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## Executive Summary

Semantic interoperability (SIOp) is a key ingredient for meeting present and future challenges of health systems like an ageing population or political pressure to reduce costs. The challenges for semantic interoperability result both from the clinical settings perspective of seamless care provision across all elements of the health care value system (like disease management programmes, clinical pathways) and from the research perspective of integrating life sciences and medical information and knowledge. *SemanticHEALTH* will develop a *roadmap* and *recommendations* for achieving semantic interoperability. This deliverable provides a key contribution to this goal by outlining a conceptual framework to be used in the project. The deliverable briefly reviews key components of healthcare systems and of eHealth as well as various definitions of interoperability (IOp) and semantic interoperability. It outlines the *SemanticHEALTH conceptual space* which takes a human actor centric and process-oriented approach and is accordingly based on three key **components**:

- health services *actors*
- healthcare delivery *processes* (health services value system) and support activities, including ICT
- interface with other *health-related domains* (public health and secondary uses such as research, training, education)

all these embedded in the **context** of their respective (national, regional) *health system* consisting of

- health *policy framework* (laws, regulations, associations, stakeholders, etc.)
- *infrastructure* (health system institutions, public health services, eHealth infrastructure).

*SemanticHEALTH* will identify the main actors involved in the different healthcare delivery processes that are of particular concern to project work, will analyse the nature of the relationships between actors, their interests and responsibilities which have influence on their need and ability to communicate with each other, and how this is best facilitated by the use of ICT. It has always been communication, the exchange of data, information and knowledge, which has bound the healthcare delivery processes (from health promotion to long term care) and actors together. The kinds of data collected is very much goal dependent. While in principle the recording may be optimised for patient care, we see at the same time data being collected in the daily clinical environment to facilitate reimbursement, other may be used for management (planning, organisation, control), clinical outcome measurements, public health statistics or research purposes.

In order to realise the benefits from the increased availability of information and communication, and in particular the possibility of sharing information, the *interoperability* of systems and teams is crucial. Technical interoperability will ensure that spatial boundaries are eliminated. However, this will not be enough for realising the benefits from the enormous supply of information – syntactic and semantic interoperability are required to make the information usable for all collaborating in delivering healthcare.

Within this complex context we outline three dimensions of semantic interoperability that we need to take into account across all other workpackages of the project. We distinguish between an **analytical dimension**, covering both technological interoperability and socio-economic aspects of semantic interoperability, the **application dimension** focusing on specific application fields, as well as the **research dimension** which will identify key future research topics. These dimensions will to be reflected upon using the broader conceptual space as a reference framework.

Based on a broad and holistic approach developed by the EU *i2-Health* project (Interoperability Initiative for a European eHealth Area), *SemanticHEALTH* will apply 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.*

The SemanticHEALTH consortium aims essentially to address the *transmission and use of meaning within the framework of seamless health care services*, between providers, patients, citizens and authorities. In essence the SemanticHEALTH goal is assuring *co-operability* and *collaboration* rather than only *inter-operability*. The project has defined three levels of semantic IOp, the highest one being defined as:

*Level 3 or full semantic interoperability, or co-operability* is reached if users of system B are able to use information acquired automatically from system A with *equivalent meaning to its local data*: the information can be processed homogenously with data captured natively within System B, as if they were entered by a user B directly into system B.

For each of the identified technological interoperability issues and socio-economic aspects of semantic interoperability it will be analysed which (additional) short-term and long-term research is necessary for the initial successful implementation and further development of eHealth systems. Furthermore it will be discussed which **level** of SIOp is necessary for initial deployment, the necessary longer-term **requirements** in order to achieve an optimal level of interoperability will be identified and recommendations for appropriate **RTD actions** will be proposed.

# 1 Introduction and objectives

## 1.1 eHealth as an enabler for better health across the Union

The health systems of the European Union are a “fundamental part of Europe's social infrastructure”<sup>1</sup>. The challenges that lie ahead are in reconciling individual needs with the available finances, as the population of Europe ages, as expectations rise, and as medicine advances.

Healthcare expenditure is expected to continue to rise, yet the scope for increase of the financial resources to meet this demand is limited. On the other hand, the scope for increase in demand for more, better, safer, and timelier healthcare is unlimited. As a consequence, a key challenge that healthcare systems are facing is optimising the use of resources in order to meet this increasing demand given the budget constraints. An associated challenge is to utilise existing and emerging technologies to best effect, even when this means changing established and valued working and clinical practices.

Information and telecommunication technology based solutions in health (loosely defined as eHealth, a term to which we will return in Chapter 2) can be used in a beneficial way in the course of addressing the key challenges faced by European healthcare systems. ICT-enabled solutions to support the implementation of improved and new models of healthcare are an old dream, already discussed and conceived about 40 years ago, but never being successfully implemented at a larger scale<sup>2</sup>. Both technical advances and pressing needs to cope with ever increasing demands on healthcare systems have led to a renewed interest in such applications, and the EU has for more than 15 years now supported technology-focused research in this field.

It seems that the second half of the first decade of the new millennium will now finally see large scale implementations of eHealth solutions, not the least instigated and stimulated by the EU eHealth Action Plan embedded in the wider context of realising the *Lisbon Strategy*, and the consequent EU and Member State activities. The creation of a European eHealth area<sup>3</sup>, free patient mobility<sup>4</sup> and empowering the citizen through eHealth tools and services<sup>5</sup> are now key policy objectives of the Union.

All of this requires a vastly improved healthcare communication space to allow all actors to not only exchange, but to share information and to collaborate on servicing each individual citizen better. This cannot be achieved without multi-level interoperability of the developing applications, systems and infrastructures, and without semantic interoperability the expected benefits cannot be realised.

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<sup>1</sup> *ibid.*

<sup>2</sup> Ed Hammond, the “grandfather” of eHealth in the USA, started already in 1967 to programme his first version of an EHR. In Germany, in the early 70's, a huge project (DOMINIK) based on main frame computers failed dismally, and also the early dreams of global satellite-based telemedicine networks developed during the same years never became reality beyond the military and research environments.

<sup>3</sup> Commission of the European Communities - COM (2004) 356: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making health care better for European citizens: An action plan for a European e-Health Area, Brussels, 2004-04-30.

<sup>4</sup> CEC (2004): Follow-up to the high level reflection process on patient mobility and health care developments in the European Union. COM(2004) 301 final, Brussels, 20.04.2004.

<sup>5</sup> This was the overriding topic of the 2004 European Presidency eHealth conference in Cork, Ireland, in May 2004. Cf. Wilson, P., Leitner, Ch. and Moussalli, A. (2004): Mapping the Potential of eHealth, Empowering the citizen through eHealth tools and services. Maastricht: European Institute of Public Administration.

## 1.2 Objectives

Once it was sufficient to have information systems for individual institutions, departments, and services. Today – and increasingly in the future – it is essential that these systems interoperate in such a manner that the persons collaborating on providing healthcare services to citizens can indeed perform their tasks in an optimal manner. They must be able to share information and, most importantly, share the understanding of what that information means – they must achieve semantic interoperability. The challenges for this result also from integrating the clinical settings perspective of seamless care provision across all elements of the health care value chain and system (like disease management programmes, clinical pathways, case management), with the management perspective (both at the organisation and the system level), the research perspective of integrating life sciences and medical information and knowledge, and the public health perspective. Many of the benefits expected from integration and interoperability will not be achieved at the individual level, they will only be realised when such a holistic, system-wide perspective is adopted.

Against this background, *SemanticHEALTH* will develop a **roadmap** and **recommendations for achieving semantic interoperability** which will contribute to the following:

- consistent use of "language" to allow for secure exchange of information and communications across professional, jurisdictional, regional and national borders
- assuring high information quality on different levels of abstraction, and allowing for aggregation and secondary uses from different research approaches and clinical and administrative viewpoints
- improving the performance and quality of information retrieval and data mining so that they can be applied at "ground level" in the health sector
- merging of bioinformatics (genomics, proteomics and related fields) into health services, like clinical diagnostic information
- harvesting the vast resources of the (semantic) web by supporting sophisticated forms of information retrieval and processing.

This paper relates to Workpackage 1 of the *SemanticHEALTH* project; which has the following objectives:

- to develop a **comprehensive conceptual framework for the identification and analysis of eHealth interoperability issues** as a foundation for project work and to ensure coherence and relevance of results across all WPs
- to identify key generic interoperability and connectivity issues, priorities and approaches at the global level
- generate an overall conceptual framework to **delineate the eHealth systems interoperability domain and to locate the semantic interoperability (sub-)domain in it**, identify relevant issues and trends.

The result will be a framework that systematically identifies and describes relevant conceptual/policy approaches consistently from a top-down point of view. The geographical scope of this framework is:

- the European Union, as expressed in the EU eHealth Action Plan;
- global, as represented by the WHO within the *SemanticHealth* consortium.

The temporal perspective of this framework is both short-term (2-5 years) and medium-term (4-10 years). The field covered includes technological and non-technological (health policy, legal, socio-economic) aspects. There are 2 deliverables for WP 1:

- Conceptual framework
- Infrastructure connectivity and inventory of key relevant Member States and international experiences.

Once the overall framework has been agreed, it will be used for an *integrated, comparative analysis* of relevant national and international interoperability initiatives.

This conceptual framework forms the *umbrella* of work undertaken in Work packages 2 to 6 of the *SemanticHEALTH* SSA. Starting from a more general analysis of the eHealth interoperability domain, a conceptual framework for semantic interoperability is outlined and operationalised. In its operational form the conceptual framework (CF) provides the row part of a matrix in which an inventory (to be developed later) will form the columns. It may be reviewed and adjusted in light of later work during the project.

### 1.3 Why do we need semantic interoperability in the first place?

The semantic interoperability workshop (Brussels in February 2005 organised by WHO, the EC and eTEN *I2-Health*<sup>6</sup>) identified a number of reasons why semantic interoperability is a crucial area for coherent research programmes:

- For *Direct care*: e.g.
  - to coordinate patient care between multiple care institutions/professionals
  - to support cross border care for EU citizens
  - to improve usefulness of automatic decision support
  - to help comply with best practice
- For *Organisation*: e.g.
  - to support exchanges across jurisdictions and to support cross border and multilingual and multicultural issues in public health
  - to incorporate primary care and community based care
- For *Costs*: e.g.
  - to improve productivity
  - to eliminate redundant testing and investigation
- For *Population*: e.g.
  - to unify clinical data in time and space for disease surveillance area of vital concern on a global scale
  - to better cope with emerging pathogens and bioterrorism

Achieving a high level of interoperability can lead the following *added value*:

- *Search using concepts above words*: for example, a construct beyond a single or multiple terms in a vocabulary could be searched given there is an information model.
- *Extraction of concepts from documents*: for example, one can search in the electronic health records for the application of evidence based treatment schemes etc.
- *Statistical index on community collections*: for example, one can collect coverage for childhood immunizations in a given community.
- *Concept navigation across collections*: for example, one can compare different communities on immunization proportions or rates of hypertensive diseases.

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<sup>6</sup> see: <http://www.who.int/classifications/terminology/en/>

## 2 Conceptual framework: initial considerations and state of play

Currently efforts at interoperability are still fragmented. Electronic Health Records (EHRs), terminology & ontologies, messages, care pathways, data types, security, and system architectures are addressed in isolation by divergent initiatives. To achieve the goal of using eHealth to meet the needs of citizens, patients and providers, these fragmented initiatives must come together in a comprehensive policy for interoperability.

In the light of the convergence of views and the needs for cross boarder and global eHealth interoperability at the global level – as represented by WHO and its collaborating centres – and at the level of the European Union Member States *it is therefore necessary to embark on a process that will prompt the divergent initiatives to join forces for the benefit of all citizens, with respect both to interoperability in general, and specifically with respect to semantic interoperability in health care.*

However, in the last decade the promises of IT have not been matched by its achievements. If the situation is difficult in the developed countries, it is much worse in the other two-thirds of the world where the information paradox – minimal information in the places of maximum need – hides the inappropriateness and inequity of global healthcare distribution. This also makes it difficult to ensure that scarce research resources, both financial and human, are allocated optimally from a global perspective. Many disparate initiatives do exist among member states, international organisations, standard organisations such as CEN or ISO, users groups such as HL7, university and research centres. They have not been very successful in disseminating and coordinating their efforts to the benefit of the end users. Because of the eminent needs the short and medium term investments are the most important. If we want to avoid further divergence in e.g. health related terminologies used in Europe, we must act in that time frame. **The question ‘Why is it so hard to do’ must be explicitly answered to break this loop.**

A major contribution by *SemanticHEALTH* will be the establishment of a roadmap of priorities to reap all the benefits expected for citizens and professionals from the eminent implementation of eHealth infrastructures in a growing number of countries.

This section briefly provides an overview of the structure of the healthcare system and its integration of eHealth. It also reviews definitions of key terms such as “eHealth” and “interoperability” and introduces a human user oriented perspective towards eHealth interoperability.

### 2.1 Health, eHealth and the healthcare system

As defined by the World Health Organisation (WHO) almost 60 years ago, "**health is a state of complete physical, mental and social well-being** and not merely the absence of disease or infirmity."<sup>7</sup>

The term eHealth is widely used by individuals, academic institutions, professional bodies, and funding organisations. It has become an accepted neologism despite the lack of an agreed-upon clear or precise definition. Similarly, definitions for eHealth vary as well - according to a recent study<sup>8</sup> which performed a search in a wide variety of databases, it appears that more than **50 different definitions are given for eHealth**. The term encompasses a set of

<sup>7</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948

<sup>8</sup> Med Internet Res 2005;7(1):e1 - What Is eHealth (3): A Systematic Review of Published Definitions

disparate concepts, including health, technology, and commerce. The recent EC "Action Plan for a European eHealth Area"<sup>9</sup> defines and describes eHealth as

"... the application of information and communications technologies across the whole range of functions that affect the health sector. eHealth tools or 'solutions' include products, systems and services that go beyond simply Internet-based applications. They include tools for health authorities, healthcare organisations and healthcare professionals at all levels as well as personalised health systems for patients and citizens. Examples include health information networks, electronic health records, telemedicine services, personal wearable and portable communicable systems, health portals, and many other information and communication technology-based tools assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management."

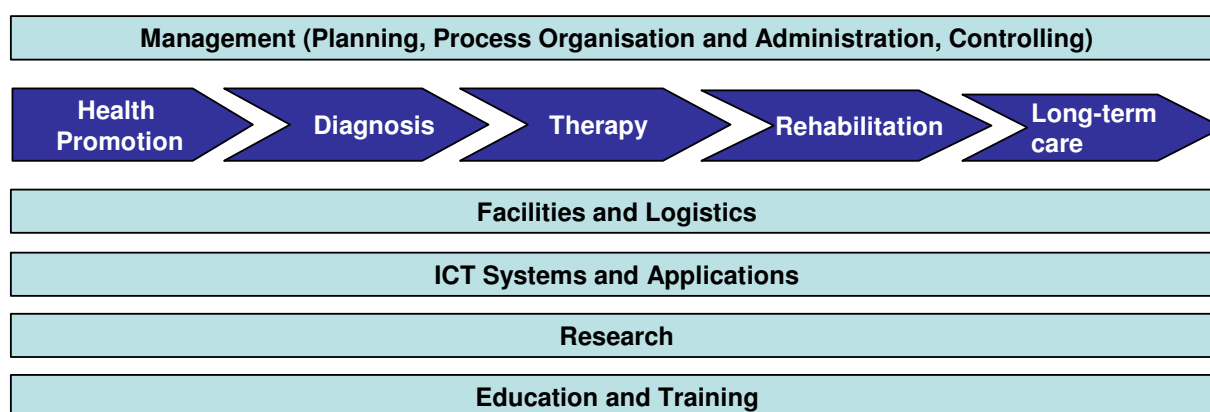
Similarly, the *Ministerial Declaration at the EU Ministerial eHealth 2003 conference* in May 2003 in Brussels pronounced that "eHealth refers to the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers."<sup>10</sup>

The EU funded project *eHealth-ERA*<sup>11</sup> has applied a process oriented and broad approach to the subject and consequently defines eHealth as follows:

**"eHealth encompasses applications of ICT providing benefits to health".**

The term health is here used in a wide meaning implying health in all its mouldings at the individual as well as at the health (care, research, societal) system level, thus encompassing all elements and contributors to the process of sustaining or improving the health of citizens. Developing this process view further, the project has analysed the field of healthcare in the framework depicted below. Besides encompassing ICT infrastructure (network) services and applications directly contributing to healthcare processes, eHealth also contributes to the various functions commonly subsumed under the term management as support for the core competence of healthcare service providers, to support services like facilities management and logistics, and - in a wider sense - to research (ranging from basic life sciences and medical research to clinical trials) as well as health-related education and training.

**FIGURE 1 THE HEALTH CARE SERVICE DELIVERY AND RELATED SUPPORT PROCESSES**



Source: © empirica, 2006

In the centre of the above *Figure* is the core service delivery process or value system.<sup>12</sup> It is surrounded by supporting processes inevitably connected to the core processes. Only as a

<sup>9</sup> Commission of the European Communities - COM (2004) 356: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making health care better for European citizens: An action plan for a European e-Health Area, Brussels, 2004-04-30

<sup>10</sup> Source: [http://europa.eu.int/information\\_society/europe/ehealth/conference/2003/doc/min\\_dec\\_22\\_may\\_03.pdf](http://europa.eu.int/information_society/europe/ehealth/conference/2003/doc/min_dec_22_may_03.pdf)

<sup>11</sup> See <http://www.ehealth-era.org/>

system of interrelated processes they effectively lead to healthy citizens. A consequence of this system view is that if one changes something in, e.g., administration other processes are affected by this change.

*Health promotion* as the first element in the core service delivery system (or "full cycle of care"<sup>13</sup>) refers to services for all citizens. Citizens should be given reliable materials to help themselves, e.g., what to do against bird flue or why tetanus vaccination is important. It's the duty of public health in general but also of doctors and citizens themselves. *Prevention* is here considered as a part of health promotion too, being mostly a public health theme covering vaccination but also epidemiology and other topics. Also, new models of individualised or personal healthcare will focus increasingly on this, in the past neglected, element, thus intervening already at an early stage to avoid citizens becoming ill. Since information is playing a central role in health promotion, ICT-enabled models are of particular relevance.

*Diagnosis* refers to a health problem encountered by a citizen. She or he may show or perceive symptoms which may relate to an objective or subjective health problem, and there may exist (measurable) signs supporting such a suspicion. Diagnosis is the act or process of attempting to identify or determine the nature and cause of the health problem (which may be a disease, illness or injury) through evaluation of patient history, examination, and review of laboratory and other data and information. It is often an activity shared between hospitals, GPs and specialists, and laboratories. In the case of self-care, it may involve only the citizen, consulting perhaps a book or an online service. Depending on the outcome of the diagnosis, treatment may be the next healthcare activity.

Three different forms of treatment may follow diagnosis:

- *Therapy* is the treatment of illness understood as acute, relative short-term, often (very) intensive treatment
- *Rehabilitation* is also part of the process of restoring a patient to good health or useful life, but through longer-term treatment. In contrast to therapy it is more focused on regaining or re-learning specific functions through longer term interventions and training.
- *Long-term care / follow up* refers to the treatment of and care for chronically ill or disabled people not expected to recover totally again, focusing on assuring at least a certain level of quality of life and preventing or slowing down the worsening of the disease.

The distinction between these three kinds of treatment is fluid and relates to the intensity and duration of care.

Further to these patient and / or directly health centred processes there are important *supporting* processes to healthcare:

- *Management* concerns the planning, organisation, and control of all health and support services.
- *Facilities and logistics* refer to the management of buildings and goods, procurement and supply. More generally it is the task to ensure the right things are at the right time at the right place.
- *Research* brings up results leading, often after a long time, to new or improved ways of promotion, diagnosis, or treatment. In this respect, it is an important instrument supporting core health processes.
- *Education and training* are strongly connected to research, but also to health care provision. On the one hand it is the training of staff during their studies but, as a second aspect, continuing medical education (CME) or continuing professional development

<sup>12</sup> Here we use the term "value system" rather than "value chain" because usually these process steps are not integrated into one single healthcare provider but rather are provided by different organisations being part of what M. Porter calls a value system. Cf. Porter, M. *Competitive Advantage*. New York: The Free Press, 1985, p. 34: "Gaining and sustaining competitive advantage depends on understanding not only a firm's value chain but how the firm fits in the overall value system."

<sup>13</sup> Porter, M. and Teisberg, E.: *Redefining Health Care*, Harvard Business School Press, 2006, p. 5: "... the full cycle of care, from monitoring and prevention to treatment to ongoing disease management."

(CPD) are of growing importance. Still today, on average, it takes about 17 years from knowing about an improved treatment from clinical trials to its becoming standard clinical practice<sup>14</sup> - which does not necessarily imply that it is being observed in the great majority of all physicians' daily practice.

This healthcare process model already allows for a first basic insight into why interoperability among all core process elements, with support processes and among actors involved is both of key importance and so complex an issue. We will return to this in Chapter 3, but here first proceed to look in some detail at the meaning of interoperability.

## 2.2 Defining interoperability

### 2.2.1 General interoperability definitions

Modern ICT capabilities raise huge information exchange expectations. Industry, regulators and other stakeholders have long recognized the need for improved interoperability, i.e. the fact that data produced in one system is readily useable in another system.

Technical and functional interoperability have by now matured to provide reliable operational platforms in most cases. Content interoperability now emerges as a domain needing much greater attention.

Initial efforts in that area were devoted to data registries, listing the data categories that should be part of any particular data set under consideration. It was then found useful to add metadata that would qualify the type of data that should be allowed in any particular data category. This ranged from specific formats (like date type) to controlled vocabularies (pick lists, where strict compliance was required). However, rigid specification of data types and pick lists has often proved too constraining. Therefore, increasingly there has been a move towards more complex metadata that allows users more freedom while preserving meaning. The biological community has been particularly successful in this regard.

More recently, automatic language processing and intelligent information retrieval have emphasized the need for true semantic interoperability, i.e. the guarantee that information is represented so as to be unambiguous and have the same meaning for subsequent user systems. To achieve this, the meaning must be captured in such a manner that it can both be formally described for processing by machines and be transformed reliably to forms easily understood by humans.

Furthermore, the need to facilitate exchange of information between different language communities has stimulated work on language-independent concept representations that can act as a reference points containing the agreed set of features required to capture any notion unambiguously. From there rule-based derivations could generate the various language realisations.

The scientific community increasingly recognizes the need to have both bottom up and top down approaches: evolutionary bottom up knowledge representation systems derived from specific requirements in specific disciplines, and designed top down standards expressing the agreements necessary for interoperability. In a multilingual multicultural setting these must be combined with understanding of national standards and practices and international multilingual frameworks permitting the efficient flow of information in multi-country settings and trans-border situations in order to deliver and assess strategies for true citizen-centred health care.

How the "conceptual space" of interoperability (IOp) is structured, i.e. the way interoperability is defined, already exerts considerable influence over subsequent discussions. It makes

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<sup>14</sup> Balas, E. A. and Boren, S. A. (2005) Managing Clinical Knowledge for Health Care Improvement. In: Haux, R. and Kulikowski, C. (eds.) Yearbook of Medical Informatics 2005. Stuttgart, Germany: Schattauer Verlagsgesellschaft.

therefore sense to present a few of the most relevant Interoperability definitions given by others.

**TABLE 1: GENERAL INTEROPERABILITY DEFINITIONS**

Organisation name	Interoperability definitions
ISO/IEC (2002) Health Informatics – Interoperability of telehealth systems and networks. Part 1: Introduction and Definitions. TC 215/SC N304. P.12, <a href="http://www.atmeda.org/ICOT/ISO-TH-TR-Pt1-Nov-15-2002.pdf">http://www.atmeda.org/ICOT/ISO-TH-TR-Pt1-Nov-15-2002.pdf</a>	Interoperability refers to the ability of two or more <b>systems</b> (computers, communication devices, networks, software and other information technology components) to interact with one another and exchange information according to a prescribed method in order to achieve predictable results
IDABC (2004) European Interoperability Framework for Pan European eGovernment Services. Version 1.0. European Commission, p. 5. <a href="http://europa.eu.int/idabc/en/document/3761">http://europa.eu.int/idabc/en/document/3761</a>	Interoperability means the ability of information and communication technology (ICT) <b>systems and of the business processes</b> they support to exchange data and to enable the sharing of information and knowledge.
CEN/ISSS (2005) Current and future standardization issues in the eHealth domain: Achieving Interoperability. Final Version. <a href="http://www.centc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf">http://www.centc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf</a>	Interoperability is a state which exists between two <b>application entities</b> when, with regard to a specific task, one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention.
National Alliance for Health Information Technology (2005) What is interoperability? <a href="http://www.nahit.org">www.nahit.org</a>	Interoperability is the ability of different information technology <b>systems, software applications and networks</b> to communicate, to exchange data accurately, effectively and consistently, and to use the information that has been exchanged.
Miller, Paul (2000) Interoperability. What is it and why should I want it? Ariadne Online, Issue 24, p.2 <a href="http://www.ariadne.ac.uk/issue24/interoperability/">http://www.ariadne.ac.uk/issue24/interoperability/</a>	[To be interoperable] one should be actively engaged in the ongoing process of ensuring that the <b>systems, procedures and culture of an organisation</b> are managed in such a way as to maximise opportunities for exchange and reuse of information whether internally or externally.
EICTA Interoperability White Paper, p. 4, <a href="http://www.eicta.org/files/WhitePaper-103753A.pdf">http://www.eicta.org/files/WhitePaper-103753A.pdf</a>	The ability of two or more <b>networks, systems, devices, applications or components</b> to exchange information between them and to use the information so exchanged.

On a meta level one could make a distinction between “narrow” views of IOp, which concentrate on technical issues (including standardization), and “broader views”, which takes organizational, social and political components into account. This distinction forms an important groundwork for the further analysis of the multi-faceted nature of interoperability, in particular as it concerns eHealth.

## 2.2.2 Defining interoperability in eHealth

Various authors define IOp specifically for a policy area or issue, such as eGovernment or, in our case, eHealth. In its communication for establishing the European eHealth Area - the eHealth Action Plan - the Commission defines interoperability in eHealth the following way: *"Interoperability should enable the integration of heterogeneous systems, allow secure and fast access to comparable public health data & patient information located in different places*

over a wide variety of wired and wireless services".<sup>15</sup> Starting from the Commission's outline, the TMA-bridge project arrives at its own eHealth interoperability definition: "*the ultimate objective of eHealth interoperability is to allow different people from different countries (meaning having different habits, traditions, cultures, languages...) to easily communicate different data and interact with different systems coming from different manufacturers or vendors with the same results"<sup>16</sup> (p.2-2). As a contrast, in the American context the US Department of Health defines eHealth IOP as "*the ability to exchange patient health information among disparate clinicians and other authorized entities in real time and under stringent security, privacy and other protections*".<sup>17</sup>*

The recent *eHealth Interoperability Staff Working Paper*<sup>18</sup> (draft version 2.5. 2006) underlines the importance that is attached to this issue on the EU level. It points out that in the 21<sup>st</sup> century health, social care and other providers must no longer work in isolation but collaborate as a team, if necessary across their national and linguistic borders. ICT can play an important part in facilitating this cooperation, but needs to be fully interoperable to do so. In other words, eHealth solutions must be interoperable in order to facilitate the collaboration of health care professionals and organisations. The various actors involved must cooperate in resolving legal, organisational and policy barriers.

As we can see, these definitions clearly go beyond the mere technical level and extend the IOP definition towards the **exchange of information among human beings in different organisations**.

In its report the *CEN/ISSS eHealth Standardization Focus Group* defines interoperability as

*"a state which exists between two application entities when, with regard to a specific task, one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention."*<sup>19</sup>

Furthermore, it notes:

*"Interoperability is the only sustainable way to help partners acting in various locations, with different expertise, perspectives, statuses and agendas, possibly cultures and languages, and using distinct information systems from different vendors, to collaborate harmoniously to deliver quality health care."*

Interoperability must be established throughout information systems. Full sharing requires at least two levels to be achieved:

1. **functional and syntactic interoperability**: the ability of two or more systems to exchange information (so that it is human readable by the receiver);
2. **semantic interoperability**: the ability for information shared by systems to be understood at the level of formally defined entities, so that the receiving system can process the information effectively and safely.

Semantic interoperability is essential for automatic computer processing to underpin real value-added EHR clinical applications, such as intelligent decision support, care planning, etc. What is at stake here is not only exchanging data and information but reusing and processing them. The degree to which information can be re-used and processed is the measure of semantic interoperability.

<sup>15</sup> CEC (2004) eHealth - making healthcare better for European citizens: An action plan for a European e-Health Area. COM (2004) 356 final. P.13.

<sup>16</sup> TMA-Bridge (2005) Interoperability Study Report. TMA-Bridge Del.4. p.2-2

<sup>17</sup> US Department of Health and Human Services, National Coordinator for Health Information Technology (2004) Request for Information. P.2, [http://www.hhs.gov/healthit/documents/NHIN\\_RequestForInformation\\_Final.doc](http://www.hhs.gov/healthit/documents/NHIN_RequestForInformation_Final.doc)

<sup>18</sup> CEC (2006) eHealth Interoperability Staff Working Paper. "Connected Health: Quality and Safety for European Citizens". Brussels, 2.5. 2006

<sup>19</sup> Cf. CEN/ISSS eHealth Standardization Focus Group "Current and future standardization issues in the e-Health domain: Achieving interoperability", draft V8.2, 2004, pp. 35-36

### 2.2.3 Initial semantic interoperability definitions

There are many different definitions of Semantic Interoperability, each for a specific purpose or perspective. Some definitions are limited to machine-machine communication, others extend it to human-machine-machine-human communication. Semantic interoperability is not a new goal – it has been one of the grand challenges of health informatics from its inception. However, the arrival of new more advanced computer technologies and widespread availability inexpensive computers capable of using those technologies allow routine adoption of much more ambitious technical solutions. As with interoperability in general, semantic interoperability has been defined in a variety of ways, as the figure below shows:

**TABLE 2: SEMANTIC INTEROPERABILITY DEFINITIONS**

<p>IDABC (2004) European Interoperability Framework for Pan European eGovernment Services. Version 1.0. European Commission. P.5, <a href="http://europa.eu.int/idabc/en/document/3761">http://europa.eu.int/idabc/en/document/3761</a></p>	<p>[Semantic interoperability] is concerned with ensuring that the <b>precise meaning</b> of exchanged information is <b>understandable by any other application</b> that was not initially developed for this purpose.” (IDABC 2004:16). It thus enables systems to combine received information with other information resources.</p>
<p>WHO/EC Workshop on interoperability of eHealth systems – with special reference to semantic interoperability. Initial considerations, Brussels, February 2005, <a href="http://www.who.int/classifications/terminology/en/index.html">http://www.who.int/classifications/terminology/en/index.html</a></p>	<p>Using a “holistic” (p.12) definition the goal of semantic interoperability is to <b>“improve ‘communication’ on medical and health related aspects both among humans and machines”</b> (p.11). In order to achieve this, a two pronged approach is necessary: achieving unified health ontology (longer-term) and tackle concrete and clearly delineated issues (short term). Within semantic interoperability various dimensions, such as medial/administrative or human/machines levels can be distinguished (p.12).</p>
<p>CEN/ISSS (2005) Current and future standardization issues in the eHealth domain: Achieving Interoperability. <a href="http://www.centc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf">http://www.centc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf</a></p>	<p>CEN/ISSS (2005:39) stresses that semantic interoperability is not an “all-or nothing” concept. That is “the degree of semantic interoperability depends on the level of <b>agreement between sender and receiver</b> regarding the <b>terminology, and the content of archetypes and templates</b> to be used”.</p>
<p>Rossi-Mori (2005) Semantic Interoperability, Power Point Presentation</p>	<p>Rossi-Mori distinguishes between two kinds of semantic IOp, each suitable in particular circumstances. In administrative and organisational contexts or for orders and reports <b>“fine grained” IOp</b>, based on detailed data structures and on coded values is suitable. When situations are poorly predictable, such as in clinical situations <b>“coarse-grained” semantic IOp</b> is the only viable solution. Coarse grained semantic IOp consists of basic structures, independent from the particular clinical issues. For intermediate solutions, several evidence based clinical pathways may be suitable. Rossi-Mori recommends that research should focus on developing the criteria to define the optimal level of semantic IOp.</p>

It could be said that the adjective “semantic” in “semantic interoperability” is used to refer to the shared meaning of a string of characters and/or symbols in some language within a context that assures the correct interpretation by all actors.

## 2.3 A multi-layer approach to interoperability

As we have seen in the preceding chapters, interoperability is a sometimes fuzzy concept used in a variety of meanings in quite disparate contexts. But it should have become obvious that realising eHealth interoperability requires policy, implementation and sustenance actions at four generic levels. We believe that structuring the IOp domain along the four dimensions chosen allows for a pragmatic approach to identify key areas of responsibilities and of action levels needed to indeed achieve IOp across Europe in the longer run:

a) At the regional, national and European **health policy layer**, fostering interoperability must be based on an approach which allows for strong political **cooperation** among all parties concerned. This is required to develop and ratify visions and strategies for interoperable eHealth systems, to initiate and implement adequate structures (like national competence centres), processes and measures to realise these strategies, to maintain a sustainable socio-economic and legal framework including adequate measures to assure privacy and confidentiality at similar levels, and to promote the certification of interoperable devices and systems.

b) At the **layer of health services** (organisations, professionals), care providers have to adjust organisational structures and professional cultures to the needs of team-based care. Only a strong spirit of **collaboration** among all parties concerned with, e.g., the care for a chronically ill citizen will allow reaping the longer-term benefits of true interoperability across Europe. Promotion of change management, fostering of systems thinking or care process re-engineering are some of the ingredients to be mentioned in this context.

c) At the **semantic layer** consensus on terminologies, classifications and ontologies needs to be established, so as to ensure common reference systems for the **interoperation** of systems and a meaningful exchange of data and knowledge. This will require translation for actors with different languages. Furthermore, sustainable (national, regional) development and implementation infrastructures as well as application support need to be implemented and maintained.

d) At the **technical and functional layer** technical standards and detailed specifications need to be available respectively continuously developed because achieving and maintaining interoperability in a dynamic, constantly changing environment is a permanent task. Hardware and software connectivity is a fundamental prerequisite for interoperability at this layer. Another vital component are user interfaces, designed in a user friendly and easily accessible way. Despite the many difficulties that exist on this purely technical layer, it is in general the easiest one to establish consensus on and to implement.

The following *Figure* provides an overview of these interoperability layers and some of the key issues related to them:

**TABLE 3: FOUR EHEALTH INTEROPERABILITY LAYERS AND RELATED ISSUES**

<b>Action layer and approach</b>	<b>Issues</b>
<b>Health policy layer:</b> <u><i>cooperation</i></u>	Vision & strategies Structures, processes & measures, incentives for actors Sustainable socio-economic and legal framework Privacy and confidentiality Certification of systems and devices
<b>Health service provider (organisational) layer:</b> <u><i>collaboration</i></u>	Organisational structures and culture Intra & inter-jurisdictional service processes Change management, behavioural change Systems thinking, business process re-engineering
<b>Semantic layer:</b> <u><i>interoperation</i></u>	Terminologies, classifications, ontologies Translation Sustainable development and implementation infrastructures, application support
<b>Technical / functional layer:</b> <u><i>interoperation</i></u>	Technical standards Hardware and software connectivity User interfaces

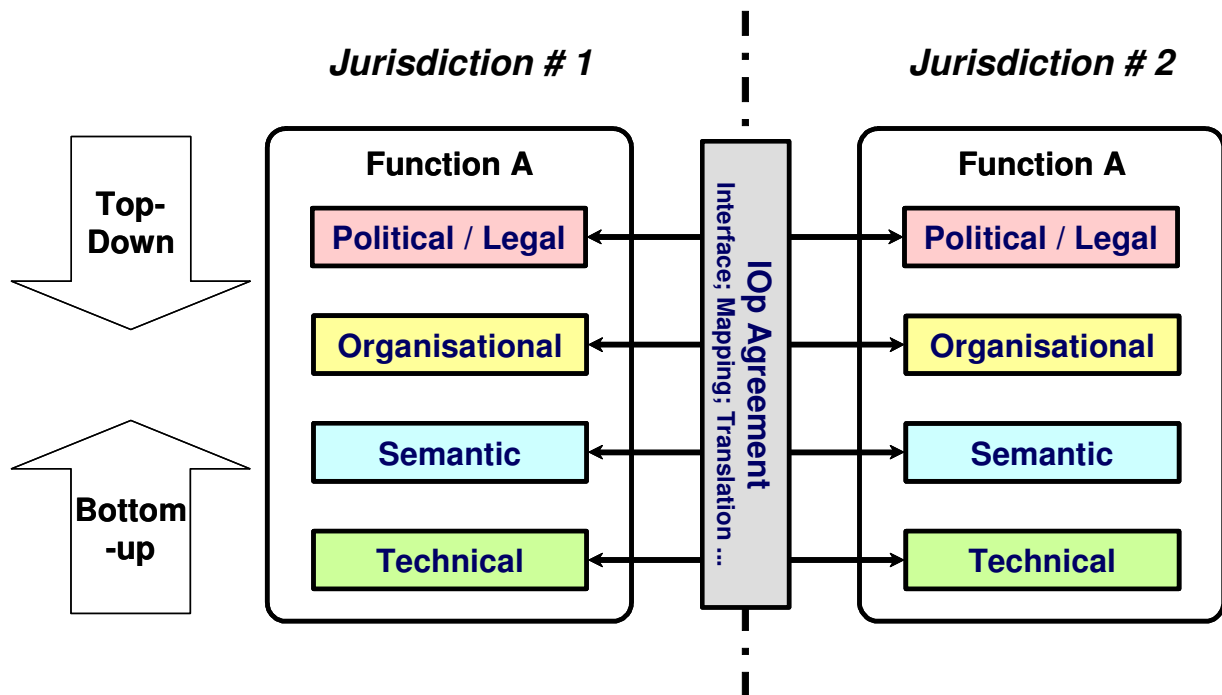
Source: © empirica / i2-Health 2006

## 2.4 The *i2-Health* IOp model

The *i2-Health* interoperability model expands on the above presented multilayer approach and illustrates the interrelationship between those four levels as well as interactions across different jurisdictions, for instance between two countries, but also between several regions or communities, even between individual health care provider organisations. However, depending on which parties are involved, the relevance and importance of the 4 layers may differ.

The model presented in *Figure 2* shows that in order to allow for exchanging, understanding and acting on patient and other health-related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors and organisations across health system jurisdictions in a collaborative manner, various sorts of formal or informal agreements, which for instance cover the specification of an interface, the mapping of functions, legal issues or agreement on common terminologies and their translation need to be present. Furthermore, both a top-down approach reflecting the regulatory requirements of European health systems and a bottom-up approach taking into account the views of and integrating all stakeholder groups concerned need to be applied in a complementary way to structure these processes, involve all actors and motivate them to collaborate.

FIGURE 2: THE I2-HEALTH INTEROPERABILITY MODEL



Source: © i2-Health, 2006

A key aspect not directly reflected in the above *Figure* is the *dynamic aspect of IOp*. The analysis has led us to conclude that *interoperability issues in the health system cannot be approached, analysed, understood and dealt with in a satisfactory manner unless reflected upon as a **dynamic, ever changing process***. From a generic perspective, the models available in the literature are rather static in that they do not sufficiently take into account that IOp is a process that has to be realized in a dynamic way.

Taking a process-oriented perspective, i.e. achieving interoperability in a comprehensive manner which explicitly considers human beings as key addressees and actors embedded in complex organisational environments, "interoperability" assumes a new "quality" far beyond that of facilitating communications among technical entities; rather, it becomes a cross-cutting issue that affects, integrates and interacts with all the above discussed dimensions of IOp and all actors concerned directly or indirectly with IOp. While the static view identifies goals to be ultimately reached, the dynamic view acknowledges that achieving and maintaining IOp is related to its implementation and sustainability, a permanent task, particularly when considering that the framework conditions like (new) techniques, regulations, medical knowledge, work flow processes as well as organisational and administrative requirements are permanently changing.

This view is also reflected in the recently published *Australian Interoperability Framework* by NEHTA where they state that "Interoperability is **a continual state of readiness** – Integration is a slice through an interoperability time line".<sup>20</sup> Two citations from presentations at the eHealth 2006 High Level Conference in Malaga in May of this year similarly reflect on this sentiment: "Systems integration is an ongoing problem because the workflow may change every day" was noticed by Miguel Cabrer, CIO, Son Llätzer Hospital, Palma de Mallorca, Spain. And Jeffrey D. Miller, VP, Hewlett Packard, observed: "Whatever you plan today, your endpoints will differ."

<sup>20</sup> Australian NEHTA (2006) Interoperability Framework Version 1.0, April 2006, p. 3, [http://www.nehta.gov.au/component?option=com\\_docman/task\\_cat\\_view/gid,123/Itemid,53/](http://www.nehta.gov.au/component?option=com_docman/task_cat_view/gid,123/Itemid,53/)

In summary, a key observation and result, when analysing interoperability in the **broad and holistic view** applied here, is that

*interoperability is not just about standardisation - which is only one, albeit a key element of it - or another isolated element, but about permanent change and adaptation of a multitude of elements and issues within and across complex systems required to exchange information, interact and collaborate in caring for the health of citizens.*

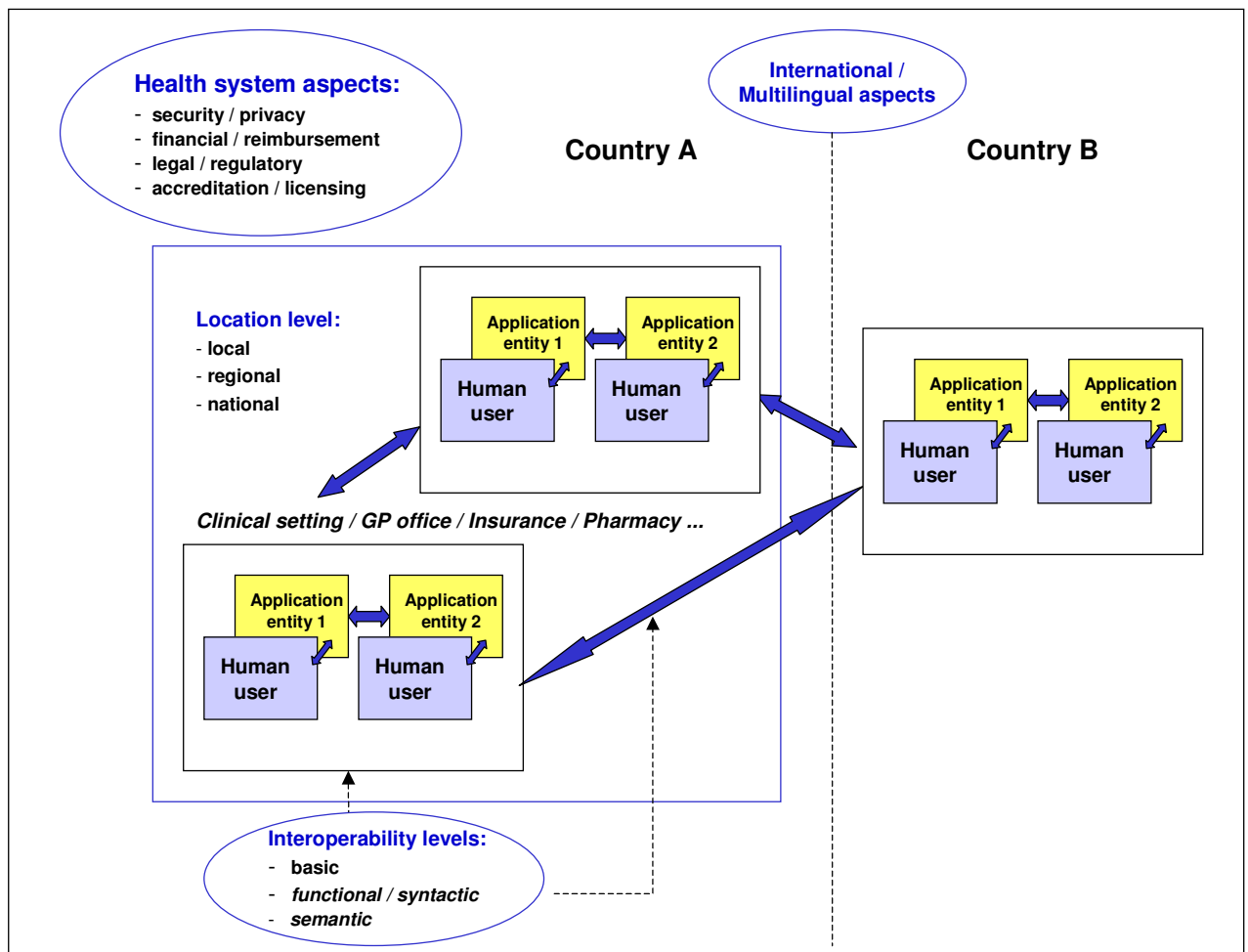
## 2.5 A human user oriented perspective

Based on this broad and holistic approach the *i2-Health* project has defined true European **health system interoperability as 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.***

This definition shows that it is necessary (particularly, in a multi-lingual context – e.g. when considering cross-border health care) to go beyond the technical level and include citizens (health professionals, patients, ...) as part of the interoperable system, i.e. we need an interface between the "separate application entity on each side" and the person (clinician, nurse, patient, ...) who inputs the information into the unit and the one who interprets and acts on the output at the other end. Therefore, in a European and global context, we need a broader definition of "semantic interoperability", a definition that includes translating concepts, meaning and terms as defined and modelled by one group into the terms used by other linguistic groups and by different clinical cultures. This broader definition is depicted in *Figure 3*.

**FIGURE 3: A BROAD CONCEPTUALISATION OF THE EHEALTH INTEROPERABILITY DOMAIN**



Source: © empirica / SemanticHEALTH, 2005

## 3 Towards a semantic interoperability framework

### 3.1 The *SemanticHEALTH* vision

*SemanticHEALTH* will develop a European and global roadmap for deployment and research in eHealth in order to realise the full potential of modern information and telecommunication technologies, thereby focusing on semantic interoperability issues of eHealth systems and infrastructures. The roadmap will be based on consensus of the research community, and validated by stakeholders, industry and Member State health authorities.

Without denying the activities working towards advanced technical or functional interoperability, *SemanticHEALTH* consortium aims essentially to address the **transmission and use of meaning within the framework of seamless health care services**, between providers, patients, citizens and legacies. As a consequence the project will not develop a new overall structure of interoperability but rather rely on work done elsewhere, for example by the *i2-Health* project and the sister *RIDE* project.

In essence the *SemanticHEALTH* goal is assuring *co-operability* and **collaboration** rather than only *inter-operability*.

The goal is to strengthen European and international work on health terminology in order to progress from the present situation of long-term low funding in most countries, suddenly contrasted by a high pressure to commit significant resources without a coherent or comprehensive goal (for example, on handling the “Terminfo crisis”, an attempt to resolve unanticipated incompatibilities between HL7 version 3 and SNOMED CT). *SemanticHEALTH* will instead propose a roadmap for strategic and systematic ongoing developments in terminology and ontology.

This chapter will first outline the understanding of eHealth and healthcare that forms the basis of the *SemanticHEALTH* project. It will then provide key components and dimensions of a conceptual framework for semantic interoperability and finally (in an appendix) make operational the outcome for use by the project in its further work.

### 3.2 eHealth and healthcare: The *SemanticHEALTH* conceptual space

Based on the initial consideration discussed in section 3, this chapter develops the broad conceptual space within which the *SemanticHEALTH* project operates. Three key “components” have been identified:

- health services *actors* (human actor centric approach)
- healthcare delivery *processes* (health services value system) and support activities, including ICT
- supporting *research*, training and education

all embedded in the corresponding **context**:

- (national, regional) *health system*
- *infrastructure* (institutions, public health services, eHealth infrastructure, ...)
- health *policy framework*, laws, regulations, associations, ...

In the following we will briefly discuss these three components, placing them in their context.

### 3.2.1 An actor centric perspective

Based on a human actor oriented perspective Denz<sup>21</sup> singles out three key groups of actors in eHealth, namely:

- Healthcare authorities
- Healthcare professionals
- Patients/Consumers/Citizens Associations

These actor groups can be further differentiated into the following categories:

- Citizens, patients and informal carers
- Physicians and other healthcare professionals
- Hospitals and other healthcare provider entities / organisations
- Pharmacies, pharmaceutical industry
- Central, regional and/or local government (health policy makers, sometimes Third Party Payers and/or owners of health care facilities)
- Health insurance (public and private)
- (Home) care management service providers, case managers

Modern healthcare is focused on making the best use of finite resources in order to balance the medical outcomes produced with the needs of all stakeholders in the healthcare arena. Responsibilities, but also interests of different participants in healthcare are diverse: A physician has interests that differ from those of the patient who receives treatment. A hospital differs from a doctor's office. Health insurances negotiate on the payment of medical services with doctors and their associations. Medical care is dependent on data in order to create the base and transparency for balancing the different needs and interests of these stakeholders. The kinds of data collected is very much goal dependent. While in principle the recording may be optimised for patient care, we see at the same time data being collected to facilitate reimbursement and for various other purposes. The latter data does not always reflect the reality of patient treatment!

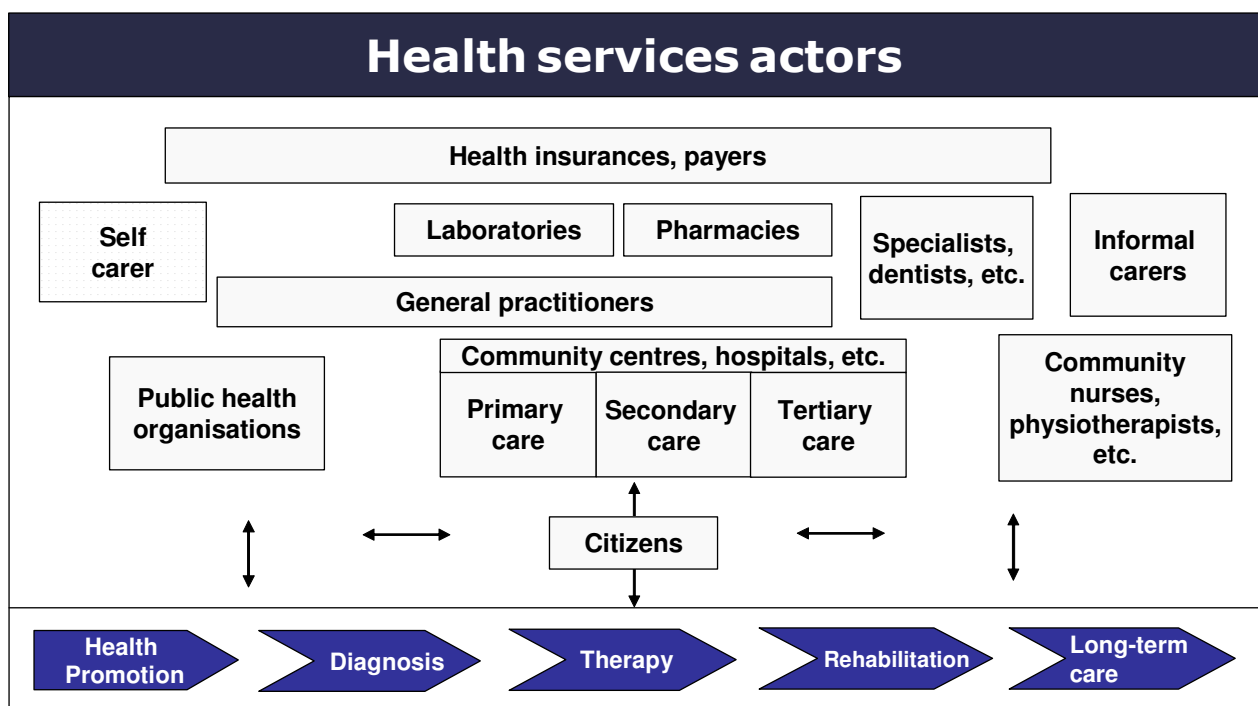
Mapping the relationships between stakeholders is a challenge. The system is complex and differs from country to country. The use of ICT in healthcare is intended to facilitate communication between actors. For instance, in ePrescribing physicians, pharmacists, informal carers and patients must communicate effectively, data must be transmitted for correct reimbursement and other administrative purposes. Another example is data collected in the daily clinical environment: some of it is important for management (planning, organisation, control), other may be used for clinical outcome measurements, public health statistics or research purposes. Further, use of ICT offers new possibilities for exchange and collaboration, requiring new forms of organisations and workflows.

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<sup>21</sup> Denz, Martin (2005) Interoperability in eHealth. Power point presentation. Workshop on Standardization in E-Health (Geneva, 23-25 May 2003) ETHEL ITU. P.9, <http://www.itu.int/itudoc/itu-t/workshop/e-health/s8-04.pdf>

Figure 4 presents an illustrative map of the health service actors involved in the health value system. All actors co-operate in the health service value system to deliver seamless, team-based, citizen-centred services. It has always been communication, the exchange of data, information and knowledge, which has bound these processes (from health promotion to long term care) and actors together. In recent decades, the fast development of ICT solutions has led to the possibility of new quality and scale of such exchanges and interactions. In order to realise the benefits from this increased availability of information and communication, and in particular the possibility of sharing information, the interoperability of systems is crucial. Technical interoperability will ensure that spatial boundaries are eliminated. However, this will not be enough for realising the benefits from the enormous supply of information – syntactic and semantic interoperability are required to make the information usable.

**FIGURE 4: ILLUSTRATIVE MAP OF ACTORS AND PROCESSES IN THE HEALTH VALUE SYSTEM**



Source: © empirica, 2006

### 3.2.2 A process perspective (value system)

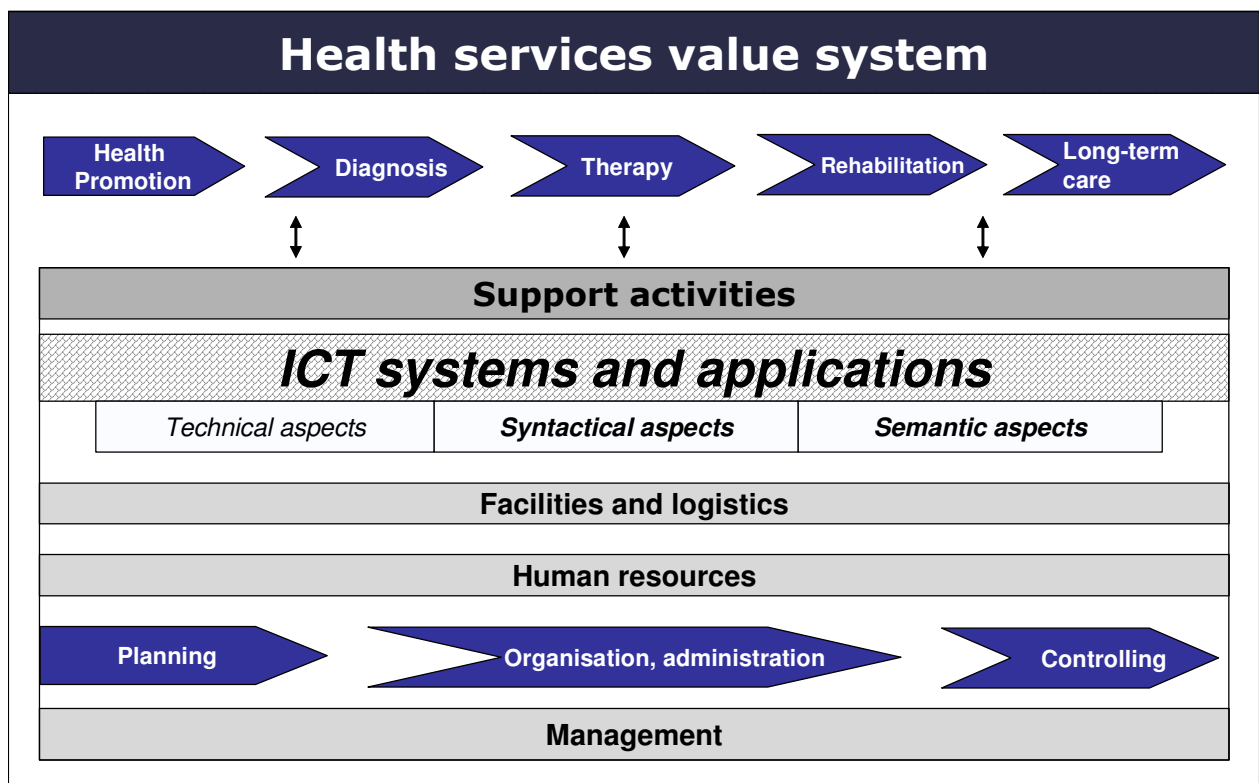
As already mentioned, modern information technology – generically named ICT for Health or eHealth – was first implemented for management and administrative functions. It has since evolved due to increasing potentialities to cover population-based considerations (aggregation for statistical purposes) and increasingly to embrace research in basic biological sciences – genetics, genomics, proteomics, etc. Today the goal is to increase quality and to control costs of healthcare by promoting an effective cooperation among healthcare professionals for continuity of care. ICT support and semantic interoperability among applications in composite workflows are recognised as essential conditions to reach improving safety, monitoring quality, providing decision support and supporting integrated research across the healthcare and biosciences.

Figure 5 below shows a general overview of support services in the health services value system. All health services, from health promotion, prevention, and diagnosis, through therapy and rehabilitation, to long-term care, are supported by management (including human resources) activities concerning the planning, organisation, and control of all healthcare and support services.

Facilities and logistics refer to the management of buildings and goods, the procurement and supply. More generally it is the task to ensure the right things are at the right time at the right place.

Further to that, ICT systems and applications support the health services directly, but also all other support services. *SemanticHEALTH* focuses on the syntactic and semantic aspects of this tier of supporting activities. The technological aspects are by no means considered of less importance, yet they are being continuously addressed elsewhere.

**FIGURE 5: HEALTHCARE DELIVERY PROCESSES AND SUPPORT ACTIVITIES (INCL. ICT)**

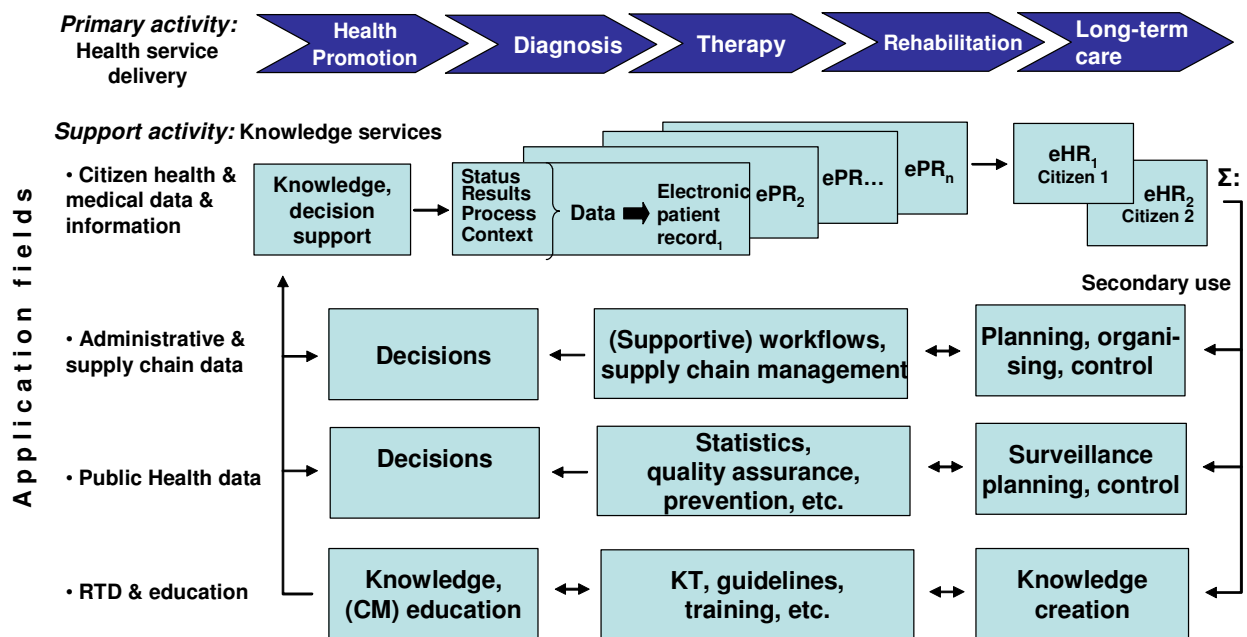


Source: © empirica, 2006

Here we may also consider one *specific actor group* - the *ICT and related industries* providing eHealth systems and solutions to health system actors. Also with respect to semantic interoperability their involvement and cooperation will be a key success factor to be considered in future RTD on our topic.

Figure 6 below illustrates the *complex pathways of information* on its way to creating an integrated, health system-wide knowledge base. Along the patient journey, including the phase of healthy citizens before they become patients, information about health status, medical data, and information are gathered continuously. This information can be structured and accumulated. ICT, or more specifically eHealth solutions, have a particular use in sharing this information with other actors and in further processing this information – its secondary use. eHealth opens new possibilities for decision support in the public health domain, administrative and other support services, as well as research and development. At the heart of these new opportunities is the *continuously growing knowledge base, accessible and understandable to all actors who need it.*

**FIGURE 6: THE CORE MEDICAL VALUE SYSTEM AND ICT-BASED KNOWLEDGE SUPPORT**

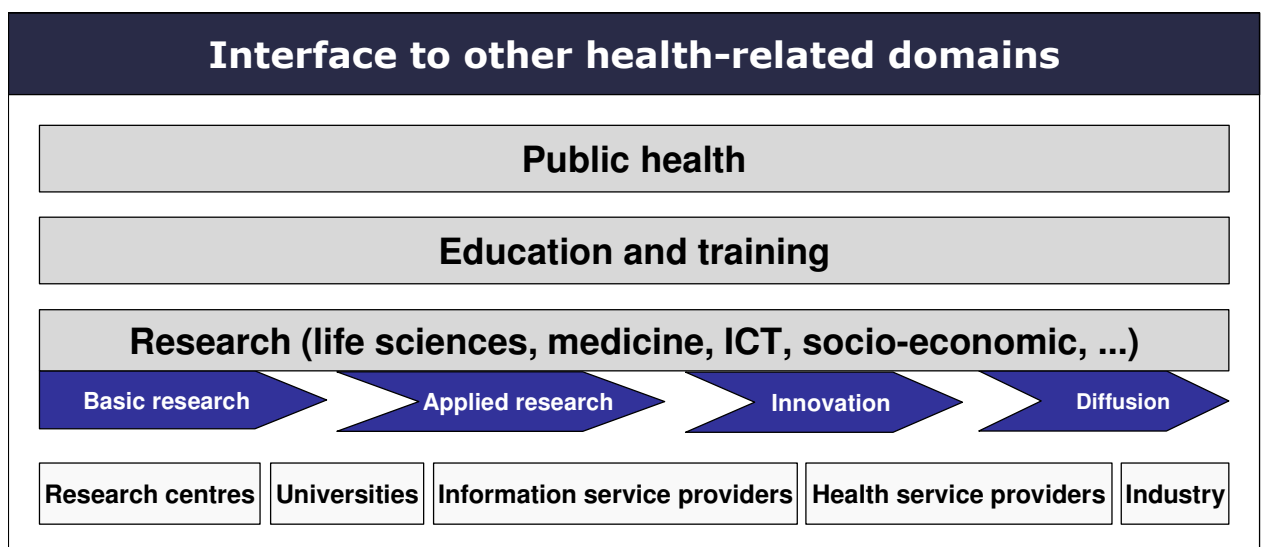


Source: © empirica / i2-Health, 2006

### 3.2.3 Interface to other health-related domains

The natural focus on healthcare when talking about eHealth does by no means create a barrier in the scope of applications, which support the health value system. Other related domains have to be taken into consideration not only because ICT has an impact on them and they have an impact on the health system, but also because eHealth acts as a bridge between the domains. Secondary use of medical information in public health, research, training, and education is nowadays essential to the development of these domains (see *Figure 6* above). In the other direction, the knowledge created by research, the skills and experience stemming from education and training and the various health promotion activities in the public health domain have a significant impact on every component of the health services value system.

**FIGURE 7: HEALTH-RELATED DOMAINS AND SECONDARY USES**



Source: © empirica, 2006

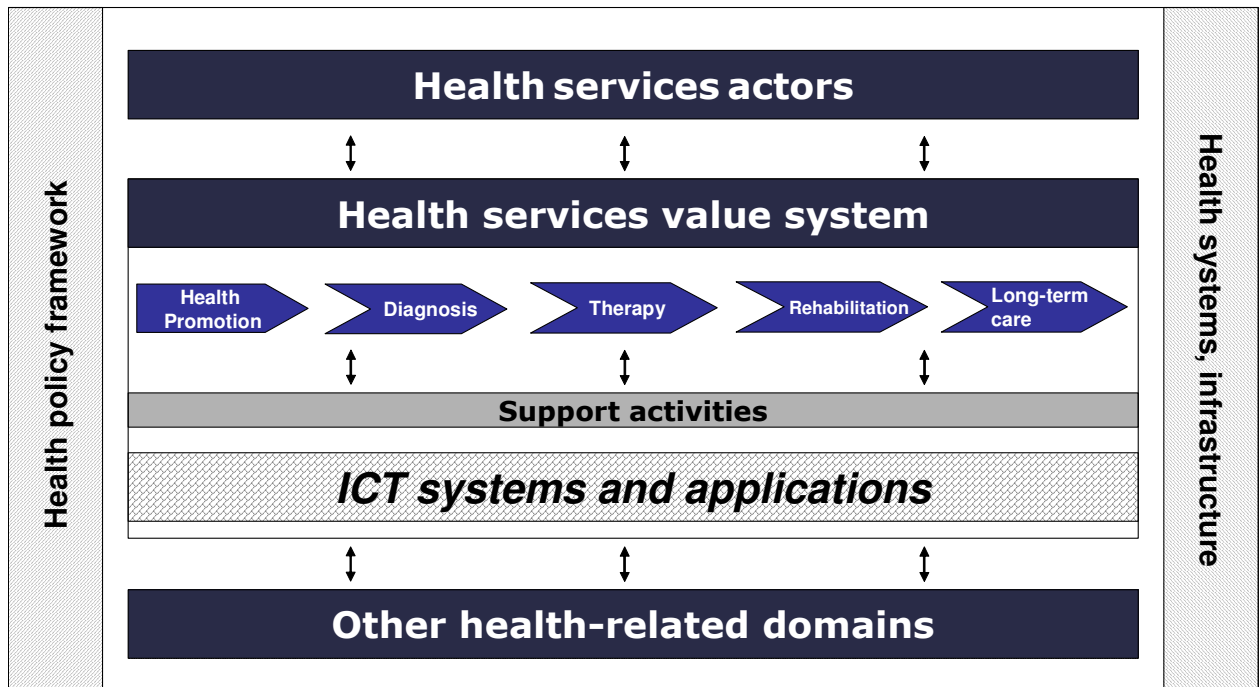
### 3.2.4 Overall context: health policy, health systems, infrastructure

It is important to stress again that all actors and processes are embedded in the **context** of their respective (national, regional) *health system* consisting of

- *health policy framework* (laws, regulations, associations, stakeholders, ...)
- *infrastructure* (health system institutions, public health services, eHealth infrastructure, ...)

This is illustrated in the *figure* below. The health system and infrastructure, as well as the policy framework, to a large extent shape the nature of the relationships between actors and their need and ability to communicate with each other. This concerns the health services value system, all the actors involved, the support services, and the health-related domains.

FIGURE 8: THE SEMANTICHEALTH CONCEPTUAL SPACE



Source: © empirica, 2006

## 4 Semantic interoperability: a three dimensional approach

In this Chapter we outline three dimensions of semantic interoperability that we need to take into account in semantic interoperability across all other workpackages of the project. These dimensions need to be reflected upon the broader conceptual space outlined in the preceding Chapter.

**TABLE 4: SEMANTIC INTEROPERABILITY: CONCEPTUAL DIMENSIONS**

Dimension	Issue
<b>A) Analytical dimension</b>	<p><b>1. Technological interoperability issues</b> (technical, syntactical, semantic aspects)</p> <ul style="list-style-type: none"> <li>- Information model</li> <li>- Architecture and messages</li> <li>- Archetype-template-interface with clinical terminology</li> <li>- Clinical terminology, ontology</li> <li>- Multilingual approach (encoding, language generation)</li> <li>- Standards (incl. de facto standards; actors in standard development: ISO, WHO, CEN; W3C; user groups – e.g. HL7)</li> <li>- Imaging</li> <li>- Security-integrity-availability</li> <li>- Open source</li> </ul> <p><b>2. Socio-economic issues</b></p> <ul style="list-style-type: none"> <li>- Health policy</li> <li>- Legal, regulatory issues</li> <li>- Economic issues (costs, benefits)</li> <li>- Management : planning, organisation (structures, processes), controlling, including change management</li> <li>- Stakeholder involvement</li> <li>- Professional culture</li> </ul>
<b>B) Application dimension</b>	<p><b>1. Clinical settings:</b> EHR, patient summary, interface with DSS, CPOE</p> <p><b>2. Public health:</b></p> <ul style="list-style-type: none"> <li>- Classifications</li> <li>- Demography (birth registration, mortality, morbidity, disability, risk factors,</li> <li>- Health indicators, etc.</li> </ul> <p><b>3. Secondary uses:</b> epidemiology, preparedness, patient safety, bioterrorism, healthcare management, financing, research, education</p> <p><b>4. Biomedical terminologies:</b> from genomics to population health (linkage and congruence)</p>
<b>C) Research dimension</b>	<p>To identify in each item of dimensions A) and B) where are the needs for research as opposed to the opportunity to apply immediately the existing knowledge</p>

For each of the identified issues/items it will be analysed which further short-term and long-term research is necessary for the initial successful implementation and further development.

Furthermore it will be discussed which *level* of SIOp is necessary for initial deployment, the necessary longer-term *requirements* in order to achieve an optimal level of interoperability will be identified and recommendations for appropriate *RTD actions* will be proposed.

Below we outline our understanding of these dimensions.

## 4.1 Analytical dimension

This includes two major groups: technological interoperability and socio-economic issues.

### 4.1.1 Technological interoperability issues

Technological interoperability issues of eHealth interoperability include issues such as information models, architecture, archetypes, terminology standards and ontology. So far, numerous divergent initiatives have tried to address interoperability issues in these domains from their individual points of view. However, none have been fully successful in combining the need for flexibility, fine granularity in terminology and healthcare record structures, the needs of healthcare professionals, and the requirements of robustness and reliability needed for a safety critical patient care enterprise. However, new technical and practical developments and the greater urgency of the requirements in the face of changing healthcare needs and practices make it appropriate to reassess these efforts. The project has identified the following technological issues to be taken into account:

Technological interoperability issues (technical, syntactical, semantic aspects)

- Information model
- Architecture and messages
- Archetype-template-interface with clinical terminology
- Clinical terminology
- Ontology
- Imaging
- Open source
- Multi lingual approach
  - Encoding
  - Language generation
- Security-integrity-availability
- Standards (incl. de facto standards)
- Actors
  - ISO
  - WHO
  - CEN
  - User groups (e.g. HL7)
  - W3C

### 4.1.2 Socio-economic issues

The project has identified the following non-technological issues for further analysis:

First, the project will look at **health policy priorities** of Member States. Here as with all other aspects, the goal will not be to analyse these in detail, but rather to identify key challenges and opportunities which may need closer attention and research when developing a comprehensive RTD roadmap.

Next, key aspects of the **legal and regulatory environment** within which semantic issues will be imbedded need to be identified. In various countries, the application of certain coding schemes like ICD may be required by law, and also **infrastructure institutions** necessary to sustain such systems may be part of the public healthcare system of a Member State - all of which will have to be considered when planning to improve semantic interoperability.

Furthermore, socio-economic aspects include **benefits and costs** related to issues of semantic interoperability. Reaching high levels of interoperability is a resource-intensive task. The general economic challenge of investing in ICT in the health domain is to maximise the benefits from eHealth, given the constraints in resources. Interoperability plays a significant role in this optimisation equation. It is often essential in realising the benefits from eHealth investments, but it also consumes a significant share of the available resources.

**Organisational aspects** are another complex dimension. Organisational aspects include:

- Changing care pathways that need new information, skills, knowledge and process in health care providers
- Increased collaborative working and exchange of information between providers
- New relationships between citizens and health care professionals and organisations

Such issues will have an impact on whether and how solutions will be implemented, and the potential implementation will often dramatically impact on organisational structures at the level of health care provider organisations (e.g. changes in power relationships and hierarchy), at the regional level on relationships and interactions among health care provider organisations (HPO), and also at the health system level (like globalisation of health care services). And implementations may fail when such considerations are not already part of the RTD and diffusion process.

Looking at another dimension of organisational issues, work flow/process organisation will equally be impacted upon.

It is known that **professional culture issues** are a key factor in health services. This concerns first of all the great diversity of attitudes, behaviour and knowledge exchange among professional and non-professional staff involved in health care, and the impact this has on the quality, efficiency and processes of services. Even among wards in the same hospitals this may differ considerably, and it quite often differs already among hospitals in the same region. Differences are more pronounced as a factor of nationality or country, respectively the idiosyncrasies of regional or national health care systems. Education and training, professional standards and bodies, rules and regulations, attitudes and behaviour all have an influence here. We may also expect that in future, ethnic diversity will play a larger role than presently in most Member States.

**Stakeholder involvement** is also a key factor to be considered here. This involves issues of, e.g., how to increase awareness of overriding, societal benefits arising from semantic interoperability and motivate stakeholders to become an active part of relevant processes and organisations to foster interoperability.

## 4.2 Application dimension

The number of application fields where semantic interoperability issues play an important role should not be underestimated. To begin with semantic issues play a key role in clinical settings, including eHealth applications such as EHR and patient summary. Furthermore, so call secondary use and public health use of clinical data needs to be taken into account. Finally, biomedical terminology plays a role. Ontologies, terminologies, classifications, and related reference knowledge resources are key tools for interoperability and developing the infrastructure for their long term maintenance and sustainability is one of the keys to achieving interoperability.

### 1. Clinical setting

#### 1.1 EHR

#### 1.2 Patient summary

### 2. Public Health

#### 2.1 Classifications

#### 2.2 Demography

##### 2.2.1 Birth registration

##### 2.2.2 Mortality

##### 2.2.3 Morbidity

##### 2.2.4 Disability

##### 2.2.5 Risk factors

##### 2.2.6 Definition of WHO standards

#### 2.3 Key health indicators

#### 2.4 Health care facilities

#### 2.5 System parameters

##### 2.5.1 Coverage

##### 2.5.2 Safety

#### 2.6 Semantic congruence between different granularity levels

### 3. Secondary uses

#### 3.1 Epidemiology

#### 3.2 Emergency response and preparedness

#### 3.3 Adverse drug reaction monitoring

#### 3.4 Patient safety

#### 3.5 Bioterrorism

#### 3.6 Health care facilities management

#### 3.7 Health financing

#### 3.8 Research

### 3.9 Teaching

4. Biomedical terminologies (from genomics to population health) linkage and congruence

## 4.3 Research issues

Within each of the different workpackages 2 to 6 the research issues will have to be identified and briefly described in term of goals, size of the effort and forecasted time schedule in order to separate which applications can start to be developed immediately based on the existing knowledge from the applications needing a research investment and which must be delayed until a consolidated knowledge is made available (for instance in ontology and genomics terminology).

In the next section we identify three key levels of semantic interoperability based on currently existing or planned implementations.

## 5 Three implementation based levels of semantic interoperability

As this Support Action is based on real existing implementations, or implementations planned for the near future, we will distinguish 3 levels of semantic interoperability:

<b>Level 1:</b>	no semantic interoperability (only technical or structural interoperability)
<b>Level 2:</b>	intermediate interoperability (partial exchange of meaning)
<b>Level 3:</b>	fully sharable semantic interoperability, or co-operability

The 3 levels are explained as follows.

Consider two independent information systems named A and B, each having its own user community (Users A and Users B), its own purpose and its own deployment settings.

**Level 1 (*technical interoperability*)** is reached if System A is able to send information electronically to System B, but without any guarantee of the safety of any automatic (machine based) interpretation of meaning. Supplementary human interpretation by User B will usually be needed to ensure that the communicated data is safely and completely usable by computational processes within System B.

**Level 2 (*intermediate interoperability*)** is reached if System A is able to send information automatically to system B, but System B (and Users B) can only interpret the meaning from the perspective of users A and System A. The use of terms or constructs reflects the culture and perspective of Users A, and this might not correspond directly with equivalent data captured by Users B in System B.

**Level 3 (*full semantic interoperability, or co-operability*)** is reached if Users of System B are able to use information acquired automatically from System A with equivalent meaning to its local data: the information can be processed homogeneously with data captured natively within System B, as if they were entered by a User B directly into System B. Note: the data might not be represented homogeneously, but sufficient transparency and sharing of meaning exists for the data to be processed homogeneously, safely.

It is also necessary to emphasise, that **interoperability is not a necessarily symmetric relation**. It may happen that system A is interoperable with system B, while system B is not interoperable with system A. The following symbolic representation summarises this set of situations:

SystA $\Rightarrow$ SystB;	but not SystA $\Leftarrow$ SystB;	asymmetric SIOP
SystA $\Leftarrow$ SystB;	but not SystA $\Rightarrow$ SystB;	asymmetric SIOP
SystA $\Leftrightarrow$ SystB;		symmetric SIOP

It is also possible to have partial interoperability with or without asymmetry: there may be subsets that are shared that enables SIOp whereas beyond these subsets the systems may not be interoperable. The partial nature could be expressed in terms of part-total ratio.

These levels could be achieved

- within an institution
- across institutions
- human-to-human

These levels should be related to the **desiderata for the SIOp**.

- a) *Readable* - with potential for reuse
- b) *Searchable*
- c) *Systematic identification with meta data*
- d) *Systematic coding with hierarchy*
- e) *Systematic coding with context information*

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***.

Within Workpackage 1 this conceptual framework will later be cross-tabulated with an inventory of key relevant Member States and international experiences. A scoring for SIOp infrastructure connectivity will be introduced based on the 3 levels of interoperability.

Finally 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. As a consequence there may be ***different ways to semantic interoperability***:

1. Everyone adopts *a single model* {which is very unlikely}
2. Everyone has its *own model but interchange standards* {this needs bilateral/multilateral agreements}
3. Everyone agrees about *common data elements* with systematic unambiguous format e.g. data descriptions (datatypes, terminologies, coding), meta data, information model
4. Everyone uses *knowledge representation framework* (classes, attributes, definitions, identification principles) and *inference mechanisms* (inclusions, exceptions, constraints, reasoning etc)
5. Other

## Appendix

### Operationalisation for use in the project

An initial set of items is listed below, along with the *SemanticHEALTH* Work package(s) that will study these items or a subset of items to identify issues and gaps. This “a priori” list will be used within *SemanticHEALTH* as a support for Work packages 2-6. Each WP will study relevant parts of the framework in more detail. As a result each item will be more precisely defined, some may be split and some merged to avoid duplication or redundancy. The final framework will be used in WP7 to identify issues and gaps. The starting point of the roadmap will probably be different and will be validated by a workshop, and by the initial mapping of the EU Member States and international initiatives.

#### A. Analytical dimension

1. Technological interoperability aspects (WP2)
  - 1.1 Information model (WP2 + WP4+WP5)
  - 1.2 Architecture and messages (WP2 + WP4)
  - 1.3 Archetype-template-interface with clinical terminology (WP2 +WP4 + WP5and WP6)
  - 1.4 Clinical terminology (WP2 + WP6)
  - 1.5 Ontology (WP2 + WP6)
  - 1.6 W3C (WP2 + WP6)
  - 1.7 Imaging (WP2 + WP4)
  - 1.8 Open sources (WP2 + WP3)
  - 1.9 Multi lingual approach (WP2 +WP5 and WP6)
    - 1.9.1 Encoding
    - 1.9.2 Language generation
  - 1.10 Security-integrity-availability (WP2 +WP4)
  - 1.11 Standards (WP2+WP4 +WP5 +WP6)
    - 1.11.1 ISO
    - 1.11.2 WHO
    - 1.11.3 CEN
    - 1.11.4 Users groups (e.g. HL7)
    - 1.11.5 De facto
2. Socio-economic aspects (WP3)
  - 2.1 Health policy
  - 2.2 Legal, regulatory issues

2.3 Economic issues: costs, benefits

2.4 Management

2.4.1 Planning

2.4.2 Organisation

Structure, processes, controlling

From artefacts to process: open approach

Flexibility in time

Localisation, globalisation

Change management

2.5 Stakeholder involvement

2.6 Professional culture

## **B. Application dimension - fields of interoperability**

1. Clinical setting (WP4 and WP6)

1.1 EHR (WP4 and WP6)

1.2 Patient summary (WP4)

2. Public Health (WP5 and WP4)

2.1 Classifications

2.2 Demography

2.2.1 Birth registration

2.2.2 Mortality

2.2.3 Morbidity

2.2.4 Disability

2.2.5 Risk factors

2.2.6 Definition of WHO standards

2.3 Key health indicators

2.4 Health care facilities

2.5 System parameters

2.5.1 Coverage

2.5.2 Safety

2.6 Semantic congruence between different granularity levels

3. Secondary uses (WP5 and WP4)

3.1 Epidemiology

- 3.2 Emergency response and preparedness
- 3.3 Adverse drug reaction monitoring
- 3.4 Patient safety
- 3.5 Bioterrorism
- 3.6 Health care facilities management
- 3.7 Health financing
- 3.8 Research
- 3.9 Teaching
- 4. Biomedical terminologies (from genomics to population health) linkage and congruence (WP6 and WP5)

**C. Research issues addressed** (all WP)