European Data Protection Directive. The latter is the major source of legislation, although the Recommendation made by the Council of Europe is also of importance for the healthcare sector since it focuses on the field of medical data and scientific research.

The Directive provides a general framework for the protection of privacy with respect to the processing of personal data in its widest sense. It is important to note here that the Directive is based on the privacy of processing of data, not privacy per se. Thus, the Directive does not confer any special rights of privacy of an individual which might be covered in a Member

State's constitution, but rather it provides rules about how personal data may be processed so that the processing itself does not infringe the privacy of an individual. Within the terms of the Directive a suitable level of privacy is to be afforded to all data related to a natural person, whether the context of such information is the private, public or professional life of the individual. The Directive thus goes beyond the concept of private life and intimate detail.

The primary purpose of the Directive is to allow the free flow of personal data between the Member States of the European Union, in order to facilitate the establishment and the functioning of the internal market, while its secondary purpose is to protect the fundamental rights and freedoms of natural persons and in particular their right to privacy with respect to the processing of their personal data. The protection granted by the Directive does, however, go further than the protection of the natural person's intimacy, i.e. generally speaking the protection of each natural person private life. It applies more particularly to any sensitive data relating to natural persons such as data concerning health -including mental health.

It is known that inconsistencies in the application and interpretation of the Directive in national legislation, also with respect to processing of medical data exist. Furthermore, the Article 29 Working Party recommendations are likely to generate further legislation/regulation at a national level to regulate EHRs, but such legislation is very likely to be based primarily around national strategies and is unlikely to support EU-wide use of EHRs or interoperability.<sup>67</sup> While this is due to some significant part to the structure of the Directive, such a non-harmonised approach would be a particular concern for healthcare stakeholders seeking to operate across European borders.<sup>68</sup>

## 5.6 Cross-language and cross-cultural aspects in an European dimension

A major expression of Europe's cultural diversity is the co-existence of numerous languages. To support this variety on the one hand and to bridge the cultural and language gaps on the other hand are essential desiderata in the process of European integration. Many efforts have been done to reduce language barriers the increasing number of bi- and multilingual European citizens bears witness of.

If discussing semantic interoperability in the European health sector context, cross-language issues play a predominant role as long as natural language remains the major carrier of health and biomedical information.

### 5.6.1 The role of English

The choice of a natural language for a given purpose depends on the language users, the subject matter and the application context. Amongst all official European languages, English plays an exceptional role as the (unofficial) lingua franca for science and business communication all across Europe:

- English dominates the biomedical basic sciences, which are characterized by a tremendous growth of knowledge and terms. In areas such as molecular biology, genomics, or proteomics, there is virtually no original research published in languages other than English. A major part of the terminology remains untranslated, and the availability of non-English textbooks and online resources is very limited.

<sup>67</sup> The Working Party has been established by Article 29 of Directive 95/46/EC. It is the independent EU Advisory Body on Data Protection and Privacy.

<sup>68</sup> Workshop results from the EUROREC Workshop on Primary and secondary use of EHR: Enhancing clinical research, Brussels 11th and 12th of October 2007, <http://www.eurorec.org/EHRWorkshop/index.cfm?actief=EHRWorkshop&selection=Prereads>

- In clinical research disciplines we observe a similar tendency, although there is still a considerable amount of original research being published in the national languages, especially in relatively large linguistic groups, such as French, German, Italian.
- Knowledge translation activities that address the delivery of new evidences to medical practitioners and laypersons mainly employ the local languages.
- Health care records are generally kept in the local language(s).

Accordingly, English language skills largely vary between the stakeholders in European health systems.

- Most Researchers all across Europe are used to read, write and speak English, often in daily routine.
- Physicians and managers are generally able to read English, but their profession seldom requires to write and to speak it on a regular basis.
- The English language skills of paramedical and administrative staff, as well as of patients vary to a great extent between countries. Only in a minor part of continental Europe (e.g. the Netherlands and the Nordic countries), good English communication skills can be taken for granted for a majority of the population.

The use of English as a lingua franca of medicine is less pervasive as it often seems. The increasing use of untranslated English terms and abbreviations (*bypass*, *beta blocker*, *AIDS*) that invade even everyday discourse among laypersons is not paralleled by the importance of English in the health sector outside the narrow realm of research.

### 5.6.2 The role of the neighbour's language

Border regions with a long tradition of cultural and economic interchange are characterized by a higher proportion of persons able to communicate across language borders without using a third language. This tendency has been fostered by the educational systems involved, at least where the languages under consideration are significantly different, such as German and French. In other cases, inhabitants of border regions hardly ever learn the neighbour's language at school but are able to communicate due to the similarity between the languages. Examples are Danish / Swedish, Spanish / Portuguese, Slovene / Croatian. These foreign language skills are however limited to oral communication and the summary reading of texts but do hardly ever include the ability of writing correctly, thus severely hampering the effectiveness of content search and retrieval.

### 5.6.3 Multilingualism affecting the quality of healthcare delivery

Language barriers matter in many scenarios of the health delivery process.

- Bilingual environment: It can be generally assumed that the official written language is also – by convention or legal requirements, the language of the health records. Multilingualism matters where more than one official language exists, such as in some regions in Spain, Italy and Belgium (e.g. Spanish – Catalan, Italian – German, French - Dutch). In these cases a medical record systems may contain texts in different languages.
- Foreign health professionals: The migration of health professional has been grown due to the evolution of the European job market and local and regional imbalances. Health professionals working abroad are obliged to read and write the local idiom. Exceptions may be allowed with very similar languages in the same language group, e.g. Czech and Slovak.
- Migrants: Working immigrants from inside and outside Europe, asylum seekers and their families often are unable to communicate with health professionals; A new

phenomenon is the permanent or periodic migration of aged people towards Southern Europe.

- Travellers: Both tourism and business travel is increasing. Cases of emergency treatment are often complicated both through patient / physician language mismatch and an incomprehensible patient record – even if available.
- Cross-border referral: large hospitals close to borders often treat inhabitants of adjacent countries. Language barriers hamper the communication between referring practitioners and hospital doctors, as well as the communication between patients and health staff.

These scenarios demonstrate how reduced semantic interoperability may result in suboptimal care delivery and patient compliance, as well as increased risks and health expenditures. Patient care episodes characterized by language barriers often affect vulnerable populations and concern acute and life-threatening events.

#### 5.6.4 The peculiarity of medical language and communication

Medical language exhibits numerous peculiarities that distinguish it from ordinary language. From the interoperability perspective the following aspects are noteworthy:

- Numerous medical terms are based on Greek and Latin word stems. This helps guess foreign medical words even for laypersons, such as *hypertension* / *hipertensão* or *Penizillin* / *penicillina*. Few people, however, are aware of false cognate words, such as *arthritis* and *cellulitis* that have completely different meanings in different languages
- Especially Germanic languages create single-word compounds in an ad-hoc manner. As they are not lexicalized their meaning can only be derived from the meaning of the word fragments, e.g. *hørselsjukdomer*, *Laktatunverträglichkeit*, *Pankreatitisverdacht*.
- Text in medical records tends to be overly concise. For the sake of language economy, short, ambiguous expressions are preferred over longer, explanatory ones. Unfamiliarity with the context severely hampers understanding even in the same language, e.g. between two different medical subspecialties.
- For the same reason, the use of acronyms is extremely common. Nearly all acronyms have more than one reading, they do rarely literally translate to any other language, and identical acronyms generally extend to different definitions in different languages.
- The names of drugs and their ingredients constitute a rapidly growing source of terminology and confusion, as the same ingredient may constitute 10 to 20 different drugs with different trade names.
- Text in medical records is often error-laden. Non-compliance with spelling rules as well as simple typing errors reduces understanding and hampers machine processing.

#### 5.6.5 Roads to semantic interoperability from a medical language point of view

The coordinated management of medical language resources covering the European languages should be a major goal. It requires a substantial commitment by health professionals, industry, policy makers, researchers, publishers, and standardization bodies and must capitalize on the state-of-the-art methods of linguistics and lexicography. We recommend pursuing the following principles:

- Development of a common specification for a multilingual medical dictionary, taking into account the morphosyntactic features of medical terms, words, and word

components in all European languages. An important deal of preliminary work has been done by the EU NoE Semantic Mining.

- The dictionary specification should deliberately not include a sophisticated semantic layer. The grouping of (quasi) synonyms and the linking of term translations is not part of its specification. Instead, the meaning of dictionary entries should be assigned by mapping them to a medical terminology / ontology.
- This medical terminology / ontology must be adopted as a standard and freely available all across Europe. In spite of its still considerable shortcomings we consider SNOMED CT as the only available candidate. In order to become fit for this purpose, SNOMED CT will still have to undergo far-reaching modifications. Above all, core SNOMED concepts must be provided by precise formal, semiformal and multimodal definitions and explanations in order to reduce the margin of individual interpretations to a minimum.
- A stable, ontology-based, multilingual medical terminology server can then be used as the centrepiece of a variety of language and content technologies such as medical text mining, information extraction, cross-language information retrieval, spelling correction, coding support, with interfaces to both spoken and written language. More knowledge-intensive applications include computerized decision support, adverse event detection, text summarization, and machine translation.