European Commission, DG Enterprise & Industry

e-Mail: entr-innov-ict-ebiz@ec.europa.eu,
info@ebusiness-watch.org

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ICT standards in the health sector: current situation and prospects

A Sectoral e-Business Watch study by empirica

Final Report

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This report was prepared by empirica GmbH on behalf of the European Commission, Enterprise & Industry Directorate General, in the context of the "Sectoral e-Business Watch" programme. The Sectoral e-Business Watch is implemented by empirica GmbH in cooperation with Altran Group, Databank Consulting, DIW Berlin, IDC EMEA, Ipsos, GOPA-Cartermill and Rambøll Management based on a service contract with the European Commission.

About the Sectoral e-Business Watch and this report

The European Commission, Enterprise & Industry Directorate General, launched the Sectoral e-Business Watch (SeBW) to study and assess the impact of ICT on enterprises, industries and the economy in general across different sectors of the economy in the enlarged European Union, EEA and Accession countries. SeBW continues the successful work of the *e-Business W@tch* which, since January 2002, has analysed e-business developments and impacts in manufacturing, construction, financial and service sectors. All results are available on the internet and can be accessed or ordered via the Europa server or directly at the *e-Business W@tch* website (www.europa.eu.int/comm/enterprise/ict/policy/watch/index.htm, www.ebusiness-watch.org).

This document is a final report of a Special Study, focusing on ICT standards in the health sector. The study describes current developments in this field and assesses implications thereof for policy makers and the health industry as a whole. The elaborations are based on literature analysis, an online survey of health experts and expert interviews

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Contact

For further information about this Sector Study or the Sectoral e-Business Watch, please contact:

empirica	e-Business W@tch	
empirica Gesellschaft für Kommunikations- und Technologieforschung mbH Oxfordstr. 2, 53111 Bonn, Germany Fax: (49-228) 98530-12 info@empirica.com	***e-Business W@tch*** c/o empirica GmbH Oxfordstr. 2, 53111 Bonn, Germany Fax: (49-228) 98530-12 info@ebusiness-watch.org	**European Commission** Enterprise & Industry Directorate-General ICT for Competitiveness and Information Fax: (32-2) 2967019 entr-innov-ict-ebiz@ec.europa.eu

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Executive Summary

Objectives and scope of the study

The objective of this report is to provide a structured overview of key ICT standards in the health sector and to understand related needs of ICT producing and using industries. Standardisation processes as well as economic impacts are analysed and policy implications are derived thereof. The report pays particular attention to standards for electronic health records. Since the field of ICT standards in the health sector is very wide and difficult to overview, it focuses on key standards, key trends in standardisation, and important implications. The report is based on literature evaluation, expert interviews, and results of an international online survey of e-health experts.

This report takes an industry perspective so that "ICT standards in the health sector" is an appropriate term. However, it is often abbreviated to "e-health standards" in this report.

Defining standards and their importance

Standards are defined here in a general, functional sense as "technical specifications". From an institutional perspective one can distinguish four types of standards: official standards which are mandatory to use, voluntary standards, proprietary standards defined by industry, and open standards. Standards are of enormous economic importance: By determining both the requirements producers have to fulfil and the expectations of the customer, standards reduce problems of risk, transaction costs and issues of interoperability (section 2.1).

For the European Commission (EC), standardisation remains a voluntary, consensus-based, market driven activity. The EC promotes standardisation because it considers standardisation as a priority issue for the competitiveness of a number of industries in Europe, including ICT manufacturing.

Sketch of the current situation of e-health standards

The current situation of e-health standards may be summarised as follows (section 2.2.1):

- **Conflicting standards, versions and implementations:** There is a lack of standards that are widely used, implying that standards often conflict and interoperability problems often occur. Many of the conflicting standards are proprietary. There may also be different or flawed implementations of the same standard that are not interoperable. In some cases even different versions of the same standard may conflict.
- **Lack of "right" standards:** There is also a lack of the "right" e-health standards, i.e. well-developed standards for particular applications and concrete use cases.

For health service providers, this situation may imply that computerised systems remain stand-alone and unable to exchange data with each other in-house or externally. Health service providers may have to invest considerable funds to make systems that operate with different standards interoperable.

Barriers to e-health standards adoption and promotion

Reasons for the currently problematic situation in e-health standards can be broken down by stakeholders: governments, SDOs, industry, and ICT users (section 2.2.2):

- **Political barriers:** On the one hand, there are many different national and also regional health systems with different standardisation approaches and standards implemented across Europe. On the other hand, there is also low governmental support for developing prominent e-health standards and the level of incentives to communicate electronically – which may spur the use of standards – is low.
- **SDO barriers:** There is a large number of SDOs developing e-health standards. The main reason why they do not simply agree on common standards or harmonise their standards is that standards development is an expensive investment, and SDOs wish to realise positive returns.
- **Company barriers:** Just like SDOs, ICT firms seek to realise the returns from their standardisation efforts. Furthermore, manufacturers may not be willing to adopt commonly used standards because these are very complex and thus expensive to implement. Finally, a situation of many conflicting standards may be favourable for companies that sell middleware or services to make systems interoperable.
- **ICT user barriers:** On the part of health service providers such as general practitioners, community care centres, and hospitals, barriers to adopt widely used e-health standards are mainly related to costs: Search costs for systems with the most suitable standards, costs of converting existing data to new standards, and costs of software upgrades which may be necessary before adopting standards.

Activities to harmonise standards

Currently there is now powerful process to harmonise existing standards. However, recently there has been a major advance in such activities. In August 2007, a collaborative e-health standards harmonisation group was formed between the European Standardisation Committee (CEN), the International Standardisation Organisation (ISO), and Health Level 7 (HL7). This initiative may potentially be very influential in the future.

All in all, the stakeholders involved in e-health standardisation are increasingly becoming aware of a need to develop the market for standards, and they are more and more active in this respect. The Member States' e-health large-scale pilot planned to start in 2008, being funded by the ICT Policy Support Programme (PSP), is expected to become a further catalyst in this respect (section 2.2.3).

Standardisation of electronic health records

Introducing electronic health record (EHR) systems and defining related standards is an important topic on the agenda of many European countries and the EC. In July 2008 the EC issued a Recommendation on cross-border interoperability of electronic health record systems. EHR applications are available for an increasing number of institutions. However, solutions are often isolated without data exchange and interoperability, and they have implemented early and limited EHR versions. Contributing to the delay of more sophisticated EHR implementations is a lack of EU-wide standards for the collection, coding, classification and exchange of clinical and administrative data (section 2.2.4).

Principal standardisation organisations and initiatives

Five principal standardisation organisations, a promising open source initiative and a major interoperability initiative have been selected for detailed analysis in this report as they can be expected to play a leading role in further e-health standards development:

- **ISO**, the International Organisation for Standardisation, as the largest developer of world-wide standards,
- **CEN**, the European Committee for Standardisation as the principal SDO in Europe,
- **IHTSDO**, the International Health Terminology SDO, as the developer of the fairly widely adopted SNOMED-CT terminology standard,
- **HL7**, Health Level 7, as the developer of the most widely used standards for electronic messages in healthcare,
- **DICOM**, Digital Imaging and Communications in Medicine, as a de facto standard for electronic medical imaging,
- **OpenEHR** as a promising open source activity for electronic health records,
- **IHE**, Integrating the Healthcare Enterprise, as a major e-health systems interoperability initiative.

Understanding the objectives, rationales and constraints of these organisations may help to form viable alliances for harmonising and consolidating standards.

Findings from an online survey of e-health experts

In November 2007, empirica conducted an online survey of e-health experts from ICT industry, user organisations, public authorities, university and research, SDOs, and consultants. 94 experts responded. The principal results were the following (chapter 3):

- **Future importance of standards development SDOs**: The majority of respondents agreed that all seven e-health SDOs mentioned (ISO, CEN, IHTSDO, HL7, IHE, DICOM, openEHR) should be important in the future.
- **Current situation in e-health standards:** Nearly all interviewees agreed that there is a lack of widely used e-health standards. There was also agreement that there is a lack of sufficiently developed e-health standards, a lack of e-health standards harmonisation activities, and that there are too many conflicting e-health standards.
- **Impacts of current situation**: Nearly three quarters of the respondents indicated that within a single health service provider the overall situation is supportive, but the majority found the situation unsupportive for cross-border care provision.
- **Current situation in e-health standardisation processes:** The respondents favoured a stronger involvement in e-health standardisation processes from many different organisations, including above all ICT user organisations and national governments, but also national competence centres, the EC and ICT industry.
- **Barriers to adopt common e-health standards in hospitals**: Hospital IT managers may first of all find internal process functionality more important than commonly used standards. The respondents also agreed that the managers miss financial incentives to electronically exchange information.

Economic implications

Business analysts assess the market for health information systems in Europe as being huge and largely untapped. However, interoperability problems may be one reason for hospitals and other health service providers to hold off investments in ICT. Consequently, growth in companies supplying ICT for the health sector is smaller than it could be. Furthermore, economic growth related to standardisation may accrue predominantly in the country or part of the world where a standard has been developed (section 4.1).

Further economic implications of a lack of commonly used e-health standards are lost opportunities for cost reduction and compromised quality of healthcare. As regards costs, due to a lack of commonly used standards, opportunities for streamlining health service processes and for delivering activity data for more effective accounting and controlling are lost. As regards health care quality, a lack of information systems integration may prolong physicians' and nurses' access to patient data (section 4.1).

Policy implications

In January 2008, the US Department of Health and Human Services recognised certain interoperability standards for health ICT which federal agencies have to include in procurement specifications for certain fields of health. This could be a step towards mandatory use of a confined number of standards for principal e-health applications. Such a regulation by the US government could have considerable impacts in the EU. In order to prevent unfavourable developments, the EC and the Member States may be well advised to develop a common strategy and roadmap for e-health standards development.

A solution for the interoperability challenge in e-health may be the common use of a more confined and harmonised number of well-developed standards. Related efforts by the EC and national governments should involve the following **objectives** (section 4.2.1):

- Promote an EU-wide agreement on priority standards. Promote an increased uptake of prominent standards, for example those developed by ISO, CEN and HL7, and thereby increase the network benefits of standards use.
- Promote the development of standards in applications areas in which there is currently a lack of well-defined standards.
- Promoting the harmonisation of key standards that conflict with each other.

In order to achieve these objectives, the following **means** may be used (section 4.2.2):

- The collaboration initiative of ISO, CEN and HL7 should be strengthened.
- Stronger involvement of industry and user groups in the standardisation process by ensuring that the outcome of the standardisation efforts are highly relevant for them.
- Member States and their national Competent Authorities should become more committed to international e-health standardisation.

The EC and Member States should implement a **roadmap** for further development of e-health standards (section 4.2.3). The large-scale pilots for patient summaries and e-prescribing planned to take place in Member States should be stepwise extended to other key applications. In parallel it will be mandatory to also develop standards for a European e-health infrastructure.

1 A need for ICT standards consolidation in the health sector

A severe lack of ICT interoperability in the health sector

The interoperability of information and communication technology (ICT) systems is indispensable for efficient business 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.[1] In short: they use ICT systems operating with different and often conflicting standards. The consequence is that information systems in the health sector are very often, if not usually fragmented and unable to exchange data in a meaningful way. 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,[2] such interoperability problems need to be solved at the international level.

The lack of ICT systems interoperability and of widely accepted standards directly implies compromised quality of healthcare and unnecessarily high costs of the health systems. Indirectly, the lack of interoperability also implies a lack of economic growth and a lack of competitiveness of European ICT manufacturers versus their competitors in other parts of the world. While there are ICT interoperability challenges in many if not all industries, they appear to be particularly high in the health sector. This is because e-health standards compound the difficulties of the general ICT field plus those specific to health ICT applications and the complexity of an ever expanding clinical field.

ICT standards consolidation to overcome interoperability problems

Standards are key to interoperability because they provide the specifications which are necessary for systems to communicate meaningfully with each other. From the perspective of the buyers and users of healthcare ICT – for example general practitioners or ICT managers in hospitals, community care centres and insurance funds – interoperability problems may arise because of various shortcomings of e-health standards and standardisation. These may include a large number of conflicting standards on the one hand but too few or insufficiently developed standards for particular solutions on the other hand. From an ICT industry perspective, there is a lack of

[1] See European Commission, Enterprise and Industry Directorate-General (2005), "e-Business Interoperability and Standards: A Cross-Sector Perspective and Outlook", for current background information on the subject.

[2] See the related declaration in eHealth 2007 Conference (2007).

sufficiently specified and commonly used ICT standards that meet user needs.

Consequently, a solution for the ICT interoperability challenge in the health sector may be the common use of a more confined number of well-developed and harmonised standards. This may in short be considered as "standards consolidation". Standards consolidation is easily stated as an objective but difficult to realise. Numerous standardisation organisations, governments, and enterprises with diverging interests are struggling to maintain or gain power in defining ICT standards for the health sector. The number of standards used and the number of organisations involved in defining standards is very high and almost impossible to overview. The complexity of the area of ICT standardisation itself is an important barrier to reach the objective of standards consolidation and even to decide where and how best to tackle it. Structuring the area of e-health standardisation and thus reducing this complexity is a key objective of this report.

Purpose of this report: structuring the area, discussing implications

Considering standards as fruit and standards development organisations as trees, the area of standardising ICT in the health sector is a jungle. The purpose of this report is to carve roads into this jungle, to identify the most important spots, trees and fruits, and to suggest how to target and grow these in a sustainable manner. An issue that is of particular importance because it is on the agenda of many European countries and of the European Commission is the definition of standards for electronic health records. This issue receives particular attention in this report. This study provides the following:

- A **structured overview** of the most important ICT standards in the health sector, key standardisation actors as well as of approaches to standardisation and barriers to adopt standards so that they become more widely used. Thereby the study pays particular attention to standards for electronic health records.
- A discussion of **economic implications** of a lack of common standards in the health sector.
- Proposals for **policy implications**, including mechanisms for a more intensive involvement of ICT industry in the development of standards and a roadmap for the development of common standards in the areas of electronic health records and electronic interchange between health professionals.

Structure of this report

Following this introduction, chapter 2 describes the state of the art of ICT standards in the health sector: general notes on standardisation (section 2.1), current key characteristics of e-health standards and standardisation (section 2.2), and a description of the most important e-health standardisation organisations (section 2.3). Chapter 3 provides findings from an online survey of international e-health experts. Finally, chapter 4 deals with economic and policy implications.

In accordance with the purpose of the e-Business Watch, this report takes an industry perspective so that "ICT standards in the health sector" is an appropriate term. However, for the sake of briefness, this term is often abbreviated to "e-health standards" in this report, a term that is commonly used in health contexts.

2 ICT standards in the health sector: a structured overview

2.1 Towards a general understanding of the importance of standards

A functional definition of standards as technical specifications

Structuring the area of e-health standards foremost requires a solid understanding of what a standard is. In an operational sense, standards are "technical specifications". A standard implies the existence or opportunity of an agreement between different parties which are interested in implementing and using these specifications. This simple functional definition is only one among many, but especially useful in supporting the analysis in this report.

The operational purpose of a standard is to achieve the highest level of order within the execution of particular activities, or the creation of particular results.[3] For example, two hospitals may decide to share patients' x-ray images over a computer network. In order to support and seamlessly integrate the information, both hospitals have to agree on, first, a data format for the content and, second, a communication format for the transmission. Data formats specify the information within data files, whereas the communication standard defines the format to physically transmit the medical images over a network. The format "Digital Imaging and Communications in Medicine" (DICOM) incorporates both specifications within a single standard.[4]

Types of standards by institution: official, voluntary, industrial and open

A distinction of types of standards by organisations developing them is important to understand the interests behind standardisation processes and who drives or could drive them, also in the field of e-health. From an institutional perspective one may distinguish four types of standards: official, voluntary, proprietary, and open standards. Official and voluntary standards may both be called "formal" standards:[5]

- **Official standards** are made obligatory through regulation by governments, for example by law. Prior to being made mandatory they were approved by Standards Development Organisations (SDOs) such as the International Standards Organisation (ISO). Well-known examples include the definition of a meter and the ISO 9000 standard for quality management.
- **Voluntary standards** are developed by SDOs, normally on request from interested parties such as industry, but are not made mandatory by governments. For example, the European Committee for Standardisation (CEN) has the objective to develop voluntary technical standards.[6]

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[3] See http://www.iec.ch/ourwork/iecpub-e.htm.

[4] See section 2.3.7 for further details about DICOM.

[5] See Blind (2004), p. 2 for a similar distinction.

[6] See http://www.cen.eu/cenorm/aboutus/index.asp.

- **Industry standards** are defined by one single company or groups of companies. Initially they are always proprietary, i.e. their specifications are not disclosed. The companies may seek to reach acceptance of such standards in the market process, i.e. by successfully selling goods that operate with these industry standards. This procedure has been successfully demonstrated multiple times in the world of ICT, including the introduction and distribution of the Microsoft operating systems MS-DOS and MS-Windows. For industry standards that are widely used, the notion "de facto standard" has become common. Companies may also develop industry standards for internal communication within a single establishment or between several establishments, without seeking to make the standard adopted by other companies.
- **Open standards** are characterised by the circumstance that everybody can participate in their development without being a member of a specific group or institution. Further aspects that constitute such a model and the idea of openness are that standards are available to anybody for free or at a low cost, and standards are free to use by anybody; in particular they are patent-free and do not require proprietary software to run.[7]

In practice, many standards do not fall neatly into one of these categories. For example, governments may be involved in unofficial SDOs and influence the development of industry standards, and industry may be involved in unofficial SDOs or influence governmental decision about standards. Nevertheless, the distinction of the four generic types of standards is useful for the analysis and conclusions in this report.

Interoperability standards, switching costs and network effects

Standards can also be distinguished by their economic implications. The most important category for this report is interoperability and interface standards which have gained huge importance in the course of ICT and e-business development.[8]

Interoperability is defined here as the ability of two or more ICT systems to exchange both computer interpretable data and human interpretable meaning, i.e. knowledge and information.[9] In the health sector, ICT systems interoperability may for example mean to be able to automatically exchange patient data from a laboratory system to a medical record system within a hospital, to exchange digital x-ray images electronically between different hospitals and general practitioners, to transmit reimbursement data electronically from a hospital to a health insurance fund, or to submit data about the occurrence of certain diseases to public health administration via computerised systems. Systems interoperability can thus contribute to improving the quality of healthcare and of public health and to decreasing the costs of the health system.

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7 See Coyle (2002).

8 See Swann (2000), pp. 4-7. Swann uses the notion "compatibility" instead of "interoperability". Swann distinguishes three further categories: minimum quality and safety standards (e.g. ISO 9000, that help buyers to identify and sellers to design high quality products), variety reducing standards (e.g. suit sizes that allow customers to buy quick and cheap and garment vendors to exploit economies of scale), and measurement and product description standards (e.g. fuel types such as leaded and unleaded, which normally are a hybrid of the three first categories).

9 See IDABC-EIF (2004).

The examples provided include the four types of organisations that are considered as the key health system actors in this report: (1) ambulatory service providers such as general practitioners or community care centres, (2) hospitals, (3) insurance funds, and (4) public administration.

From an economic perspective, there are two particular phenomena that influence producer and customer decisions with regard to interoperability. First, systems producers and customers face **switching costs**. Before they were committed to a particular standard, they were free to choose between different ones. But once they have invested in a particular system or standard it may be expensive to switch over. Second, producer and customer choices are influenced by so-called **network effects**: it is desirable to choose a system and standard that is widely used by others. Network effects also imply that it may not be meaningful to invest in communication systems or standards at all when they are not widely used. When both the "switching cost" and the "network effects" phenomena exist, there is a risk that markets can get locked into inferior designs because both sides are reluctant to switch to something better unless they can be sure that all others will too. This has been described as a problem of **technological lock-in**.[10]

Economic benefits of standards: increased trade, innovation and growth

Standards do not merely ease technological processes, standards are of enormous economic importance. Historians researching about the influence of standards have observed that standards were essential for the growth of trade from the earliest times.[11] This is because any trade involves risks, transaction costs and issues of interoperability. Standards serve to reduce these problems by defining characteristics of products and processes and thereby determining both the requirements producers have to fulfil and the expectations of the customers. Standards hence can foster trade. Consequently, standardisation can increase the volume of trade, imports as well as exports, and contribute to economic growth.[12] More detailed, a comprehensive study by the German Institute for Standardisation (Deutsches Institut für Normung, DIN) including analyses of the macro-economic benefits of standardisation found the following:[13]

- Standards have a positive effect on trade and do not seem to act as barriers to trade.
- International standards are more important than national standards in encouraging intra-industry trade.
- Standards contribute to economic growth at least as much as patents.

For modern, technology-driven economies, one important aim of standardisation is to *"help create a strong, open, and well-organised technological infrastructure that will serve as a foundation for innovation-led growth"*.[14] Standardisation helps to foster *"credibility,*

[10] See Swann (2000), p. 4, for a more detailed discussion.

[11] See Dilke (1987); Erwin (1960); Groom (1960); Skinner (1957); Sullivan (1983); Varoufakis (1999).

[12] See Swann (2000), p. v, and Blind (2004), p. 51.

[13] See DIN (2000).

[14] Swann (2000), p. iv.

focus and critical mass in markets for new technologies".[15] This is because standards may ensure that new technology products are interoperable and thus increase network effects and reduce costs of switching to other technologies. A good example may be the Global System for Mobile communications (GSM) standard that was launched in 1990 and opened up a world-wide market for mobile phones.[16] In principle, the use of common standards can create economies of scale, accelerate the innovation and diffusion of new products and services, reduce equipment costs and thereby increase competitiveness of firms, industries and regions. However, imposing standards may stifle innovation so that it is important to generally leave it to industry to agree on common standards.

Against this background, the European Commission considers standardisation as a priority issue for the competitiveness of a number of manufacturing industries in Europe, including ICT manufacturing.[17]

2.2 Overview of ICT standards and standardisation in the health sector

2.2.1 Characteristics of the current situation of ICT standards in the health sector

Structuring ICT standards in the health sector

Since there is a vast amount of ICT standards in the health sector, a first step in an attempt to structure this area is to define categories or domains of standards. Standards used in the e-health domain can be clustered into at least seven different sub-domains according to their function in a computerised system (see Exhibit 2-2): Standards for architecture, modelling, communication, infrastructure, data security and confidentiality, patient safety, as well as terminology (including ontology).

Standards in the different categories are highly interrelated, sometimes with repeating aspects from a slightly different focus, but often dependent on others. This adds to the complexity of the standards and their development as well as understanding in the e-health domain. For example, DICOM is primarily considered as a communication standard, namely for digital images. However, DICOM includes security aspects, too, and can therefore also be listed as a security standard. Exhibit 2-2 provides explanations and a couple of examples of standards of the seven types.

For this report, only a limited number of standards closely related to electronic health records (EHRs) and electronic messages between health service providers are considered. These are primarily within the field of architecture, terminology and communication of clinical data which are marked in the Exhibit.

[15] Swann (2000), p. iv.

[16] See http://www.etsi.org/WebSite/AboutETSI/Introduction/history.aspx.

[17] See European Commission (2005).

Exhibit 2-1: Domains of ICT standards in the health sector, explanations and examples

Domain	Explanation	Examples
Architecture Standards (here: focus on EHR)	Standards for an overall structure or plan of a health information system, including components and their connections and relationships. A particular type of architecture standards is that for Electronic Health Records (EHRs).	CEN EN 13606, CEN EN 12967 Service Architecture (HISA), HL7 v3, openEHR
Modelling Standards	Standards for ways to design and define architectures of a health information system.	CEN TR 15300 Framework for Formal Modelling of Healthcare policies ISO 10746 ODP
Communication Standards	Bi-directional exchange of information between two health system entities.	CEN EN 13606 EHR Communication, CEN EN 13609-1:2005 Messages for maintenance of supporting information in healthcare systems, Part 1: Updating of coding scheme, DICOM, HL7 v2.x, HL7 v3, ISO 11073 Point of Care Medical Device Communications
Infrastructure Standards	Standards for a group of communication components to collectively provide support for the distribution of information within a network of peers within the health system, e.g. machines and institutions.	CEN ENV 13729 Secure User Identification, Strong Authentication using microprocessor cards, ETSI TS 101733 Electronic Signature Formats, HL7 Service-oriented architecture, ISO 17090 Public Key Infrastructure
Data Security Standards	Standards for protection of patient data by means of e.g. data encryption and electronic signatures to prevent loss and theft.	DICOM, ISO DTS 25237 Pseudo-anonymisation, ISO 22600 Privilege Management and Access Control,
Safety Standards	Standards in healthcare to emphasize and support the reporting, analysis and prevention of medical error and adverse healthcare events.	CEN TR 13694 Safety and Security Related Software Quality Standards for Healthcare
Terminology and Ontology Standards	Standards for health sector specific vocabulary to describe concepts and their interrelationships	CEN EN 13940 System of Concepts to Support Continuity of Care, ISO/CD 17115 Vocabulary on Terminological Systems, LOINC, SNOMED

Source: Adapted from Blobel (2006). Domains relevant to this report marked.

Sketch of the situation of ICT standards in the health sector

The current number of ICT standards in the health sector is unknown – at least the authors of this report did not identify any consistent attempt to estimate them. In any case the number is vast and increasing. While the number of official standards may be relatively small, the world-wide number of voluntary standards can be estimated to be

several thousands. The number of industry standards can be assumed to be even higher. However, a large number of standards as such may not be the principal problem. It may hamper market transparency and make it difficult for users to decide which system operating with which standards to choose. But well-designed technical processes often require many standards. One of the experts interviewed for this report used an analogy: One needs many standards to switch a light on: e.g. standards for electric currency, switches, and bulbs. In a Sectoral e-Business Watch (SeBW) e-health expert survey conducted for this study in November 2007, 56% of the respondents believed that there are generally too many e-health standards. This was a relatively low level of agreement compared with other statements about the current situation in e-health standards mentioned in the following.

The principal problem seems be that many e-health standards conflict. There may also be conflicting versions and conflicting implementations of the same standards. On the other hand there are not only too many but also too few standards – there is a lack of standards for specific processes. The principal problems with the current situation of e-health standards can thus be described as follows:

- **Conflicting standards:** There is a lack of widely used e-health standards implying frequent standard conflicts and interoperability problems. Consequently, network effects are low and costs of switching to technologies operating with different standards may be high. In the SeBW e-health expert survey, almost all of the respondents (95%) stated that there is a lack of widely used e-health standards, and 72% said that there are too many conflicting standards (see section 3.2.3). Interoperability conflicts may occur particularly in the case of proprietary standards with undisclosed specifications. The use of proprietary standards is quite common by health service providers. The e-Business Survey 2006 found that 30% of European hospitals use proprietary standards, versus only 12% of firms in other sectors included in the survey.[18] Often these standards have been developed by small or medium-sized local vendors of ICT systems.
- **Conflicting versions:** It may also be that different versions of the same standard conflict. Standards development continuously loops through a cycle in which standards are improved, extended and corrected. Some of the standards undergo radical changes and make backwards compatibility impossible, which is for example the case with HL7 versions 2 and 3.[19] This leaves users with the question whether to implement the older and highly tested version, which is used by many other institutions, or implement the new version with the disadvantage of having fewer institutions to exchange data with.
- **Conflicting implementations of same standard:** It may even be that information systems from different ICT manufacturers that operate with the same version of the same standard cannot communicate because ICT manufacturers implemented the standard in a different way. Possible reasons may include that the standard was modified somehow, not correctly implemented or not well enough specified at the outset.

[18] See European Commission, Enterprise and Industry DG (2007).

[19] See section 2.3.6 about HL7.

- **Lack of specific standards:** Despite a generally large number of conflicting e-health standards, versions and implementations, there may be a lack of the "right" standards. For particular applications and for concrete processes there may be no well-developed standards. In the SeBW expert survey, 80% of the respondents stated that there is a lack of sufficiently developed standards, and 64% said that there is a lack of standards for electronic health records (EHRs) (see section 3.2.3).

Practical problems arising from the current situation

For users such as hospitals or general practitioners, this situation may imply basically two solutions. First, computerised systems, e.g. for patient administration, radiology, laboratory, pharmacy and order entry, may remain stand-alone and unable to exchange data with each other in-house or externally. Second, health service providers may invest considerable funds to make separate systems, that operate with different standards, interoperable.

The following example of John Paul II Hospital in Krakow, Poland, which is taken from the 2006 e-Business Watch report about hospitals[20], highlights practical problems of the current situation in e-health standards.

Interoperability challenges with imaging systems in John Paul II Hospital, Krakow, Poland

Among the main lessons learned during digital imaging implementation and system integration at John Paul II Hospital in Krakow, Poland, were interoperability issues. According to Zbigniew Les from the hospital, "only with closely integrated ICT systems throughout the hospital, the full image-enabled medical electronic patient record can become reality". However, while extending the ICT network within the hospital and interconnecting it with the systems of other institutions, the hospital faced interoperability problems. Due to a lack of interoperability, John Paul II Hospital cannot take full advantage of the technology in place to extend its usage outside the campus.

On the one hand, "there are still too many versions of software that are not compatible within the sector causing difficulty to exchange data", Mr. Les said. A lack of state regulation is a further reason: "The process of system integration within the hospital and with other institutions, for example the National Health Fund, is hampered by a lack of clear state regulation about electronic data storage and exchange as well as a lack of standards for exchanging medical information." Consequently, beside technical solutions, "the involvement of policy makers is equally important to bring clarity and impose some common solutions for the healthcare sector".

Currently, large institutions with competitive advantage such as John Paul II Hospital impose their solutions to others, Mr Les explained. This may lead to several competitive standards. Their coexistence may result in unnecessary complications for the users and may make the creation of interoperable solutions at the national level more difficult.

Source: European Commission, Enterprise and Industry DG (2007b), p. 116.

This example provides evidence on four issues important for this report: Interoperability

[20] European Commission, Enterprise and Industry DG (2007b).

problems arise when computerised systems within hospitals and between hospitals and other organisations are meant to communicate with each other, competing standards may hamper systems interoperability on a regional or national level, the interoperability problems prevent the full exploitation of data exchange opportunities, and public authorities may need to become more active in standardisation processes.

A premature market for e-health standards

Referring to the economic phenomena of switching costs and network effects described above in section 2.1, the overall situation in the health sector appears to be that producers and customers are free to choose between different ICT standards because for most applications there are no standards widely used by others. Therefore, the market for ICT standards in the health sector can be considered as premature. A mature market for standards would be characterised by well-established, i.e. commonly used standards in core areas. This is not the case in the health sector. Notwithstanding there are de facto standards for a few health functions, e.g. DICOM for digital image transmission (see section 2.3.7).

2.2.2 Barriers to developing the e-health standards market

Overview

A question following from the description of the status of e-health standards is why the situation is as unsatisfactory as it is. Why are there so many conflicting e-health standards? Why are e-health standard specifications so complex? Why are there not more well-developed and commonly used e-health standards? Answers to these questions are particularly important with regard to policy implications. One may attribute particular barriers to promote and adopt widely used standards to stakeholders of the e-health standards market and their rationales, i.e. the reasons for the way they act: governments, SDOs, industry, and ICT users. This sequence is not meant to indicate a ranking of importance; it rather goes from general to specific issues.

Political barriers: different health systems and often low support for standardisation

There are two principal barriers to developing the market for e-health standards on the part of governments: many different national and regional health systems with different standards and standardisation approaches on the one hand but low support for standardisation on the other.

Firstly, Member State health systems are highly determined by state entities and there are many different national and regional health systems, traditions and regulations. This has also led to different national standards and standardisation approaches in e-health. EC health policy is limited to “narrow responsibilities and weak tools relevant to marginal areas of policy”,[21] for example issues of public and occupational health, but not provision of healthcare and finance. However, the European Commission is stimulating and

[21] Greer (2006), p. 134.

supporting cooperation across the Union, and thereby gaining more influence on the health services of Member States.

Secondly, although governments are important stakeholders in the health sector, they support international standardisation issues at a varying degree. In the SeBW e-health expert survey, 88% of the respondents stated that national governments should become more involved in e-health standardisation processes – the largest percentage mentioned for all types of stakeholders (see section 3.2.5).

Governments may support e-health standardisation directly and indirectly. **Direct support** may take place by regulating the use of particular standards and by supporting SDOs with experts and funds. As regards standards regulation, some EU Member States like Denmark, the UK, France, Germany, the Netherlands or Slovenia established platforms or organisations in charge of standardisation at the national level on implementing large scale e-health projects.[22] The US Department for Health and Human services recognised certain interoperability standards which federal health agencies have to use when implementing, acquiring or upgrading health ICT systems.[23] Since federal health agencies constitute an important part of the US health systems, this regulation may accelerate the adoption of certain e-health standards in the US. As regards support by experts and funds, some of the members of the International Standardisation Organisation (ISO, see section 2.4.2) have a mandate from national governments. Another example is the newly formed International Health Terminology Standards Development Organisation (IHTSDO) that manages the SNOMED-CT standard and has presently nine country members (see section 2.3.4). However, many large countries did not yet join.

As regards **indirect incentives**, governments can for example make electronic communication between health service providers economically viable by regulating the reimbursement of related costs. The health sector is a laggard in ICT and e-business use in general and in electronic communication in particular.[24] Demands and attempts to interconnect health service providers such as hospitals and general practitioners by electronic networks are a fairly recent phenomenon. Indirect incentives could help spur such communication. However, few governments have yet provided such indirect incentives. In the SeBW expert survey, 72% of the respondents said that hospitals may have little financial incentives to communicate electronically with other health service providers (see section 3.2.6).

SDO barriers: seeking returns from an expensive standardisation process

There is a large number of SDOs defining and publishing ICT standards in the health sector, thus contributing to a large and continuously increasing number of conflicting standards. The main reason why SDOs do not simply agree on a confined number of

[22] An example is the establishment of the gematik GmbH (see http://www.gematik.de (October 2007)) in the course of preparing the introduction of a nation-wide health card in Germany. Gematik is in charge of defining common standards for the health card infrastructure so that nationwide interoperability of card-related information systems is assured.

[23] See Department of Health and Human Services (2008).

[24] See the e-Business Watch reports about the health sector of 2002 and 2004 as well as the report about hospitals in 2006.

standards or harmonise their standards is that e-health standards development is a long, complex, and expensive process. In the SeBW e-health expert survey, 81% of the respondents agreed that e-health standards development is currently too slow (see section 3.2.5). Standards development is an investment, and SDOs wish to realise the returns from this investment. This is why people who have been deeply involved in standards development may defend and promote "their" standards very strongly.

The basic reason why e-health standards development is long, complex and expensive and why e-health standards are often very complex or insufficiently developed is that health and medicine are very complex domains. They are fields with a huge amount of issues that potentially need to be standardised. A crucial issue is that e-health standards are not just a matter of technology, they are also a matter of semantics.[25] Semantic standards have to address cultural, social, and philosophical aspects which often carry local, regional and domain-specific values. The complexity of health and medicine requires an involvement of experts from different areas in standards development. In SDOs, experts from domains such as medicine, ICT, and business take part. Although quality and credibility of the final standard gain by different expertise, the domain-specific views, beliefs, and sometimes commercial mandates of the experts imply extended discussions.

Furthermore, the initial cost of developing a standard is often exceeded by the further development. Since medical knowledge is rapidly expanding and changing, e-health standards have to adapt with it, requiring costly and continual revisions.

Company barriers: seeking returns from own standardisation

The suppliers' side of the ICT for healthcare market is difficult to overview and evolving rapidly. Software, not hardware, is the key issue for interoperability of e-health applications. Large European-based suppliers of e-health applications include Agfa Healthcare, iSoft,[26] Philips Medical Systems, and Siemens Medical Solutions. Large US-based suppliers include for example General Electric, Hewlett-Packard, IBM, and Oracle. According to research for this report, the large suppliers generally seek to implement prominent e-health standards in their products. They may have an interest in world-wide standards because they market their products globally. In fact, many of the large vendors mentioned are actively involved in SDOs such as HL7 and DICOM.[27] Beside these big players there are many small and medium-sized suppliers, often operating only at a local or regional level.

Other manufacturers of ICT for healthcare may not be willing to adopt prominent standards, mainly for the following reasons:

- **Prevent sunk costs:** Companies may promote particular standards which they have invested in, mainly proprietary standards. Switching to other, more commonly

[25] See European Commission, Information Society and Media Directorate General (2006), chapter 5, for explanations about the various types of interoperability in e-health. See also the publications of the European Commission's i2Health project at http://www.i2health.org (October 2007).

[26] Since October 2007, iSoft is part of the Australian-based IBA Health Group.

[27] See section 2.3.

used standards causes so-called sunk costs, i.e. costs that cannot be recovered in further business activities. Just as for SDOs, standards development is an investment for companies and they are seeking related returns.

- **Revenues from systems integration:** The current situation of many conflicting standards may be economically favourable for some companies because it allows to sell middleware and related consulting to make incompatible systems interoperable. According to a survey by Integrating the Healthcare Enterprise (IHE), more then 20% of hospital ICT costs are represented by systems integration costs.[28]
- **High adoption costs in SMEs:** Small or medium-sized ICT manufacturers may not be willing to adopt commonly used standards because these are very complex and thus difficult and expensive to implement.[29] This applies for example to HL7 version 3. It may be less costly to develop proprietary standards on their own.

In order to foster the adoption of potentially widely used e-health standards by ICT industry, a deeper involvement of this industry in official standardisation bodies will be indispensable. In the SeBW e-health expert survey, 73% of the respondents stated that there should be more industry involvement in e-health standardisation processes (see section 3.2.5).

ICT user barriers: seeking to prevent costs of using standards

The users of ICT in the health sector considered in this report are the health service providers: primary care providers such as general and specialised practitioners as well as community care centres, and secondary care providers, the hospitals. Practising physicians will usually not be familiar with e-health standards and will have no time to deal with them. In hospitals and community care centres, there may be Chief Information Officers or other IT managers dealing with information systems and e-health standards.

There are many barriers to the wide adoption of ICT standards among healthcare providers which were confirmed in the SeBW e-health survey (see section 3.2.6):

- **Focus on internal efficiency:** An important barrier seems to be that health service providers focus on their own needs; they may find internal process efficiency more important than commonly used standards. In the SeBW e-health survey, 84% of the respondents agreed to this item with regard to hospitals.
- **Standards not designed to user needs:** It may be that available prominent standards are not sufficiently designed to fulfil user needs.[30]
- **Ignorance about standards:** Health service providers may be ignorant of standards currently used within the organisation, of standards generally available on the market, or standards prospectively available in the future. 66% of the respondents in the SeBW expert survey agreed to this.

[28] See the presentation of G. Cleys from IHE Europe - http://www.srdc.metu.edu.tr/webpage/projects/ride/workshops/istanbul.htm

[29] The costs of purchasing the standard and related documentation are generally not high, see Annex.

[30] This was confirmed in some of the expert interviews conducted for this report.

Many other barriers are related to costs:

- **Implementation costs:** Many ICT standards in the health sectors have been developed for a wide spectrum of applications, as opposed to confined processes. This makes their specifications and guidelines complex and their implementation difficult and prone to flaws. Costs of becoming accustomed with the complex specifications and documentations of standards or the costs of hiring experts may appear to be too high, particularly with regard to frequent updates. In the SeBW survey, 77% of the experts assumed that hospital IT managers may not adopt common e-health standards because these are too complex (see section 3.2.6).
- **Migration costs:** The costs of migrating from proprietary e-health solutions to other applications that support fairly common standards may be too high. For example there may be a need to convert massive amounts of data before new software operating with different standards can be implemented. This situation may be considered as "vendor lock-in".
- **Lack of financial incentive** to electronically exchange data with other healthcare providers, which would make the benefits of commonly used standards more obvious. In the SeBW expert survey, 72% of the respondents agreed that there may be a lack of financial incentives to electronically exchange information, and 75% said that there may not be sufficient benefits of commonly used e-health standards (see section 3.2.6).
- **Lack of certification:** Since there is no certification authority for e-health standards, users may lack trust that prominent standards work properly so that benefits of implementing them outweigh the costs. 77% of the SeBW survey participants agreed to this (see section 3.2.6).

In order to foster the adoption of more widely used e-health standards by health service providers, a deeper involvement of them in standardisation processes may be helpful. In the SeBW e-health expert survey, 85% of the respondents stated that there should be more involvement of ICT user organisations in e-health standardisation processes (see section 3.2.5).

In conclusion of this section about barriers to develop the market for e-health standards, there are numerous barriers related to various stakeholders. This indicates that a comprehensive multi-tier approach will be necessary to improve the e-health standards situation. In the following, current related activities are described.

2.2.3 Joint activities to maturing the market for e-health standards

European Commission activities in e-health standardisation

For the European Commission, standardisation remains a *"voluntary, consensus-based, market driven activity"*.[31] Standardisation is to be carried out by a number of stakeholders, including manufacturers, service providers, users, independent consultants, and authorities, who need to reconcile their positions. Thus the EC expects that *"the main*

[31] See http://ec.europa.eu/enterprise/standards_policy/action_plan/index.htm.

influence and input on the work in the European Standardisation Organisations must originate from the stakeholders".[32] There are three official European standardisation organisations: European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC), and European Telecommunications Standards Institute (ETSI). CEN's ICT standardisation activities are named CEN/ISSS, the latter acronym stands for "Information Society Standardisation System".

The EC's eHealth Action plan of 2004 includes a section 4.2.2 about "interoperability of health information systems". In this section, *"the need for new standards is clearly emphasised"*, favouring open standards.[33] The Action Plan further defines two items of particular importance for further standards development, namely patient identifiers and electronic health records.

The EC also drafted an "action plan for European standardisation" that *"will serve as a tool to provide transparency and further promote European standardisation"*.[34] This action plan also includes two items on e-health:[35]

- A mandate addressed to CEN, CENELEC and ETSI for work in the domain of e-health in March 2007. The mandate foresees two phases: A planning and analysis phase to "list existing relevant standards and technical reports with short descriptions, list relevant needed tasks for achieving the result" and an execution phase *"to agree on implementable standards, technical reports, guidelines, methods"* and the like.[36]
- Continue standardisation work under CEN Technical Committee 251 on Health informatics, CENELEC Technical Committee 62 on e-health and ETSI Technical Committees on Human Factors and ERM[37]. For this activity, CEN, CENELEC, and ETSI are in charge.

In autumn 2006 a European Commission (EC) e-health interoperability report was published that supports related activities and increases awareness on needs across Member States.[38] EC services are currently preparing a draft standardisation mandate, addressed to European Standardisation Organisations and inviting them to prepare an integrated standardisation work programme in response to current e-health policy needs in the EU. Furthermore, the 2005 Report from CEN/ISSS[39] and its e-health Standardisation Focus Group, recommended the creation of a European interoperability

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[32] See http://ec.europa.eu/enterprise/standards_policy/action_plan/index.htm.

[33] See European Commission (2004), p. 16 – 17.

[34] See http://ec.europa.eu/enterprise/standards_policy/action_plan/index.htm.

[35] See European Commission, Enterprise and Industry DG (2007), p. 21, item 15. See also the ICT standardisation work programme at http://ec.europa.eu/enterprise/ict/policy/standards/ict_index_en.htm.

[36] See European Commission, Enterprise and Industry DG (2007c), p. 5.

[37] ERM stands for "Electromagnetic compatibility and Radio spectrum Matters".

[38] See European Commission, Information Society and Media Directorate General (2006). In a wider healthcare perspective, the European Commission (DG Health and Consumer Protection) opened a consultation for the future EU legislation on health care services until January 31, 2007. Following this consultation, the Commission intends to bring forward appropriate proposals. See http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm.

[39] See http://www.cenorm.be/cenorm/businessdomains/businessdomains/isss/index.asp.

platform or initiative. Among other tasks, this initiative would establish a European-wide view on the requirements for e-health standardisation and its implementation, in collaboration with standardisation organisations. This could be based on input from relevant stakeholders' communities. Such an initiative could be led by respected neutral organisations in the field of ICT standards for the health sector.[40]

Current EC funded projects in the area of semantic interoperability include RIDE ("A Roadmap for Interoperability of eHealth Systems") and SemanticHealth.[41] RIDE is a roadmap project for interoperability of e-health systems developing recommendations for actions at the European level. SemanticHealth is a specific support action to develop a European and global roadmap for deployment and research in health-ICT, focusing on semantic interoperability issues of e-health systems and infrastructures. In the field of electronic health record software certification, the Q-REC project ("European Quality Labelling and Certification of Electronic Health Record systems)" is a Specific Support Action with the objective to create an efficient, credible and sustainable mechanism for the certification of EHR systems in Europe.[42]

Standards consolidation activities – the joint initiative of CEN, ISO and HL7

A powerful process to harmonise existing standards has not yet been established. The opposite appears to be the case, with even more conflicting standards emerging, making the "jungle" of e-health standards and standards development procedures more complex and incomprehensible.

However, recently there has been a major advance in standards harmonisation activities. In August 2007, a collaborative standards harmonisation group was formed between CEN, ISO, and HL7 after months of planning by the various leaders of these SDOs. In organisational terms the initiative consists of a Joint Initiative Council and a Joint Working Group. The group was created following a *"call for coordination and collaboration of health informatics standards developments from government, health provider and vendor communities across the world."*[43] The work to be performed by the Joint Working Group will build upon existing agreements and recognise existing standards collaboration work that is already in place. To do this, each member shared their complete list of work items, so that they could rectify any work overlaps or work gaps that were found between them. The first four work items selected by the Work Group for immediate review were: EHR communications architecture standard, a joint data types standard, care information model standards requirements, and patient and medication safety standards. An article in the Healthcare IT News quoted the Joint Initiative Council saying that this meeting resulted in *"significant and positive development towards [standards] harmonization."*[44] The initiative is open to further SDOs and may potentially be expanded in the future.

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[40] See the recommendations in the *e-Business W@tch* Special Report about standards and interoperability in European Commission (2005), p. 9.

[41] See http://www.srdc.metu.edu.tr/webpage/projects/ride/ and http://www.semantichealth.org/.

[42] See http://www.eurorec.org/projects/qrec.cfm.

[43] See "CEN TC, ISO TC and HL7 Launch first Joint Working Group and Integrated Work Program Activities", Joint Initiative of SDO Global Health Informatics Standardization, Press Release, Brisbane, Aug 28, 2007, http://www.e-health.standards.org.au/downloads/SDO%20Joint%20Initiative.pdf.

[44] See Healthcare IT News, http://www.healthcareitnews.com/story.cms?id=7770.

The experts consulted for this report assessed the joint initiative in differing ways. Some were generally positive; one expert said that the initiative could *"put an end to competition"*. One expert said it is *"still unfolding"* but *"the potential influence is significant"*. Another expert was also generally positive but said that it may require external funding for more influential activities in the future. A fourth expert assessed the potential influence of the initiative as limited because CEN and HL7 compete with each other; the initiative could only be strengthened if the roles and relationships of both organisations were realigned. A further expert stated that the most important question would be whether the initiative would be too dominated by what he considered *"legacy standards"* and a *"legacy approach to health informatics standardisation"*. There were differing assessments among the experts whether other SDOs should join the initiative or not. One expert said this would be useful, another one stated that it would only be useful after a *"reorganisation"* or *"integration"* of CEN and HL7.

All in all, the stakeholders involved in e-health standardisation are increasingly becoming aware of a need to develop the market for standards, and they are more and more active in this respect. The Member States' e-health large-scale pilot planned to start in the summer of 2008, being funded by the ICT Policy Support Programme (PSP) in the context of the European Competitiveness and Innovation Framework Programme (CIP), is expected to become a further catalyst in this respect.[45]

2.2.4 Electronic Health Records standardisation

Defining and distinguishing types of EHRs

Introducing electronic health records (EHRs) and defining related standards is an important issue on the political agenda of many European countries and also of the European Commission. In its eHealth Action Plan, the European Commission states that *"Member States, in collaboration with the European Commission, should identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts"*.[46] EHRs will therefore receive particular attention in this report.

Presently available hospital information systems have implemented limited versions of EHRs. They already began to emerge in the late 1960s with the primary purpose of improving in-house communication and capturing charges. Since then, a large number of terms have been used to categorise different variations of what one may generally call "patient data file". Although they all contain patient and health administrative data of a single person, they differ greatly in the inclusiveness of clinical information, e.g. whether data is available from one ward or unit, from one institution only, a collection of selected institutions or a cradle-to-grave record with data from all involved institutions. Related definitions have often been controversial or vague resulting in inconsistent and confusing use of the term. The Medical Records Institute,[47] a not-for-profit advocacy organisation

[45] http://www.ehealtheurope.net/news/3727/pan-european_sos_project_about_local_interoperability.

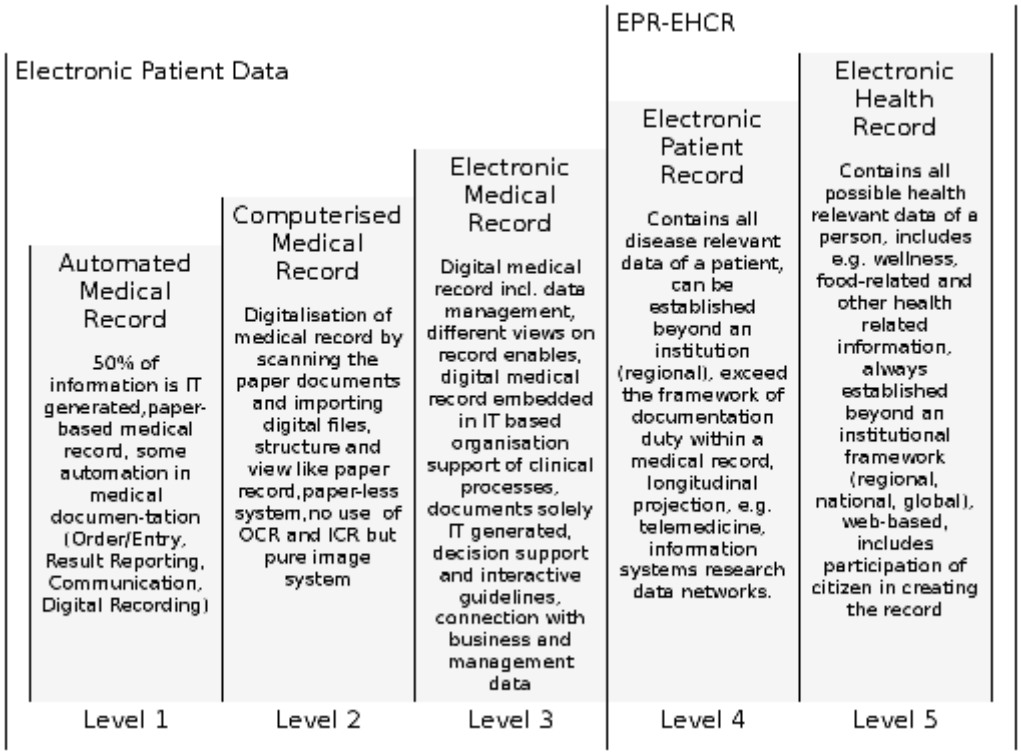
[46] See European Commission (2004), p. 14.

[47] See Waegemann (2002).

based in Boston (US) defines five levels of patient data files as seen in Exhibit 2.2. This includes, from the lowest to the highest level of sophistication: Automated Medical Records (AMR), Computerized Medical Records (CMR), Electronic Medical Records (EMR), Electronic Patient Records (EPR), and Electronic Health Records (EHR).

These five levels can be clustered into "Electronic Patient Data" (EPD) files (levels 1 to 3) and "EPR-EHCR"[48] (levels 4 to 5) primarily to emphasise interoperability requirements.[49] EPD files typically contain medical data about one patient in one institution. The use of standards for interoperability is not a requirement in this case. On the other hand, "EPR-EHCR" documents contain by definition data that go beyond a single institution. Therefore, standards and interoperability are a prime requirement. For clarity and consistency this report adheres to these definitions. This means that the term EHR is used for a comprehensive file that contains all relevant data of a person and that is used beyond a single institution.

Exhibit 2-2: Five levels of patient data files



Source: adapted from Waegemann (2002) and Blobel B (2003).

Importance of electronic health records in theory and practice

Within the field of health informatics, EHRs have always been of utmost interest and importance for both academia and business. The expectations attributed to EHRs by policy are also very high. EHRs may be much more than a single (virtual) location for "cradle-to-grave" patient data. Access to the combined data of single EPRs may for example allow public health agencies to discover the outbreak and spread of infectious

[48] EHCR = electronic healthcare record.

[49] See Waegemann (2002).

diseases very early. EHRs may also be a source for clinical research and continuing medical education. Some policy makers attribute EHRs the role of a panacea for problems of healthcare delivery and its expenses, and such high expectations drive governments to implement EHRs as soon as possible.[50]

Over the past years, European governments have identified the EHR as the prime solution and indispensable basis for the opportunity of nation-wide exchange and seamless integration of patient data. This has led to a more aggressive promotion of standards and application development together with their further utilisation. A recent study in the framework of the project eHealth ERA funded by the European Commission found that most European countries have some sort of EHR activity among their e-health policy priorities.[51] The focus of activities appeared to vary considerably, reflecting the complexity of the term and related challenges. Out of the 17 countries for which information on EHR developments was more specific, the majority reported activities both in primary and in hospital-level care. An explicit intention to introduce a life-long EHR as a strategic target was made by few countries, namely the UK, Estonia and Switzerland. For several countries the EHR is supposed to be a cornerstone of a national health information system as a source of statistical data. This applies for example to Greece, Cyprus, the Czech Republic, Hungary, and Italy.

Furthermore, the eHealth ERA project found that the development of a summary record or minimum data set primarily for emergency care purposes and for communication between professionals at different care levels was as a key target for 13 countries. Several of these countries have already made specific progress towards that goal.

Current state of EHR standardisation

Underlying and contributing to the delay of stand-alone, regionally networked or country-wide implemented EHR systems is a lack of EU wide standards for the proper identification, collection, coding, classification, and exchange of clinical and administrative data. This concerns both, technical and syntactical as well as semantic interoperability, not to mention issues which arise at the organisational, legal and policy levels.

EPR applications are available in an increasing number of institutions such as general practitioners' offices, laboratories and hospitals. However, the increasing number of isolated solutions without data exchange and interoperability is of growing concern. This does not only apply within a single healthcare provider. Of much greater concern is the missing standardisation across the diverse healthcare actor community, because the wider benefits from e-health solutions will only materialise at a greater scale once it becomes possible to seamlessly network hospitals, rehabilitation facilities, doctors in private practice, social care and the many other players such as public health, insurance companies, teaching and research at the local, regional and national level. Activities in various Member States to plan, develop, implement and run national e-health infrastructures and the enormous problems they all have encountered give vivid testimony to the need for faster, more focused and integrated standards development at EU level.

[50] See Kay (2006).

[51] See the forthcoming report by Hämäläinen/Doupi/Hyppönen (2007).

Examples of EC funded e-health projects that had an important influence on the development of standards in the e-health domain include Synapses[52] (FP4) and SynEx[53] (FP5). The work undertaken in the two projects shaped the design of EHR architectures and contributed significantly to the publication of the European Standard ENV12265, the basis for European Standard EN13606 – see also section 2.3.3 about CEN.

A Recommendation for EHR interoperability

In July 2008 the European Commission issued a Recommendation on cross-border interoperability of electronic health record systems.[54] The Recommendation is intended to support the premise that connecting people, systems, and services is vital for the provision of good healthcare in Europe, and contributes significantly to the establishment and functioning of the internal market by ensuring the free flow of patients and e-health products and services. Interoperability of health information systems such as electronic health record systems should enable improved access, quality and safety of patient care throughout the European Union by providing patients and health professionals with relevant and up-to-date information while respecting data privacy and confidentiality.

Through this Recommendation, the Member States are invited to undertake actions at four levels to improve e-health interoperability: at political, organisational, technical, semantic level.

2.3 Key standard development organisations and standards

2.3.1 Overview of key standards and SDOs selected for analysis

Principal standardisation organisations analysed in this report

The following part is an overview of the key SDOs which are at the time of writing this report actively involved in developing standards for EHRs and electronic messages in the health domain. The following seven organisations were selected based on their relatively large user base, relatively wide distribution, relatively large national support, and due to their composition of leading experts and companies in their fields and their direct importance for the realisation of EHRs. The SeBW expert survey confirmed that these SDOs are the most important ones for ICT standards in the health sector (section 3.2.2).

The SDOs and standards discussed in the following chapters, their domain and the framework developed by these organisations are shown in Exhibit 2-3. The sequence of the organisations is by level of formalisation, with ISO and CEN as official organisations listed first, followed by the International Health Terminology SDO (IHTSDO) whose members are national governments. HL7 and DICOM have a mixed membership and are listed by increasing influence of industry. openEHR as an open source activity is listed at the end. IHE is not a genuine SDO but a major interoperability initiative that deserves more detailed discussion. The organisational overviews address the following issues:

[52] Synapses homepage: http://www.cs.tcd.ie/synapses/public/ (accessed December 2007).

[53] SynEx homepage: http://www.gesi.it/synex/suite.htm (accessed December 2007).

[54] See European Commission (2008) and European Commission (2007a) for a document preparing this Recommendation.

what the organisation is about ("organisation"), what the organisation's goal is ("mission"), its membership and structure ("members"), its current work ("activities"), as well as a brief assessment of the organisation's current situation in the field ("assessment").

Exhibit 2-3: Key ICT standardisation organisations in the health sector

Organisation name	Acronym	Domain	Principal e-health standards developed
International Standardisation Organisation	ISO	General standards development	ISO/TR 18307
European Committee for Standardisation	CEN	General standards development	ENV 13606 (parts 1-5), HISA
International Health Terminology Standards Development Organisation	IHTSDO	Terminology	SNOMED
Health Level 7	HL7	Communication and architecture	HL7 v2.x, HL7 v3.0, CDA, RIM, CCOW
Digital Imaging and Communications in Medicine	DICOM	Imaging	DICOM
openEHR	openEHR	EHR architecture	openEHR
Integrating the Healthcare Enterprise	IHE	Standards frameworks	Integration profiles

Source: empirica

Formal characteristics of standards development processes

Before analysing SDOs, it is useful to have a general understanding of their work. In general, each SDO holds a number of regular face-to-face meetings of variable length each year. SDOs are subdivided into, for example, working groups, special interest groups or technical committees (TCs) whose members work independently on sub-standards in their respective field. Information exchange between subdivisions is typically achieved during the face-to-face meetings.

The ***life-cycle*** of standards development often includes stages similar to software engineering, such as feasibility analysis, requirements definition, design, implementation and coding, integration and test and finally maintenance. However, a big difference is the availability of a democratic but lengthy balloting process in the standards development process. It typically takes place during the first three phases of the development life cycle.

Some SDOs operate national subsidiaries that discuss and propose standards additions or changes of national interest before submitting a "request for adoption" to the SDO. These national inputs together with all other requests are discussed at the international meetings and forwarded to the community with the labels such as "accepted", "rejected" or "delayed for further evaluation".

2.3.2 International Standardisation Organisation (ISO)

Organisation and objectives

The International Organisation for Standardisation (ISO) is the world's largest developer of international standards.[55] It was founded in 1947 with a Central Secretariat in Geneva, Switzerland, and had 153 employees at the end of 2007. ISO is a network of the national standards institutes of 157 countries. ISO standards are being developed for a wide range of activities in areas such as manufacturing, trade, legislation, innovation, and consumer protection. Thus e-health standards are only a small part of ISO's work.

ISO's national members pay subscriptions in proportion to the country's Gross National Income and trade figures that meet the operational cost of the Central Secretariat. Another source of revenue is the sale of standards. However, the ISO Central Secretariat represents only about one fifth of the operational costs of the ISO system. The main costs are borne by the member bodies and business organisations that pay travel costs and allow time of experts to participate in the technical work.

Members

ISO is a non-governmental organisation, but members include public sector institutes that are part of the governmental structure or are mandated by their government. Each country is represented by at most one member, which is typically the national standards institute most representative of standardisation in the country. Other members are part of the private sector and have been set up by national partnerships of industry associations. This profile with members from both the public and private sector provides ISO with a bridging position. Requirements of business and society, such as the needs of consumers and users, are considered for consensus finding.[56]

Individuals or corporations are not eligible for membership. However, opportunities exist to participate in various ways in the standardisation process, including serving as experts on national delegations participating in ISO technical committees or supporting the process of developing a national consensus for presentation by the delegation. Additionally, technical committees can offer liaison status to international organisations and associations from the field of non-governmental and industry sectors.

Activities

ISO standards are developed by technical committees with selected experts from the industrial, technical and business sectors. According to the most recent available figures for the end of 2006, there were 3,041 technical bodies in the ISO system, including 193 technical committees.

ISO launches the development of new standards in response to business sectors that express a clearly established need for them.[57] Typically, representatives of government

[55] See http://www.iso.org/

[56] See http://www.iso.org/iso/about.htm.

[57] See http://www.iso.org/iso/about/discover-iso_meet-iso/discover-iso_how-iso-decides-to-develop-a-standard.htm.

agencies, testing laboratories, consumer associations, non-governmental organisations as well as academic circles join the process to also represent the views and needs of other stakeholders. National delegations of experts of a technical committee meet to discuss, debate and argue until they reach consensus on a draft agreement. This is circulated as a Draft International Standard to ISO's members for comment and balloting. If the voting is in favour, the document, with eventual modifications, is circulated to the members as a Final Draft International Standard. If that vote is positive, the document is then published as an International Standard. One of ISO's principles is that it does not publish a standard that conflicts with any standard that ISO published before. ISO thus supports standards harmonisation.

In the field of e-health, ISO is actively involved in the standardisation of health ICT to achieve compatibility and interoperability between independent systems. The related Technical Committee is TC 215 "health informatics".[58] TC 215 currently has nine working groups for which the following six are most relevant for this report:[59] WG 1 Data structure, WG 2 Data interchange, WG 3 Semantic content, WG 5 Health cards, WG 8 Business requirements for Electronic Health Records, WG 9 Harmonisation.[60] By the end of 2007, ISO TC 215 had published 44 standards, and 36 standards were under development. Among the most important published ones for this report is ISO/TR 18307:2001, "Interoperability and compatibility in messaging and communication standards". An important part of ISO's work is the further development and world-wide approval of standards that have originally been developed by other SDOs. For example, ISO standard 12052:2006 is a DICOM standard, and ISO currently further develops EHR standards that were in first instance developed by CEN.

Assessment

In the SeBW e-health expert survey, a very large share of the respondents, 84%, agreed that ISO TC 215 should be important in the future. This very positive assessment may be due to ISO's position as the world's largest developer of international standards and a supposed need for international standards in the field of e-health. It may also be due to ISO's bridging position between the public and the private sector. ISO also took a position in harmonising e-health standards by becoming involved in a co-operation initiative with CEN and HL7 in 2007.

In the expert interviews and other statements received for this report, positive assessments about ISO included that it is a powerful organisation and that its standards are technically well elaborated. Weaknesses that were mentioned included that ISO standards are developed mainly by academics and that the documentations are too sophisticated for the market. ISO standards lack market adoption because there is insufficient implementation support. ISO works "too much detached from reality" and would benefit from more involvement from users.

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[58] See http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54960.

[59] The other working groups are WG 4 Security, WG 6 Pharmacy and medicines business, and WG 7 Devices.

[60] WG 9 is a recent implementation and not listed on ISO's website at the time of writing this report.

2.3.3 European Committee for Standardisation (CEN)

Organisation and objectives

Founded in 1961, the European Committee for Standardisation (Comité Européen de Normalisation, CEN) is a not-for-profit organisation headquartered in Brussels. It contributes to the objectives of the European Union and European Economic Area with voluntary technical standards which promote, among other items, interoperability of networks.[61] The objective of CEN is to "foster the European economy in global trading, the welfare of European citizens and the environment".[62] ICT standards in the health sector are only one part of CEN's work.

CEN, CENELEC and ETSI together constitute the "European standardisation system". While CENELEC and ETSI were also included in the EC's e-health mandate issued in March 2007,[63] they deal with standards for medical devices that are not subject of this report. Thus CENELEC and ETSI are not described in detail here.

Members

CEN members include Counsellors, Associate Members and National members. Two Counsellors represent the EC and the European Free Trade Association (EFTA) secretariat. Seven Associate Members represent particular sectors of industry as well as consumers, environmentalists, workers, and SMEs. 30 National Members include one member from each of the 27 Member States plus three EFTA countries. The National Members vote for the acceptance of the CEN standards and implement those accepted standards within their nations.

Formal adoption of European standards is decided by a weighted majority vote of the National Members and is binding on all of them. They must implement the standards at national level and withdraw conflicting standards. The National Members also delegate the CEN Technical Committees (TCs). These are *"responsible for the programming and planning of the technical work in the form of a Business Plan, for the monitoring and the execution of the work in accordance with the agreed Business Plan and for the management of the standards making process"*.[64]

Activities

CEN is responsible for developing the following standard publications: Pre-Standards (ENV), European Standards (EN) and drafts (prEN), Technical Specifications (CEN TS), Technical Reports (CEN TR), and CEN Workshop Agreements (CWA). In August 2007, it was reported that CEN had published 12,706 European standards and approved documents, and that CEN had 275 active Technical Committees, responsible for the development of 3,510 active documents.[65]

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61 See http://www.cen.eu/.

62 See http://www.cen.eu/cenorm/aboutus/generalities/strategy/censtrategy2011.pdf.

63 See section 2.3.2 for a brief description of this mandate.

64 Information in this section about members was taken from http://www.cen.eu/.

65 See http://www.cen.eu/cenorm/aboutus/information/statistics/.

CEN/TC 251 is the Technical Committee responsible for health informatics standards. This committee *"organizes, coordinates and monitors the development of standards, including testing standards in healthcare informatics, as well as the promulgation of these standards"*.[66] CEN/TC 251 is divided into four workgroups: Information Models; Terminology and Knowledge Representation; Security, Safety and Quality; and Technology for Interoperability.

Workgroup I, Information Models, is responsible for the development of standard 13606 for electronic health records. It *"defines a conceptual data model which is capable of structuring any medical data in a uniform way, presenting the multitude of different facts while the preserving meaning and context of the data"*.[67] Standard 13606 was first released as a four-part pre-standard in the year 2000. The release of this pre-standard in the UK, Denmark, the Netherlands, Sweden, and Norway exposed weaknesses which limited its uptake in the rest of Europe. The pre-standard was found to be too complex with too much optionality for practical use, due to its single-level modelling approach.[68] CEN/TC 251 is now in the final stages of revising their four part 13606 pre-standard into a five-part European Standard called EHRcom (EHR communications) or EN 13606. The five parts are: EN 13606-1: Reference Model, EN 13606-2: Archetype Interchange Specification, EN 13606-3: Reference Archetypes and Terms Lists, EN 13606-4: Security Features, and EN 13606-5: Exchange Models. This standard will attempt to address the issues that were identified with the pre-standard. Work on the new European standard has been performed collaboratively with openEHR as well as HL7. The *"convergence of EHRcom, openEHR and HL7 makes the success of the new standard certainly more likely compared to older CEN works such as the pre-standard ENV 13606".* [69]

Assessment

Up to now, CEN/TC 251's standards have had limited success due to their complexity and difficulty for practical use. CEN/TC 251's standards thus have a weak position against alternative industry standards. Expert statements about CEN collected for this report included that CEN is generally a powerful means to strengthen the EU market but not yet in healthcare. Part of the reason may be that Europe, until a few years ago, had no strong health ICT industry that could have supported the spread of CEN's e-health standards. Furthermore, CEN standards were described as being mainly developed by people with theoretical backgrounds which makes them hard to read, understand and use as well as too much detached from reality. Finally, there are no strong incentives to use CEN standards.

In the SeBW e-health expert survey, 74% of the respondents stated that CEN should be an important SDO for developing e-health standards in the future (see section 3.2.2). At first sight this looks like a very positive assessment. However, of all SDOs listed, CEN had the highest percentage of respondents stating that CEN should not be important.

[66] See http://www.cen.eu/.

[67] See Maldonado et al. (2001).

[68] See Eichelberg et al. (2005).

[69] See Eichelberg et al. (2005).

2.3.4 International Health Terminology Standards Development Organisation (IHTSDO)

Organisation and objectives

The International Health Terminology Standards Development Organisation (IHTSDO) was established in 2006 with a main office in Copenhagen, Denmark.[70] It is responsible for the ongoing development, maintenance and governance of a standard named "Systematized Nomenclature of Medicine – Clinical Terms" (SNOMED-CT) as well as of other healthcare terminology standards. IHTSDO promotes and enables the uptake and correct use of SNOMED-CT in health systems, services and products around the world. Before 2006, the standard was owned and developed by the College of American Pathologists and the UK's National Health Service (NHS). The decision to form IHTSDO was made to allow *"other countries the opportunity to take a leading role in the ownership, development, maintenance, and promotion of the SNOMED-CT clinical terminology"*.[71]

SNOMED-CT seeks to ensure that clinical staff has consistent and easy to understand information about a patient's medical history, illnesses, treatments, and test results immediately available. It seeks to provide a single and comprehensive system of terms, centrally maintained and updated for use in all national health service organisations as well as in research. The standard is meant to improve the communication consistency of patients' clinical records.

The terms in SNOMED-CT are developed twofold: Firstly, they exist in a pre-coordinated form with a high level of detail. Secondly, terms can be combined using low level terms such as disease, site, manifestation and cause. For example, the detailed term „diarrhoea, caused by staphylococcus" (SNOMED-CT Code: 398570005) is defined as a combination of the low-level terms "disease" (64572001), associated with a site "intestine" (113276009), the manifestation "diarrhoea" (62315008) and the cause "staphylococcus" (65119002).[72] The use of such a terminology allows for interpretation and integration of medical information from different systems. Such terminologies are indispensable for EHRs.

Members

IHTSDO members can be either agencies of national governments or other bodies endorsed by a national government authority such as corporations or regional government agencies. The costs of becoming an IHTSDO member are based on the nation's Gross Domestic Product and population, i.e. the ability to pay, and the total cost to the Association of maintaining SNOMED-CT. The IHTSDO currently has nine national members:

- Australia, represented by the National E-Health Transition Authority (NEHTA),
- Canada, represented by Canada Health Infoway,

[70] See http://www.ihtsdo.org/.

[71] See http://www.ihtsdo.org/ (accessed October 2007).

[72] Taken from GMDS (2007).

- Denmark, represented by the Danish National Board of Health's Department of Health Informatics,
- Lithuania, represented by the National Centre of Pathology, which is a component of the Ministry of Health,
- Netherlands, represented by the 'Nationaal ICT Instituut in de Zorg' (NICTIZ),
- New Zealand, represented by the Ministry of Health,
- Sweden, represented by the Swedish National Board of Health and Welfare,
- The United Kingdom, represented by the National Health Service (NHS), and
- The United States, represented by the U.S. National Library of Medicine (NLM), The National Institute of Health, and the Department of Health and Human Services (HHS).

Other countries are still considering whether joining SNOMED-CT is the best option. Many existing systems are currently working well with the World Health Organisation's International Classification of Diseases (ICD).

Activities

The IHTSDO is currently transitioning the SNOMED-CT standard from its previous US and UK ownership to its new global market. IHTSDO is aiming to do this through the *"harmonisation with WHO, HL7, CEN, ISO and other relevant bodies"*.[73] These collaborations are meant to help reaching IHTSDO's goal of making SNOMED-CT a multi-lingual standard. Beside the basic English version there may be translations – in varying completeness – into Spanish, French, German and Danish. This might help supporting health systems interoperability across nations in the future.

Assessment

The movement of SNOMED-CT from its previous owners in the US and the UK to the new international body of IHTSDO may be a milestone for the standardisation of EHRs. For EHRs to be truly interoperable, there must be no boundaries in the form of national standards limiting data communication networks.

Since the change in ownership of the SNOMED-CT standard occurred recently, it is difficult to determine the success the IHTSDO will have. SNOMED-CT is *"considered to be the most comprehensive, multilingual clinical healthcare terminology in the world""*[74] Thus the probability of the continual success of the standard is likely. Its success may also be desirable: In the SeBW e-health expert survey: 87% of the respondents said that IHTSDO should be important in the future. However, in the expert interviews conducted for this report and further expert statements received, there was also the opinion that the terminology market is open and confused. Many countries would prefer to focus more on

[73] See http://www.ihtsdo.org/uploads/media/Collaboration_between_WHO_and_IHTSDO.pdf (accessed October 2007).

[74] See "SNOMED sold to new international standards organisation", eHealth insider, Apr 27, 2007, http://www.e-health-insider.com/news/2646/snomed_sold_to_new_international_standards_organisation (accessed October 2007).

ICD than SNOMED-CT. But these terminologies are complementary rather than substitutive.

Factors that could inhibit IHTSDO's success are the difficulty in balancing the high costs of maintaining SNOMED-CT: Firstly, knowledge in the healthcare field is constantly changing and growing. This requires continual and costly revisions of the standard, amounting to roughly 8-9 million US dollars per year.[75] Secondly, it is challenging to keep the product as accessible as possible and at the same time turn it into a truly international standard through the adoption and incorporation of new languages. One expert statement was that country specific interpretations lead to SNOMED "dialects" which undermine IHTSDO's intention to support world-wide interoperability.

2.3.5 Health Level 7 (HL7)

Organisation and objectives

Health Level Seven (HL7) is a not-for-profit, multi-national standards development organisation with headquarters in Ann Arbor, Michigan, US. It is accredited at the American National Standards Institute. Founded in 1987, HL7 specialises in standards development for clinical and administrative data. The number 7 stands for the highest level in the Open Systems Interconnection reference model for implementing computer protocols, the "application level".[76] The mission of HL7 is to *"create standards for the exchange, management and integration of electronic healthcare information"*.[77] This includes the aim to promote *"the use of such standards within and among healthcare organisations to increase the effectiveness and efficiency of healthcare delivery"*. [78] HL7 has national bureaus in 29 countries across the world and is continuously growing.

Members

HL7's membership base is divided into four levels of rising privileges: individual membership, organisational membership, supporter membership and benefactor membership. A relative majority of 44% of the more than 550 members listed on the HL7.org web site are vendors. 22% are healthcare providers, i.e. users of standards. The others are mainly from general interest groups, academia, consulting and the pharmaceutical industry. The large share of corporate numbers indicates a discrepancy between the influence of providers and healthcare providers in HL7's standardisation process. It can also be assumed that vendors typically support the standardisation process with more manpower than healthcare providers.

Vendors include hard- and software manufacturers from a wide range of small, medium-sized and large companies. Their interest is to shape standards to their needs as well as being first time users of a standard. The benefactors include some of the most important providers in the ICT for health market: General Electric Healthcare Integrated IT

[75] See http://www.ihtsdo.org/about-us/faq/ (accessed Oct 19, 2007).

[76] See http://webopedia.internet.com/quick_ref/OSI_Layers.asp.

[77] See http://www.hl7.org/.

[78] See http://www.hl7.org/.

Solutions, Philips Medical Systems, and Siemens Medical Solutions Health Services. Large software producers such as Microsoft and IBM are also benefactors.

Activities

The work of HL7 "encompasses the complete life cycle of a standard's specification – development, adoption, market recognition, utilization, and adherence"[79]. HL7 encourages the use of HL7 world wide and provides education, certification services and methodologies for extending standards. HL7 also collaborates with developers of other healthcare ICT standards to leverage their respective skills, knowledge, and standards.[80] HL7 has technical committees which are directly responsible for the development of standards, and special interest groups which investigate the areas of healthcare that may require the development of new standards.

HL7's most prominent standards are for electronic messages: HL7 version 2 – which has been made available in consecutive updates (2.x) – and HL7 version 3 (v3). Version 3 is a completely new development that has only partly been completed and that is not compatible with version 2. The cornerstone of the HL7 v3 development process is a Reference Information Model (RIM), a large pictorial representation of clinical data.[81] Further standards include a Clinical Document Architecture, Clinical Context Object Workgroup, and the Arden Syntax for Medical Logic Systems. HL7 also develops standards for EHRs.[82] To some extent HL7 standards are an alternative to e-health standards developed by ISO and CEN so that HL7 is a competitor to them.

Assessment

According to HL7, the organisation *"produces the world's most widely used standards for healthcare interoperability. Most of the leading suppliers use and support the development of HL7 standards"*.[83] This assessment was confirmed in the e-Business Watch 2006 Survey: 46% of the large hospitals included in the survey said that they use systems operating with the HL7 standard.[84] In the SeBW e-health expert survey, 90% of the respondents said that HL7 should be important in the future (see section 3.2.2). Together with DICOM this was the highest level of support for all SDOs asked for in the survey. One of the experts interviewed for this report stated that a strength of HL7 is user representation.

Indeed, HL7's v2.x standards were important steps towards standardising clinical messaging. However, several issues caused difficulties, above all different options to implement the standard. To correct this issue, the RIM was developed for v3.0, eliminating most of the implementation options. The concept behind HL7 v3.0 has been generally well received. However, the RIM caused new problems:[85] Firstly, it is unlikely

[79] See Dolin et al (2001).

[80] See http://hl7.org.uk/marketing/hl7worldwide.asp (accessed: October 2007).

[81] See http://www.hl7.org/about/ for further details.

[82] See http://www.hl7.org/ehr/.

[83] See http://www.hl7.org.uk/marketing/hl7worldwide.asp.

[84] Base: 539 hospitals from ten European countries. See European Commission (2007b), p. 48.

[85] See Smith/Ceusters (2006).

that the defined RIM classes and attributes could be applied to every domain in healthcare – which is what they are intended to do. Secondly, the RIM documentation is described as being *"disastrously unclear"*, poorly integrated with HL7 v3.0 documentation, and inconsistent.

Under these circumstances, it may be difficult for HL7 v3.0 to establish a large user base. Currently HL7 v3.0 is still in the early adoption phase. Without a large user base, this standard is rendered ineffective – for the same reason that telephones can not be effective unless there are multiple users. HL7 already has a well established user base for their 2.x messaging standards in many countries of the world. However, since HL7 v3.0 is not compatible with v2.x, this user group must be re-established. Convergence with Europe's CEN/TC 251 standardisation work is under way, which may help HL7 in this respect.[86] HL7's involvement in the joint initiative with ISO and CEN may have the objective to move faster to international adoption of HL7 standards. The outcome of this convergence work as well as the organisation's ability to create a satisfactory RIM may determine the future importance of HL7. Convergence may also be of importance for the European ICT for health industry. In the expert statements received for this report, there was a reservation against a possible dominance of HL7 in the European market.

2.3.6 Digital Imaging and Communications in Medicine (DICOM)

Organisation and objectives

Digital Imaging and Communications in Medicine (DICOM), or the DICOM Standards Committee, was established in 1993 and has its headquarters in Rosslyn, US. The Diagnostic Imaging and Therapy Systems Division of the US National Electrical Manufacturers Association[87] is responsible for the development, maintenance, and governance of the DICOM standard. Many countries have local DICOM subsidiaries or national representatives. The objective of DICOM is to *"ensure the interoperability of systems used to: produce, store, display, process, send, retrieve, query or print medical images and derived structured documents as well as to manage related workflow".*[88]

Members

The DICOM Standards Committee currently includes 45 members.[89] Of those members, 55% are categorised as vendors (e.g. Philips Medical Systems), 27% as users (e.g. the American College of Radiology), and 18% as general interest groups (e.g. Canada Health Infoway). The members are predominantly headquartered in the US. The DICOM Standards Committee selects the members of the DICOM Working Groups which are responsible for the development and the maintenance of the DICOM standards. Membership to the DICOM Standards Committee requires an annual fee of 1,000 - 5,000 US dollars depending on the type of membership.[90]

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86 See Geissbuhler (2005), p. IT54

87 See http://medical.nema.org/dicom/geninfo/Strategy.pdf.

88 See http://medical.nema.org/dicom/geninfo/Brochure.pdf.

89 See http://medical.nema.org/members.pdf.

90 See

Activities

The Work Groups of the DICOM Standards Committee *"perform the majority of work on the extension of and corrections to the standard"*.[91] There are currently 26 active DICOM Work Groups, each responsible for a particular classification of task. For example, Work Group 1 (WG-01) is responsible for Cardiac and Vascular Information and WG-02 is responsible for Projection Radiography and Angiography.[92] A vote of at least two thirds the DICOM Members is required for passing a standard.

Assessment

DICOM is a success story. It has established itself as a de facto standard for electronic medical image processing all over the world, as *"one of the most important standards on which this integration in healthcare relies."*[93] Several DICOM standards have been officially approved by ISO. One of the reasons for DICOM's success may be the early and prominent involvement of user groups and industry together with an orientation towards concrete use cases. Currently there are hardly any other standards for electronic medical imaging which could be considered as serious competitors to DICOM. In the SeBW e-health expert survey, 90% of the respondents said that DICOM should be important in the future (see section 3.2.2). Together with HL7 this was the highest level of support of all SDOs asked for in the survey.

The future of DICOM may be determined by its ability to grow and expand with the continually changing industries of healthcare, ICT, and media. In an attempt to assure this continual adaptation, DICOM has established numerous working groups with other key organisation, including many other standards bodies such as ISO, CEN and HL7.

2.3.7 openEHR

Organisation and objectives

OpenEHR is a not-for-profit foundation which was formed in 2002 by the University College London (UCL) and the Ocean Informatics company after their collaborative work on the Good European Health Record (GEHR) project. openEHR is not a formal SDO as it does not have balloting and consultation processes implemented like the other organisations described in the preceding sections. The aim of openEHR is to make EHRs *"adaptable and future-proof"*[94] through the use of a technology independent architecture. openEHR seeks "to improve the clinical care process by fostering the development and implementation of open source, interoperable EHR components. These components should be based on internationally agreed requirements and address the need for privacy and security, while supporting the development of interoperable and evolving clinical

http://medical.nema.org/dicom/handbook/DICOM_Standards_Committee/Apply_for_DSC_Membership.xls.

91 See http://medical.nema.org/dicom/geninfo/Strategy.pdf.

92 See http://medical.nema.org/dicom/geninfo/Strategy.pdf).

93 See Mildenberger et al. (2002).

94 See http://www.e-health-insider.com/news/item.cfm?ID=1726.

applications".[95] The open source aspect of openEHR methodology refers to the development characteristic of "distributed peer review and transparency of process".[96]

Members

According to a 2006 article in the e-health insider magazine on openEHR, the foundation has roughly 700 members from around 70 different countries.[97] *"Membership of openEHR implies a commitment towards realising the vision of high quality, interoperable EHRs, and a willingness to share ideas and experience. Membership is free, and is available simply by registration on the openEHR.org website."*[98]

Activities

The main activities of openEHR are to *"promote the uptake of openEHR technologies globally; to maintain the openEHR specifications and control the change management process for the openEHR model; to protect the copyright of open source software components based on openEHR; and to act as a forum for discussion and contribution on openEHR and related technologies"*.[99] Numerous projects, five commercial as well as ten research projects, are currently being undertaken within openEHR. These projects, which are synchronised with the openEHR specifications, are related to the development of tools, reference implementations, conformance criteria and test frameworks.[100]

Assessment

The open source movement is relatively new to the healthcare IT field. This may be one reason why many potential users are hesitant to adopt openEHR. There may be the perception of limited technical support for open source applications.[101] Furthermore, although open source software is free to be used, nevertheless distribution, warranties, support, installation, and customisation of the open source products all still constitute costs for the users. Finally, supporting a facility with an out-of-the-box solution requires customisation, and it may be cheaper to develop a new, in-house system, than it is to customise a ready made application.

An advantage of open source product support is that there are no proprietary rights to the product so that any company willing to provide support for it can do so. This is different with proprietary systems for which often only the creator of the system is able to provide support. Support opportunities from any company does not only create a healthy competition among system support providers, likely increasing the quality of the support received for the product. It also means that open source system users cannot be left stranded for the support of their system if their system developer goes out of business. It is also more likely the case that openEHR would be less costly to implement and

95 See http://www.cancerinformatics.org.uk/Documents/OpenEHR.pdf).

96 See http://www.opensource.org/ (October 2007)

97 See http://www.e-health-insider.com/news/item.cfm?ID=1726.

98 See http://svn.openehr.org/specification/TRUNK/publishing/openEHR/introducing_openEHR.pdf.

99 See Schloeffel (2004).

100 See http://www.openehr.org/ (October 2007)

101 Ermini (2005).

maintain than any other proprietary EHR system, due to its free licence, ease of use, and its probable longevity, even if the initial customisation costs are high.

Although the hesitance to adopt unknown open source applications in healthcare may serve as a barrier to adopt openEHR, there are numerous trials of the standard being performed across the world. Most notable is Australia's HealthConnect trial, where the standard is showing some promising results.[102] The aspect of openEHR that is looking most appealing is its ability to separate content and knowledge through the use of a two-level archetypes modelling approach.[103] This methodology is viewed by many as the possible key enabler of the lifelong EHR. This may make a strong case for the success of openEHR in the future.

In the SeBW e-health expert survey, 65% of the respondents said that openEHR should play an important role in the future. This is a high level but still the lowest level of all SDOs that were asked about in the survey.

2.3.8 Integrating the Healthcare Enterprise (IHE): a major interoperability initiative

Organisation and objectives

Integrating the Healthcare Enterprise (IHE) is *"an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information"*.[104] IHE's objective is to facilitate interoperability of healthcare ICT. It promotes *"the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care"*.[105] IHE thus does not develop standards itself but it provides a framework for the adoption of certain standards.

IHE was created in 1998 through the leadership of the Healthcare Information and Management Systems Society (HIMSS) and the Radiology Society of North America (RSNA). HIMSS and RSNA together with the American College of Cardiology (ACC) are the principal sponsors of IHE. The organisation thus has its origin and main pillar in the US but there is also strong support from Europe and Japan.

Sponsors

IHE has a total of 30 sponsors located in three regional sectors: North America, Europe, and Japan. The majority of these members (65%) belong to societies and associations involving healthcare and ICT. Many of the European sponsors are in the field of radiology, for example the European Association of Radiology (EAR) and the Coordination Committee of the Radiological and Electromedical Industries (COCIR). Academia, e.g. the American College of Cardiology (ACC), accounts for 24% of IHE's members. Governmental ministries from Japan, e.g. Ministry of Economy, Trade, and Industry (METI), account for the remaining 11% of the members. IHE invites other groups

[102] See Garde (2005).

[103] Archetypes are formal content specifications; they do not contain any content themselves.

[104] See http://www.ihe.net/About/ihe_faq.cfm.

[105] See http://www.ihe.net/About/ihe_faq.cfm.

representing healthcare stakeholders to participate.

Activities

IHE involves a collaboration process among key parties in four phases:

- **Problem identification:** Clinicians and IT experts identify common integration problems in access to information, clinical workflow, administration and infrastructure.
- **Integration profile specification:** Stakeholders select standards that address each identified integration need. The technical specifications for implementing these standards are documented in the "IHE Technical Framework".
- **Implementation and testing:** Vendors implement integration profiles and test their systems with software tools and with other vendors' systems.
- **Integration statements and requests for proposals:** Vendors publish IHE Integration Statements to document the integration profiles supported by their products. Users can reference integration profiles in requests for proposals, simplifying the systems acquisition process.

The backbone of IHE's work is the IHE Technical Framework, which is a *"detailed, rigorously organized document that provides a comprehensive guide to implementing the defined integration capabilities"*.[106] From the IHE Technical Framework, so-called IHE Integration Profiles can be developed. The profiles show under which circumstances specific standards should be used, and how these standards should be applied. Adoption of these profiles is supposed to help eliminate the ambiguities that are present in using the large amount of differing and often conflicting healthcare ICT standards.[107]

As regards EHRs, IHE has defined a *"common framework to deliver the basic interoperability needed for local and regional health information networks"*.[108] It includes a Cross-Enterprise Document Sharing (XDS) support, a security framework, and patient identification management.

Assessment

IHE's approach has been well received among the ICT for health industry as well as healthcare providers. An exemplary statement from a high-level hospital manager is that *"the IHE initiative is producing useful protocols that standardise communication between various health information system components."*[109] In the SeBW e-health expert survey, 82% of the respondents found that IHE should be important in the future.

A report on "the Challenge of Integrating the Healthcare Enterprise" suggests that IHE's ultimate success will depend on receiving broad industry support.[110] IHE has already made great steps in achieving this support through their "Connectathons". At these

[106] See http://www.ihe.net/About/ihe_faq.cfm.
[107] See http://www.himss.org/ASP/topics_ihe.asp.
[108] See http://www.ihe.net/About/process.cfm.
[109] See Geissbuhler (2005), p. IT54:
[110] See Grimes (2005).

events numerous medical system vendors test their systems' interoperability with other medical systems through the IHE Framework. For example, in April 2006 the Connectathon in Barcelona was attended by 300 participants monitoring 2,800 test cases from 120 different systems.[111] Through such activities, over 160 medical system vendors have developed IHE compliant systems from 1999 to 2005.[112] IHE's influence is underlined by the fact that *"standards recommended by IHE have a high probability of a quick uptake in the medical market."*[113] Such market influence may also lead to newly developed standards as well as currently released standards to seek conformance with the IHE Framework. In the future, possibly a standard for interoperability between standards may also be created.

However, in the expert statements received for this report, there were also critical voices about IHE. One experts stated that *"IHE is loosing the plot"* because it recently started to develop standards itself.

[111] See Parisot (2007).

[112] See Eichelberg et al. (2005).

[113] See Eichelberg et al. (2005).

2.4 Summary of ICT standards and standardisation in the health sector

Chapter 2 provided a structured overview of e-health standards and standardisation processes. Such a map is necessarily incomplete because e-health is a very complex as well as fast and constantly changing field. The following key issues of the situation, barriers, harmonising activities, electronic health records, and SDOs have been analysed:

- **Situation sketch:** Currently the market for e-health standards has the following characteristics: A large number of often conflicting standards, a lack of "right" standards for particular applications and concrete processes, high complexity of standards, and widespread proprietary standards with undisclosed specifications. This situation makes health systems interoperability difficult to realise.
- **Barriers to improve the situation**: Barriers to promote and adopt prominent standards so that they are more widely used can be broken down by stakeholders in the health sector: governments, Standards Development Organisations, industry, and ICT users. All in all the principal barriers are related to returns on investment in standardisation on the part of SDOs and industry as well as costs of adopting standards on the part of users.
- **Harmonising activities:** There is currently no powerful process to harmonise standards, and a process to decrease the number of concurrent standards is not yet fully established. However, the stakeholders are increasingly becoming active in this respect. The collaboration initiative of ISO, CEN and HL7 is an important activity. Further SDOs joining this collaboration as well as the large-scale pilot for patient summaries and e-prescribing in EU Member States which are currently starting, funded in the framework of the European CIP Programme, may become further catalysts in this respect.
- **Electronic health records** (EHRs) introduction is an important issue on the political agenda of many European countries and also of the European Commission. However, there are yet no comprehensive EHR implementations. This is also due to a lack of EU-wide standards for EHRs, more precisely for the collection, coding, classification, and exchange of clinical and administrative data. It can be expected that the EC's "Recommendation on cross-border interoperability of electronic health record systems" will have a strong influence on further developments in this field.
- **SDOs:** Six principal standardisation organisations and one interoperability initiative have been selected for more detailed analysis in this report because they can be expected to play a leading role in further eHealth standards development: ISO as the largest developer of world-wide standards, CEN as the principal official SDO in Europe, IHTSDO as the developer of the very comprehensive SNOMED-CT terminology standard, HL7 as the developer of the most widely used standards for electronic messages in healthcare, DICOM as a de facto standard for electronic medical imaging, OpenEHR as a promising open source activity, and IHE as a major eHealth systems interoperability initiative. Understanding their objectives, rationales and constraints may help to form viable alliances for harmonising and consolidating standards.

3 Results of an online survey of e-health experts

3.1 Methodology

Survey rationale

In November 2007, empirica conducted an online expert survey about ICT standards in the health sector as part of this report. The purpose of this survey was to validate, extend and deepen insights from literature evaluation and telephone interviews with experts also conducted for this report. To the best of the knowledge of the authors of this report, no such survey had been conducted before, so that it would provide a unique source of evidence.

Expert selection

Through numerous international e-health projects and professional relationships, empirica has access to several hundreds of European and internationally renowned experts in the field of e-health, many of them in leading professional positions. These experts are primarily related to ICT manufacturing and services enterprises, national ministries of health, national competent authorities, hospitals, universities, research institutes, professional associations, and other organisations. empirica selected the experts for the survey from this group of people in a deliberate process. On selecting the experts, empirica followed three principal criteria:

- ensuring that the most renowned experts that empirica has contacts to are included;
- ensuring a fairly even distribution of experts across affiliations, notably industry, public authorities, and user groups;
- ensuring a fairly even distribution of experts across EU Member States.

In the end, the survey included experts not only from Europe but also from other parts of the world: a minor but important number of experts came from the US, Canada, Australia, and Asia. Since the pool of people from which the experts were selected was limited and since the selection was deliberate, not random, findings presented in the following are not representative in a stochastic sense. Nevertheless the survey provides insightful opinions about e-health standards development.

Survey organisation

The survey took place during two weeks in the first half of November 2007. On 6 November, empirica sent out an e-mail to invite 358 people to participate in the online survey. The experts were asked to fill in an online questionnaire by 19 November 2007, allowing two weeks to respond. Altogether 94 complete replies were received, resulting in a very good response rate of more than 26%. There were further 30 people who started to fill in the questionnaire but abandoned it before completion. The reasons are unknown but since some of these participants may not wish to have their responses included in the overall results, empirica only considered questionnaires that were regularly submitted with all questions answered.

The form of an online survey was chosen because it ensured an effective procedure: resources required for set-up, conduction and data evaluation were relatively low compared to telephone interviews or paper-based surveys. Survey participants could access the survey over the web at http://survey.ebusiness-watch.org/. The participants received an individual token to ensure that the questionnaire was being answered exactly once by each invited expert. A key design aspect of the online survey was to allow for a reasonably quick completion while ensuring insightful findings. The intended average time to fill in the questionnaire was ten minutes. Several interviewees confirmed that the questionnaire met this intention. The experts were ensured that they remain anonymous.

Survey contents

The survey included six sets of questions:

- interviewee's professional affiliation and continent of origin,
- future importance of e-health standards development organisations,
- current situation in e-health standards,
- impacts of current e-health standards situation,
- current situation in e-health standardisation processes,
- barriers to adopt common e-health standards in hospitals.

The first question set was necessary to support the grouping of answers based on the participant's main professional affiliation – for example ICT industry, health service provider – and their continent of residence. The remaining five question sets related to e-health standards issues. The interviewees were asked to tick boxes on a scale with five options, for example "I strongly agree", "I slightly agree", "I slightly disagree", and "I strongly disagree" and the additional option to refrain from an answer. At the end of each question set, the interviewees had the opportunity to provide individual comments on the topic. Many of the respondents made active use of this opportunity. The complete set of individual statements is provided in Annex II of this report. The complete survey questionnaire is provided in Annex I to this report.

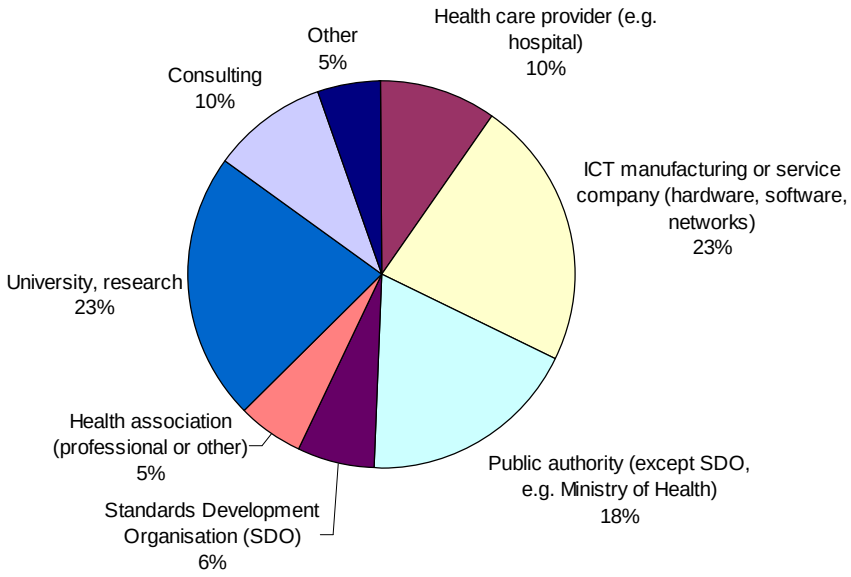
3.2 Survey findings

3.2.1 Respondent affiliation and origin

Respondents' professional affiliation

The respondents were asked to indicate their professional affiliation according to eight pre-defined options. If several options applied, the respondents were asked to choose the most appropriate one or the one that they feel most affiliated with. Exhibit 3-1 shows the related indications.

Exhibit 3-1: Respondents' affiliation in e-health standards survey 2007



Source: SeBW e-Health Online Expert Survey 2007

Almost two thirds of the survey respondents were affiliated with three groups: ICT manufacturing or services companies, i.e. hardware, software or networks companies (23%), university and research (23%) as well as public authorities, except SDOs, for example from national Ministries of Health (18%). Other respondent were affiliated with health care providers such as hospitals (10%), consulting firms (10%), SDOs (6%), health associations such as professional organisations (5%) and other organisations (5%).

Respondents' origin

The vast majority of the respondents, 94%, came from European countries, primarily EU Member States. 4% were from North America and 1% from Asia. The responses do not allow a further breakdown by country.

3.2.2 Future importance of standards development SDOs

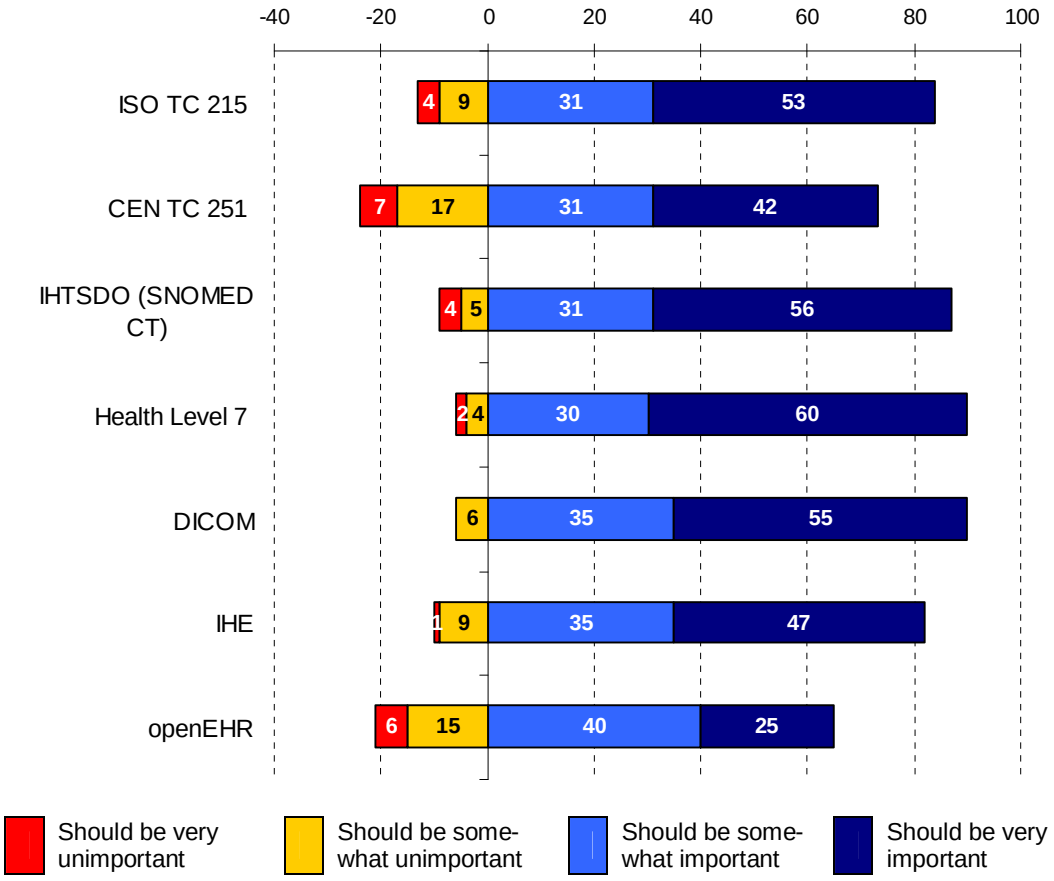
Overall findings

In the first question, the interviewees were asked how important particular e-health standards organisations should in their opinion be in the foreseeable future; seven names were given:

- International Standardisation Organisation (ISO), TC 215 (health informatics),
- European Committee for Standardisation (CEN), TC 251 (health informatics),
- International Health Terminology SDO (IHTSDO), SNOMED-CT,
- Health Level 7 (HL7),
- Digital Imaging and Communications in Medicine (DICOM),
- Integrating the Healthcare Enterprise (IHE),
- openEHR.

The majority of respondents indicated that all these organisations should be considered "very important" or "important" (see Exhibit 3-2). The highest wished importance was attributed to HL7 (60% "very important" and 30% "somewhat important" out of 94 responses), followed by DICOM (55% "very important" / 35% "somewhat important") and IHTSDO (56% "very important" / 31% "somewhat important"), ISO (53% "very important" / 31% "somewhat important"), and IHE (47% "very important" / 35% "somewhat important"). Somewhat behind were CEN (42% "very important" / 31% "somewhat important") and openEHR (25% "very important" / 40% "somewhat important"). The lower level for openEHR is partly due to a fairly high level of respondents who gave no answer (11%), probably because they did not know this organisation or did not know it well enough.

Exhibit 3-2: Desired future importance of selected e-health standards organisations (in %)



n = 94 respondents. Figures do not add up to 100% because of answers of "no response".

Source: SeBW e-Health Online Expert Survey 2007.

Findings by affiliation

The 21 respondents affiliated with ICT industry gave without exception positive assessments about HL7 and DICOM, and only one respondent from industry considered IHE and IHTSDO as "somewhat unimportant". However, a relatively large share of the respondents from ICT industry was critical about CEN (28% "somewhat unimportant" / 9% "very unimportant"), openEHR (23% "somewhat unimportant" / 9% "very unimportant") and also to some extent ISO (14% "somewhat unimportant" / 4% "very

unimportant"). Apparently ICT industry affiliates favoured SDOs driven by industry while they were particularly critical with public SDOs. Interviewees affiliated with public authorities were also relatively critical about CEN and openEHR but not so much about ISO. In contrast, the negative assessments provided by respondents affiliated to university and research were fairly evenly distributed across the various SDOs. The nine respondents affiliated to health care providers gave positive answers about all SDOs.

Individual statements

The respondents had the opportunity to add other SDOs they consider as important in the future. 17 interviewees seized this opportunity, mentioning altogether 17 additional organisations and standards which reflects the diversity of the e-health standards area. The organisation mentioned most often was the World Health Organisation (WHO), mentioned altogether seven times: twice merely as "WHO", once referring to the WHO Family of International Classifications (WHO-FIC), three times by mentioning to the International Classification of Diseases (ICD) for which the WHO is responsible, and once by mentioning the Anatomical Therapeutic Chemical Classification System (ATC) controlled by the WHO. The World Wide Web Consortium (W3C) was mentioned three times; the Continua Health Alliance and the Organisation for the Advancement of Structured Information Standards (OASIS) were mentioned twice.

The following organisations were mentioned once: American Society for Testing and Materials (ASTM), Certification Commission for Healthcare Information Technology (CCHIT), the Continuity of Care Record (CCR), Clinical Data Interchange Standards Consortium (CDISC), European Telecommunications Standards Institute (ETSI), Institute of Electrical and Electronics Engineers (IEEE), International Classification of Primary Care (ICPC), International Classification of Functioning, Disability and Health (ICF), International Conference on Harmonisation (ICH), Internet Engineering Task Force (IETF), Logical Observation Identifiers Names and Codes (LOINC), Object Management Group, Common Object Request Broker Architecture (OMG/CORBA), and the French PN13. "National mirror groups to CEN" were also mentioned once.

3.2.3 Current situation in e-health standards

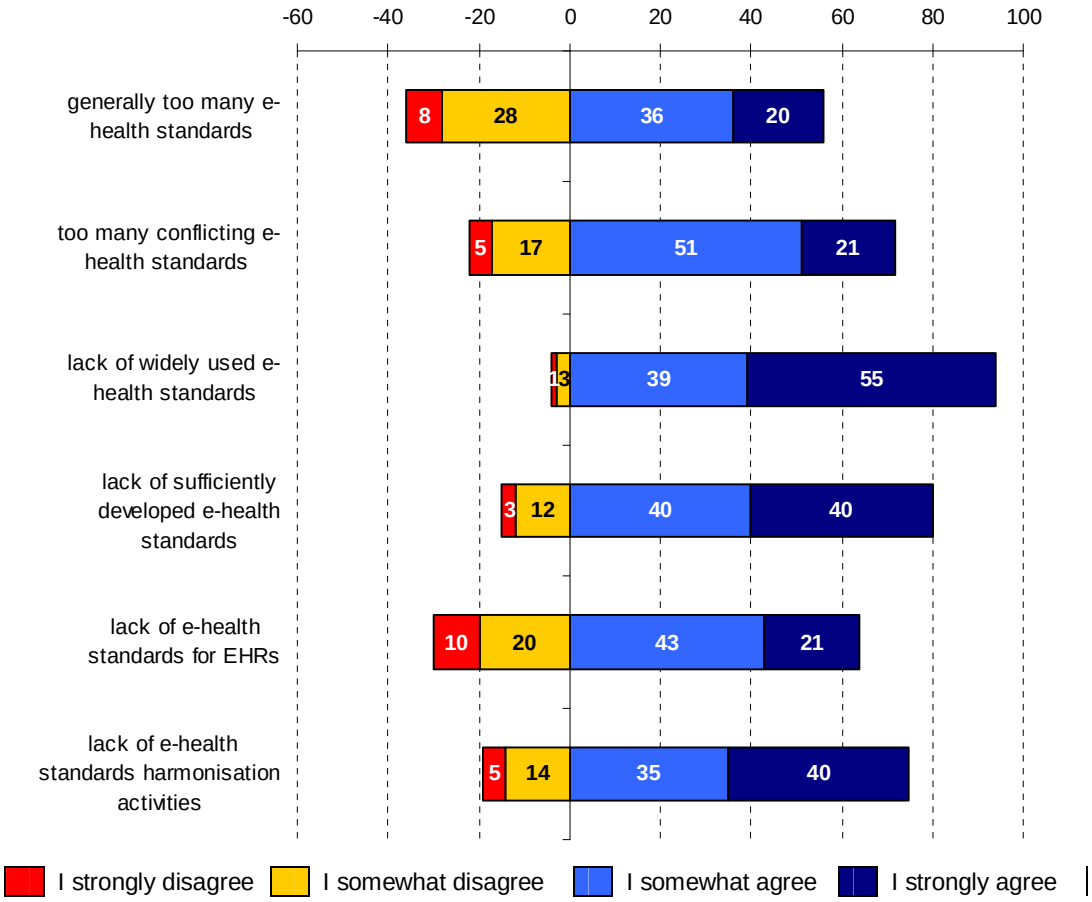
Overall findings

The interviewees were asked to indicate their level of agreement to six statements about the current situation of e-health standards. For all six statements, the majority agreed, but the levels of agreement differed – see Exhibit 3-3. Nearly all interviewees agreed that there is a lack of widely used e-health standards (55% "agree strongly" / 39% "agree somewhat"), confirming the basic assumption on which this study was carried out. There was also a high level of agreement that there is a "lack of sufficiently developed e-health standards" (40% "agree strongly" / 40% "agree somewhat"), a "lack of e-health standards harmonisation activities" (40% "agree strongly" / 35% "agree somewhat") and that there are "too many conflicting e-health standards (21% "agree strongly" / 50% "agree somewhat"). A "lack of standards for electronic health records" was strongly agreed by 21% and somewhat agreed by 43%. The smallest level of agreement – but still agreed by the majority – turned out for the statement that there are generally too many e-health

standards (20% / 36%).

There were not many differences between the responses of the various sub-groups. One of the more striking deviations was that a majority of four of the six SDO representatives disagreed that are “generally too many e-health standards”.

Exhibit 3-3: Assessment of the current situation in e-health standards (in %)



n = 94 respondents. Figures do not add up to 100% because answers of “no response” are included but not shown.

Source: SeBW e-Health Online Expert Survey 2007.

Individual statements

21 respondents commented in various ways, often favouring strong measures to improve the current situation. For example, one respondent commented on a supposedly inefficient development of standards: *“We've been researching on e-health standard for decades, and advances seem terribly slow. Many groups redo what other did almost a decade ago. (…) Publicly available reference implementation may be one approach to speed up uptake of standards and innovative research in this field.”*

Further suggestions included enforcing harmonisation activities between the existing SDOs – particularly with regard to EHRs –, starting a certification process for e-health standards and adoptions, developing open standards, and increasing user orientation and participation in the development process.

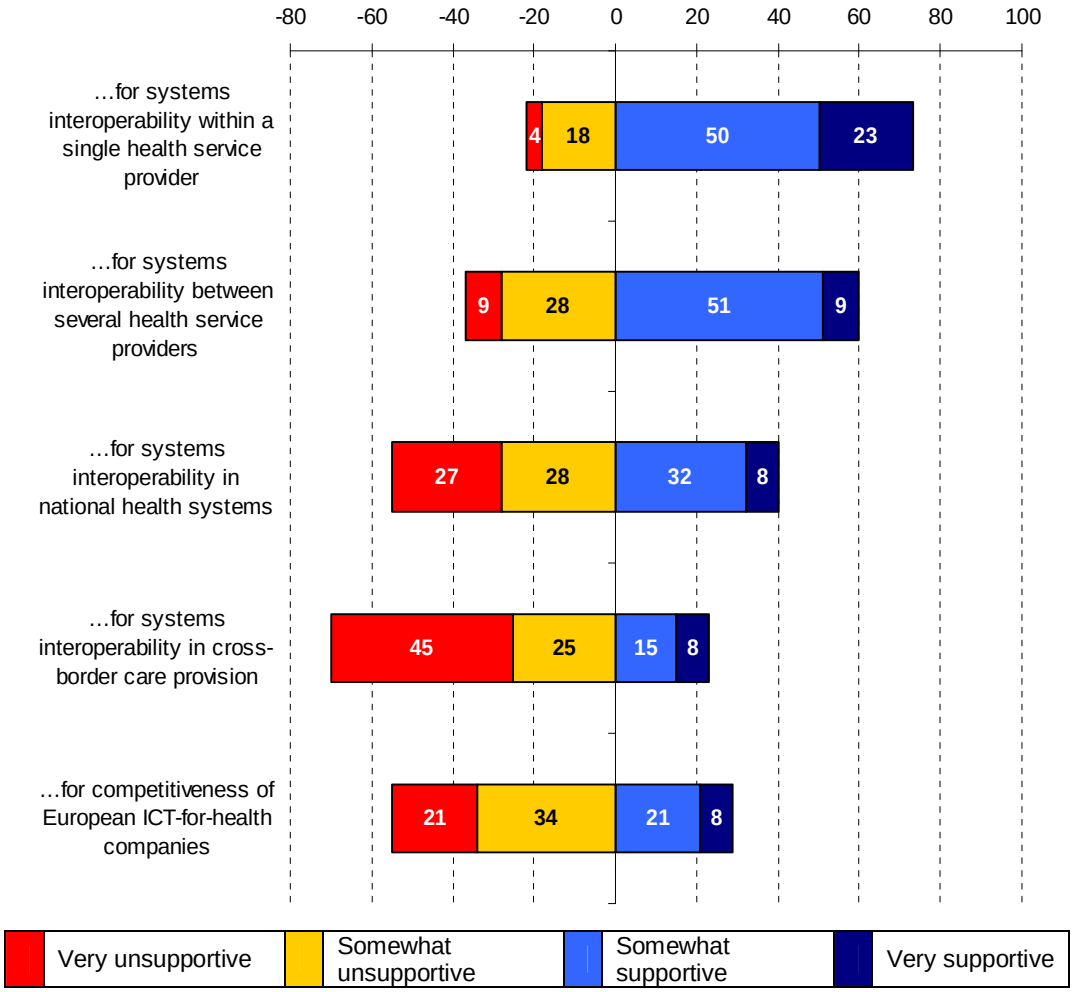
3.2.4 Impacts of current e-health standards situation

Overall findings

The survey participants were asked to assess whether the overall situation with respect to e-health standards is supportive in enabling interoperability among health service providers at various institutional levels. It turned out that the level of distance (internal, between several providers, national, cross-border) determines the assessment of how supportive the situation of e-health standards is – see Exhibit 3-4.

Exhibit 3-4: Impact of the current e-health standards situation (in %)

The current situation of e-health standards is very unsupportive / somewhat unsupportive / somewhat supportive / very supportive …



n = 94 respondents. Figures do not add up to 100% because of answers of "no response".

Source: SeBW e-Health Online Expert Survey 2007.

Nearly three quarters of the respondents indicated that within a single health service provider the overall situation is supportive (23% "very supportive" / 50% "somewhat supportive"). The support declines gradually the more "borders" have to be crossed to exchange clinical information, from interoperability between several health service providers (9% "very supportive" / 51% "somewhat supportive"), within one national health

system (8% "very supportive" / 32% "somewhat supportive") and in cross-border cases (8% "very supportive" / 15% "somewhat supportive"). Thus there may be a particularly strong need to foster international interoperability of standards. The opinion that the e-health standards situation is favourable for systems interoperability within a single organisation may be due to the fact that single organisations often use proprietary standards or that problems with conflicting standards are manageable.

Furthermore, the majority of participants indicated that the current situation is unsupportive for the competitiveness of European ICT-for-health companies (21% "very unsupportive", 34% "somewhat unsupportive"). This supports the view that promoting e-health standardisation should have a high priority on the industrial policy agenda of Member States and the European Commission.

The overall findings are without exception reflected in the results of each sub-group.

Individual statements

Twelve participants provided individual statements highlighting many different aspects. These were rarely about the impacts of the current situation in e-health standards but rather described related problems. For example, one respondent stated that *"today the focus of users is in-house communication and we are talking too much about cross-enterprise or cross-border communication. In most countries there are just small or no budgets for a cross-X communication."* Another one commented that *"the problem is not the standard (…) from a technical perspective"* but *"the political will to make decisions - and to show a business case with high economic, cultural impact"* as well as *"the fear of the transparent doctor, hospital or healthcare system"*. Another one said that there is no incentive for ICT industry "to build their products to be standards compliant ICT industry" because the firms *"can charge for integration of disparate systems"*.

3.2.5 Current situation in e-health standardisation processes

Overall findings

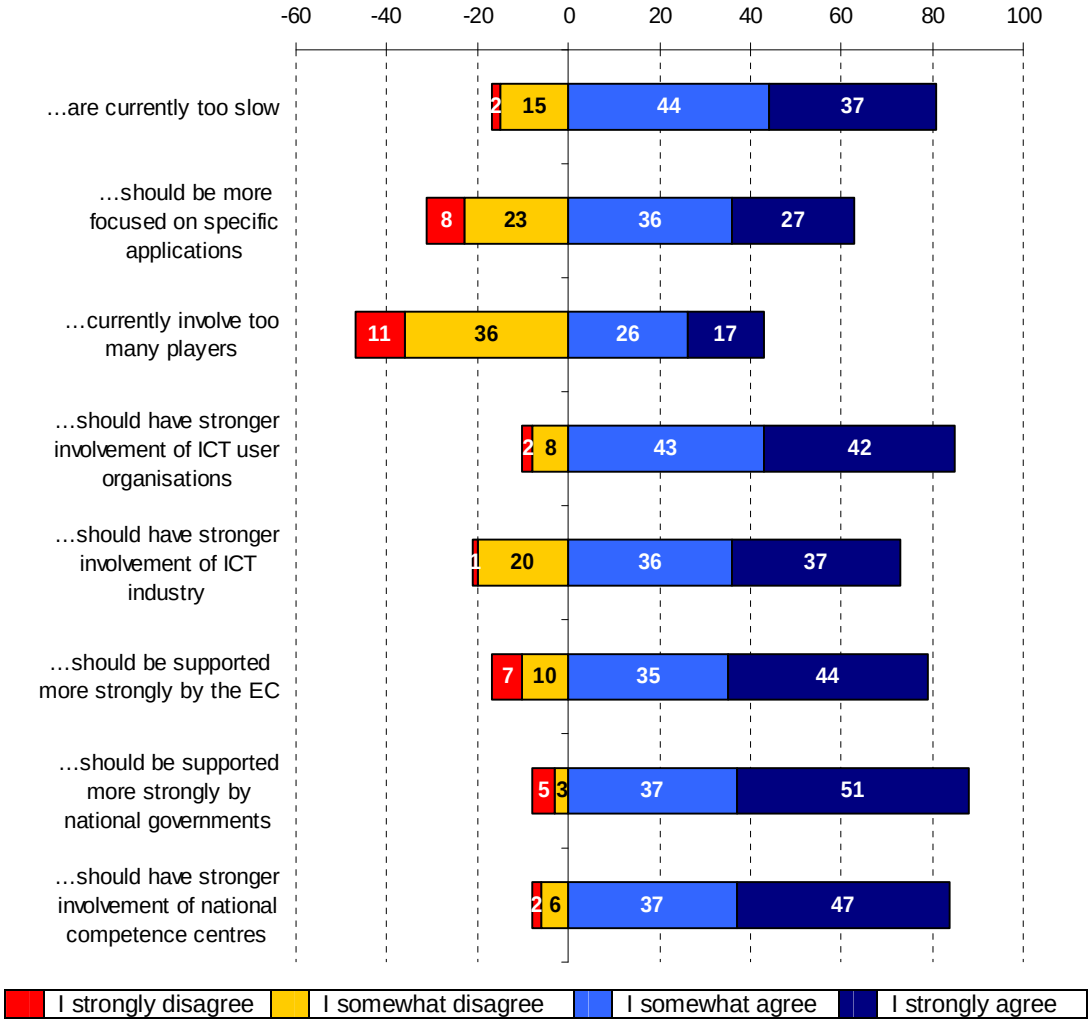
The survey participants were also asked about their opinions about the current situation in e-health standardisation processes. The respondents favoured a stronger involvement in e-health standardisation from many different organisations – see Exhibit 3-5. More than four fifths of the respondents agreed that e-health standards development processes should be supported more strongly by national governments (51% "agree strongly" / 37% "agree somewhat"), should have stronger involvement of ICT user organisations, for example from hospitals (42% "agree strongly" / 43% "agree somewhat"), should have stronger involvement of national competence centres (47% "agree strongly" / 37% "agree somewhat"), and that e-health standards development processes are currently too slow (37% "agree strongly" / 44% "agree somewhat"). Stronger support from the European Commission and stronger industry involvement was favoured by more than two thirds of the respondents.

Corresponding to these answers, only a minority of the respondents supported the statement that e-health standardisation processes currently involve too many players (17% "I strongly agree" / 26% "I agree somewhat"). Furthermore, the majority of

respondents supported the statement that e-health standardisation should be more focused on specific applications. This supports the view that e-health standards development should be more oriented towards concrete use cases.

Exhibit 3-5: Current situation in e-health standardisation process (in %)

e-Health standards development processes…



n = 94 respondents. Figures do not add up to 100% because of answers of "no response".

Source: SeBW e-Health Online Expert Survey 2007.

Individual statements

Individual statements from 17 respondents are available, most of them on very specific issues. One respondent suggested that *"the development process has to include also deployment activities where key players (users, governments) can play an important role"*. Another one suggested that *"the EU Commission should not only support e.g. CEN but especially organisations like IHE, Continua"*. Two respondents commented on the "national competence centres". One criticized that they are *"becoming more and more political"* and that mostly the *"e-part is focused on and the health part is overlooked"*. Another one said that the competence centres' degree of independency and ability to influence standards developments varies.

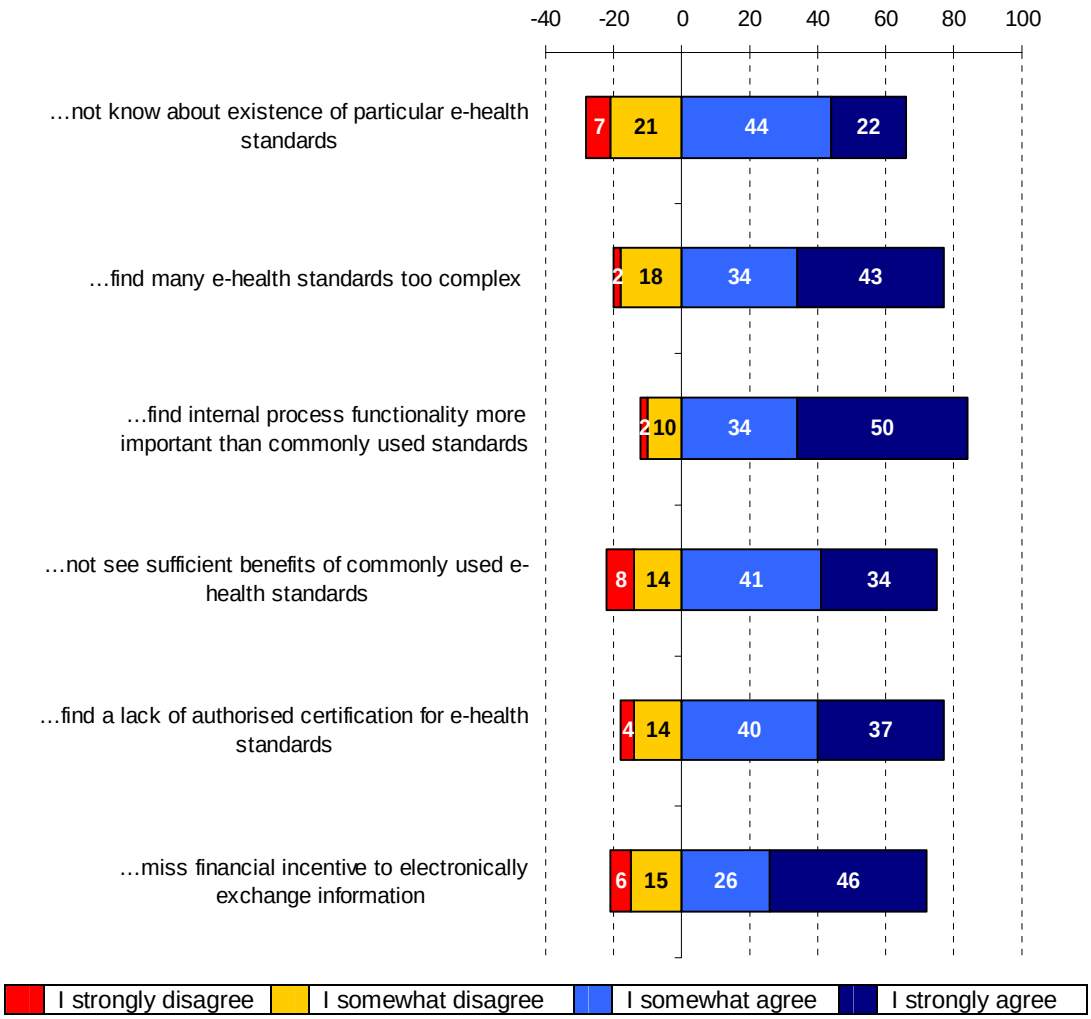
3.2.6 Barriers to adopt common e-health standards in hospitals

Overall findings

This last part of the survey tried to answer the question of how the survey participants assess the hospital IT managers' knowledge and understanding of e-health standards. The hospital CIOs are typically the decision makers when it comes to system procurement and adherence to standards. The background for this question set was that an *e-Business W@tch* survey in 2006 found that the use of proprietary standards for information systems is more prevalent in hospitals than in other, non-health sectors in Europe.[114]

Exhibit 3-6: Barriers to adopt common e-health standards in hospitals

Hospital IT managers may…



n = 94 respondents. Figures do not add up to 100% because of answers of "no response".

Source: SeBW e-Health Online Expert Survey 2007.

[114] See European Commission (2007b).

The statement that was supported most was that *"hospital IT managers may find internal process functionality more important than commonly used standards"* (50% "agree strongly" / 34% "agree somewhat") – see Exhibit 3-6. This supports the view that electronic communication with other health service providers is supposedly of little importance to hospitals – a view that was already supported in the previous question about interoperability between different health service providers. However, the respondents did not blame hospital IT managers for this: they agreed that the managers miss financial incentives to electronically exchange information with other health service providers (46% "agree strongly" / 26% "agree somewhat"). More than three fourth of the respondents supported the statement that hospital IT managers find many IT standards too complex (43% "agree strongly" / 34% "agree somewhat"), do not see sufficient benefits of commonly used e-health standards (34% "agree strongly" / 41% "agree somewhat") and find a lack of authorised certification for e-health standards (37% "strongly agree" / 40% "agree somewhat"). Furthermore, the majority of respondents found that hospital IT managers do not know about the existence of particular e-health standards (22% "agree strongly", 44% "agree somewhat").

There was little variation in the answers between the different user groups.

Individual statements

15 respondents provided individual comments in the free text section of this question. One said that hospitals *"are totally focussed on the mandatory communications with payers and government, missing totally the health process"*. Other ones elaborated on hospitals' difficulties to implement common standards. One pointed to a possible dilemma of using common ICT standards in hospitals: On the one hand, IT people *"cannot calibrate in clinical terms the REAL advantages of such a process"*, while *"the clinical professionals on the other hand lack the technical terminology to explain their needs"*. Another one said that *"public procurement processes are so difficult that standard-related demands are easily forgotten"*. A further respondent was critical about systems certification. In his opinion *"authorised certification is no guarantee for quality"* because *"the costs increase and the pressure for more than 20 certification processes in an IT company and short-termed changes in the certification process is a very big problem"*. Two respondents pointed to the necessity of good business cases to explain the need for e-health standards to hospital IT managers.

3.3 Summary of survey findings

In conclusion, survey participants confirm a considerable lack of widely used ICT standards in the health sector and negative impacts thereof. Harmonisation of standards is seen as a possible way to improve the current situation. Stronger involvement of representatives from many different stakeholders may in the opinion of the respondents improve the e-health standards development process. More detailed, the online survey found the following:

- **Future importance of standards development SDOs**: The majority of respondents agreed that all seven e-health SDOs mentioned (ISO, CEN, IHTSDO, HL7, IHE, DICOM, openEHR) should be important in the future.
- **Current situation in e-health standards:** Nearly all interviewees agreed that there is a lack of widely used e-health standards. There was also a high level of agreement that there is a lack of sufficiently developed e-health standards, a lack of e-health standards harmonisation activities, and that there are too many conflicting e-health standards. The smallest level of agreement – but agreed by the majority – was for the statement that there are generally too many e-health standards.
- **Impacts of current e-health standards situation**: The level of distance (internal, several providers, national, cross-border) determined the assessment of how supportive the situation of e-health standards is: nearly three quarters of the respondents indicated that within a single health service provider the overall situation is supportive, but the majority found the situation unsupportive for cross-border care provision.
- **Current situation in e-health standardisation processes:** The respondents favoured a stronger involvement in e-health standardisation processes from many different organisations, including above all ICT user organisations and national governments, but also national competence centres, the European Commission and ICT industry.
- **Barriers to adopt common e-health standards in hospitals**: The statement that was supported most was that hospital IT managers may find internal process functionality more important than commonly used standards. The respondents also agreed that the managers miss financial incentives to electronically exchange information with other health service providers. Ignorance about the existence of standards, complexity of standards, a lack of authorised certification, and lacking visibility of the use of common e-health standards were found to be further barriers.

4 Implications for economic performance and policy

4.1 Economic implications of the current situation in e-health standards

Summary and conclusions from the previous analysis

Key results from the analysis so far may be summarised as follows: Standards can contribute to economic growth and increase competition as well as competitiveness (section 2.1). However, the situation in e-health standardisation is characterised by, firstly, conflicting standards and thus a lack of network effects as well as, secondly, a lack of well-developed standards for specific use cases (section 2.2). Various standardisation organisations developed standards that have become fairly prominent, but further development and harmonisation appears to be necessary (section 2.3). This has been confirmed by an e-health expert survey (section 3). Consequently, the wide use of prominent ICT standards could impact positively on economic growth and competition, and on the global competitiveness of manufacturers supplying ICT to the health sector. In the Sectoral e-Business Watch (SeBW) e-health expert survey, 55% of the respondents stated that the current situation in e-health standards is unfavourable for the European ICT for health industry. 29% found that the situation is rather favourable, and the rest did not have an opinion about this issue.

High costs of lacking interoperability

According to the report "Connected Health" published by the European Commission,[115] the potential value of the interoperable exchange of health information between healthcare institutions is substantial. A recent study estimated that net savings from national implementation of fully standardised interoperability between providers and five other types of organisations could yield about 75 billion US dollars annually, or approximately 5% of the projected 1.7 trillion US dollars spent on US health care in 2003.[116] Interoperability in the e-health area could have, e.g., an impact on avoiding those treatments that do not improve health status, are redundant, or are not appropriate for the patient's condition.

Moreover, according to an IHE survey, more then 20% of the costs that hospitals spend on information technology is represented by integration costs. The e-Business Watch 2006 report about hospitals includes case studies of three hospitals that had to invest in the creation of integration engines in order to solve ICT interoperability problems.[117]

[115] See http://ec.europa.eu/information_society/activities/health/docs/policy/connected-health_final-covers18092006.pdf.

[116] See Walker et al. (2005).

[117] See the case studies about Son Llàtzer Hospital, National Heart Hospital, and Ambroise Paré hospital in European Commission (2007b).

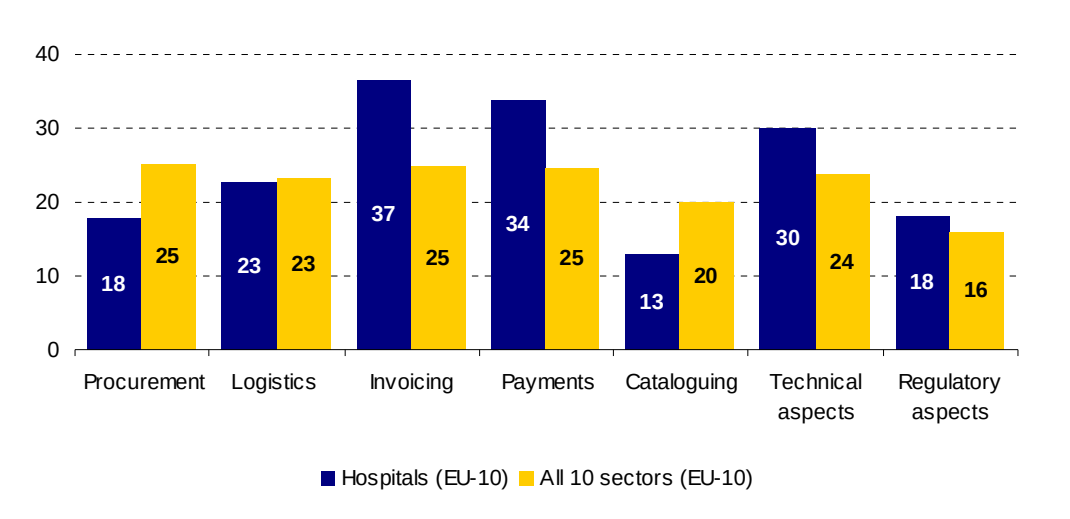
Untapped market potential for health information systems

The market for health information systems in Europe is huge. In the course of research for this study, no reliable data about the potential market volume were identified. In any case, there is consensus in business and also industrial policy that the market for health information systems is largely untapped. For example, the e-Business Survey 2006 found that only a minority of European hospitals uses departmental information systems, for example for pharmacy (42% or European hospitals were found to use a related system), radiology (25%) and computerised physician order entry (19%). The Hospital Information Network Europe (HINE) came to similar conclusion in its surveys.[118]

The EC acknowledges this potential in its "Lead Market Initiative for Europe".[119] The initiative is aimed at the creation and marketing of innovative products and services in promising industrial and social areas. It includes e-health, and one of the key areas targeted for action is e-health interoperability.

However, the e-Business Survey 2006 also found that the percentage of hospitals stating that a lack of technical systems interoperability is a barrier to adopt e-business solutions was larger than in other sectors surveyed, 30% versus 24%.[120] Moreover, the survey found difficulties caused by a lack of systems interoperability to be larger than in the all-sectors average see Exhibit 3-1.[121]

Exhibit 4-1: Problems due to a lack of interoperability: hospitals experiencing difficulties in ...



Base (100%): Hospitals that say that interoperability is critical for their e-business. N (for hospitals, EU-10) = 306. Other sectors: food and beverages, footwear, shipbuilding, ICT manufacturing, consumer electronics manufacturing, construction, tourism, telecommunication.
Weighting: firms representing … % of employment in the sector. Questionnaire reference: G6

Source: *e-Business W@tch* (Survey 2006)

[118] See European Commission, Enterprise and Industry DG (2007b), p. 89-90, for findings from the e-Business Survey and from HINE.

[119] See European Commission (2007b), pp. 4-5.

[120] Employment-weighted figures, i.e. firms representing 30% and 24%, respectively, of employment in the sector.

[121] For the following see European Commission, Enterprise and Industry DG (2007b), p. 44-45.

In three of seven categories, the share of hospitals reporting difficulties due to a lack of interoperability was larger than the all-sectors average: invoicing (37% in hospitals versus 25% in all ten sectors), payments (34% versus 25 %), and technical aspects (30% versus 24%). The shares were similar in regulatory aspects (18% versus 16 %) and logistics (23% both). Only in procurement (18% versus 25%) and cataloguing (13% versus 20%), the difficulties in the hospital sector were reported to be lower than in all ten sectors taken together.

Interoperability problems due to immature e-health standards may be one reason for hospitals and other health service providers to hold off investments in ICT. Consequently, growth in companies supplying ICT for the health sector is smaller than it could be. If there were more widely used ICT standards in the health sector, interoperability would be easier and cheaper to achieve, and health service providers' investments in ICT may increase. This would contribute to overall economic growth.

Growth benefits possibly accrue mainly in the country of standards origin

It may be relevant for economic growth in which country or in what part of the world a standard has been developed. ICT manufacturers from some parts of the world, notably the US, may through their market power set de facto standards for ICT and reap larger economic benefits than economies in other parts of the world where their products are merely purchased and applied. Microsoft is a good example of a US company that defined standards, in this case for personal computer software, that became de facto standards all over the world and opened up a huge market. Although the economic benefits of these products apply everywhere they are used, the revenues from Microsoft's standards are to a considerable part with Microsoft and its employees and shareholders in the US.

It is an open question whether US companies also benefit more than their European competitors from e-health standards defined by US SDOs. US firms may have been involved deeper in the standardisation processes of US SDOs right from the beginning and thus be more familiar with implementing these standards in their products. Consequently they may potentially experience higher growth than European manufacturers that merely deploy standards developed without input from European institutions. However, in the course of research for this report, no confirmation of such a mechanism was found.

Lost opportunities for cost containment and improved service quality

A further economic implication of a lack of commonly used standards manifests itself in lost opportunities for cost containment. Due to a lack of commonly used standards, opportunities for quality improving and streamlining health service processes and for delivering activity data for more effective planning, accounting and controlling are lost. Possible cost optimisation and containment is not achieved.

Secondly, a lack of commonly adopted standards is an important reason for a lack of information systems integration within hospitals and between health service providers. It often prolongs the time needed for access to patient data for physicians and nurses or even obviates it, thus increasing costs and compromising the quality of health care. Benefits of interoperability include better care for chronically ill citizens, better quality

surveillance and control, improved public health services as well as benefits for education, training and research. The e-Business Watch 2006 report about hospitals provides case studies that substantiate the healthcare benefits from interoperable systems.[122]

4.2 Policy implications for further developing e-health standards

4.2.1 Importance and objectives of political support for e-health standardisation

Strategic importance of e-Health standardisation for industrial policy

Standardisation policy can have a deep impact on ICT industry developments. A good example is the US policy towards accessibility of ICT products and services for people with disabilities (e-accessibility). Recently, governmental bodies in the US focused on referencing standards or other technical documents in legislation and other regulations to make them mandatory for manufacturing industries. Examples include the following: the regulatory approach to public procurement addressed in Section 508 of the Rehabilitation Act of 1998, Section 255 of the Telecoms (Reform) Act of 1996 which places obligations on the telecommunications services and equipment industry, as well as the Americans with Disabilities Act (1990) which also has e-accessibility implications. The multiplicity of legislation and regulations in relation to e-accessibility is a growing feature of the US ICT market situation. In this context, a recent study[123] suggests that through e-accessibility-related standards and technical guidelines US legislation has started to impact on the European market for accessible ICT as well.

Similar developments may take place in the field of e-health. On 17 January 2008, the US Department of Health and Human Services recognised certain interoperability standards for health ICT which federal health agencies further on have to include in tender specifications when procuring in the following three fields: EHR laboratory results reporting, biosurveillance, and consumer empowerment. [124] The list includes numerous standards, for example HL7 versions 2 and 3, DICOM, SNOMED-CT, LOINC, ICD-10, and IHE standards. The small number and scope of fields covered as well as the great

[122] These include for example the Son Llàtzer Hospital in Spain and the Hospital System of Helsinki and Uusimaa in Finland.

[123] See empirica and WRC (2007): Measuring Progress of eAccessibility in Europe (http://ec.europa.eu/information_society/activities/einclusion/docs/meac_study/meac_report_06_11_final.pdf)

[124] See Department of Health and Human Services (2008), p. 14: *"We recognize that certain legal obligations may flow from the recognition of these interoperability standards. First, pursuant to Executive Order 13410 (EO 13410) dated August 22, 2006, recognition of interoperability standards would require each Federal health agency, as it implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, to 'utilize, where available, health information technology systems and products that meet interoperability standards recognized by the Secretary'. Therefore, Federal agencies would be required to appropriately consider health information technology systems and products that comply with these Interoperability Specifications when purchasing, implementing, or upgrading such items."*

variety of standards included may not necessarily lead to a significant impact in the short run. However, one may expect this recognition to be a step into the direction of mandatory use of a confined number of standards for principal e-health applications. Such a regulation by the US government could have considerable impacts not only in the US but also in the EU. In the US, federal health agencies include many large hospitals, for example veterans' hospitals. Their purchasing behaviour and constraints with regard to ICT standards may have considerable impact on the products offered by the US ICT industry. Industry would have to comply with the standards defined by law. Possibly, in order to realise economies of scale in production and marketing, it would confine the product portfolio also for non-federal health agencies to operate with the standards mandatory for federal agencies. Eventually, the vast majority of health service providers in the US would apply information systems operating with a fairly confined number of standards.

For the EU ICT manufacturing industry, such a development may have serious consequences. Since some Member States currently favour national standards for developing their e-health systems, the EU ICT manufacturing industry will have national foci. It would thus not be able to realise scale economies as large as the US industry. For applications operating with the standards that are mandatory in the US, the US ICT manufacturing industry will have an advantage over their EU competitors. The EU ICT manufacturing industry may loose market shares.

In order to prevent such an unfavourable development, the EC and the Member States may be well advised to quickly develop a common strategy and roadmap for ICT standards development in the health sector as proposed in the EC Recommendation on cross-border interoperability of electronic health record systems.[125]

Assuming that public policy should play an active role in e-health standardisation, several questions follow: What should be the objectives, the means, the suggested sequence of implementation, and the guidelines? In the following, suggested objectives of further e-health standardisation are summarised, a development mechanism is suggested, and a roadmap is outlined.

Objectives: seeking standards consolidation

Considering the problems resulting from the current situation in e-health standards which were outlined in section 2.2.1, public policy should seek to promote the following:

- **Union-wide agreement on priority standards:** Member States health systems and their Competent Authorities, with the support of the relevant stakeholder groups, should identify and agree on priority standards appropriate for strategic e-health systems and services. The agreement process should be coordinated at the EU level and supported by European and possibly world-wide SDOs as well as industry and user groups.
- **Increased uptake of priority standards:** Fostering the uptake of priority e-health standards and thereby reducing the overall number of standards in concurrent use needs to be supported by the Member States. The uptake of priority standards may

[125] See European Commission (2008).

be driven by government regulation and procurement rules, but it may also be driven by coordinated supplier decisions or policy measures providing appropriate incentives to buyers.

- **Developing specific standards:** Developing and establishing standards for applications and priority use cases for which there is currently a lack of well-developed standards.
- **Harmonising conflicting standards**, i.e. ensuring that applications that operate with different standards for the same purpose will in the future nevertheless become interoperable as standards are further developed during their life cycle.

4.2.2 Policy means: international co-operation involving industry and users

Establishing a mechanism for international e-health standards life cycle management

In order to achieve the objectives mentioned, stronger involvement of stakeholders and closer co-operation between the different global and regional SDOs are indispensable. A sound and enduring mechanism for e-health standards life cycle management and consolidation should be established. Co-operation should be at the global level because the market for e-health systems is world-wide. The collaboration between ISO, CEN and HL7 appears to be an important activity in this respect. However, the collaboration is seems currently still weak and should be strengthened and expanded.

- ISO as a truly world-wide standardisation organisation should take the lead in the collaboration leading to a global, sustained life cycle management of a comprehensive set of e-health standards for priority use cases and core application fields.
- CEN should be encouraged to more vigorously coordinate and integrate the various national activities like national HL7 groups and the various stakeholder groups into one European voice to achieve a greater impact at the global level.
- It seems advisable that further SDOs join the collaboration activity.

Ensuring more intensive involvement of industry and user groups

Within such collaboration mechanisms, the involvement of key stakeholder groups should be expanded and reinforced.[126] This implies the involvement of industry and user organisations as well as of national or regional infrastructure institutions and Competent Authorities.

- At the Union level, a truly European industry association reflecting the interests and needs of the European e-health industry – i.e. hardware, software and services – should be promoted and supported.
- As regards user organisations, professional medical and hospital associations as

[126] See also DLA Piper/TU Delft/Uninova (2007), chapter 7, for the importance of user involvement.

well as patients' and citizens' lobbying groups should play a role.

Key stakeholders need incentives to invest into standardisation efforts. They will be willing to invest time and funds only if it is clear that the standards to be newly developed or managed will be highly relevant for them.

The EC should initiate and support the monitoring of the requirements of industry and user organisations and assess whether they are adequately reflected in the standardisation process.

The experts from key stakeholder groups should preferably have a multi-domain, interdisciplinary background. e-Health is a complex field that needs more input by people that have expertise in at least two of the following domains: medicine, ICT, politics, and economics. Experts should be able to address and solve not only technical but also cultural, organisational, social and policy issues.

Ensuring active support from Member States

Member States' governments as well as national Competent Authorities should support international collaboration mechanisms to the largest possible extent. They should actively promote and facilitate investments in international standardisation organisations and efforts. Currently there is a certain tendency towards focusing on national standardisation activities.

- **Providing incentives for collaboration:** National governments could provide financial or other incentives for health service providers to exchange, cooperate and communicate, also electronically, with other relevant partners and organisations towards better integration at the Union level and a unified, stronger voice at the global level.
- **Raising awareness about standards benefits:** Finally, policy makers should increase awareness among ICT producers as well as managers and users in hospitals, other healthcare provider organisations and public health institutions about the benefits of and the need for standards and interoperability. Benefits from interoperable systems are not necessarily reaped by those who provide them. Interoperability benefits are generated within the overall system, e.g. by improved healthcare across the healthcare value system. Therefore, seeking interoperability is not necessarily in the interest of those producing, managing and using ICT in the health sector. Voluntary use of standards could contribute tremendously to e-health interoperability.[127]

4.2.3 A roadmap for developing standards for EHRs and e-messages

A suggested sequence of application areas

Considering the complexity of e-health standardisation, the step-wise development and incremental implementation of EHR and electronic messaging systems between health professionals should be based on standards and detailed specifications organised in well-

[127] See European Commission, Information Society and Media Directorate General (2006), p. 23.

defined sequences and servicing concrete use cases. The following sequence of applications is suggested here:

- **Patient summaries including medication records,** an **emergency data set and e-prescribing** which are the subject of the large-scale pilot currently starting in the framework of the EC's CIP ICT PSP Programme by a core group of twelve Member States may provide appropriate starting points.
- **Laboratory results** may be the next step because they constitute one of the most important part of patients' medical records and because the development of related standards is quite developed.
- **Medical image storing, management and exchange** may be another step because they constitute also an important part of medical records and, again, because the development of standards is already quite far developed in this area.

In parallel and early into this process, it will be mandatory to also develop a high-level architecture and standards for a **European e-health infrastructure.** This should cover fields such as identity management for citizens, patients and professionals, data protection, security and reliability of systems as well as certification of software.

Considering the linguistic and cultural diversity of the Union, standards for securing a certain level of **semantic interoperability** with respect to priority use cases will be mandatory in the short term. For the longer term more comprehensive levels of semantic standardisation need to be accomplished.

Each step may take three to five years, with parallel developments to standardise horizontal activities and infrastructure components. Consequently, the development of standardised solutions for EHR and e-messaging systems and other advanced applications may take anywhere from 10 to 15 years and more, particularly when considering the wider diffusion necessary to achieve the desired benefits for the health system and society.

In order to make reasonable decisions in any of these phases, consistent knowledge about the situation in the Member States is necessary.[128] This may imply, firstly, that the Member States and the EC for each step undertake a comprehensive survey of existing e-health systems infrastructures and services as well as the providing companies throughout the European Union. Secondly, the Member States and the EC should explore the barriers and missing elements for e-health interoperability, and identify the necessary pre-conditions and incentives for achieving interoperability.

Implementing and further developing the **Open Method of Coordination** (OMC) in the health sector may constitute an appropriate process to guide these developments.[129]

The Member States, where appropriate, should exchange and apply as good practice the

[128] For the following see the draft recommendation on e-health interoperability in European Commission (2007a).

[129] The open method of coordination is an intergovernmental means of the EU, based on the voluntary cooperation of its Member States. It rests on "soft law" mechanisms such as guidelines and indicators, benchmarking and sharing of best practice. There are no official sanctions for laggards. Its effectiveness relies on peer pressure and "naming and shaming".

achievements and lessons learned from each phase.[130]

Guiding principles for e-health standardisation

Within the various phases of EHR development, the following guiding principles should be followed to ensure successful developments and wide adoption of them:

- **Focus on concrete use cases:** e-Health standards developments should be more focused on concrete use cases, i.e. concrete applications with well-defined users and processes. The success of the DICOM standard provides an example of process focus in e-health standardisation. The focus of the large-scale pilot on patient summaries and e-prescribing is also an example of a specific use case. In the SeBW e-health expert survey, 63% of the respondents agreed that e-health standards development should be more focused on concrete use cases (see section 3.2.5).
- Start with a **core set of limited requirements**, related detailed specifications, implementation guidelines and conformity testing to assure basic stability over an extended period of time.
- **Ensure backward compatibility:** Whenever meaningfully possible, develop backwards compatible standards to allow easy migration to an updated version. The incompatibility of HL7 versions 3 and 2 may be a negative example in this respect (see section 2.3.6).
- **Seek to reduce complexity:** Find compromises in defining details to avoid increasing complexity of standards. In the SeBW e-health expert survey, 76% of the respondents agreed that hospital IT managers may not be willing to adopt prominent e-health standards because their specifications are too complex (see section 3.2.6).
- **Consider open standards:** Use of open standards may further strengthen collaboration and adoption. For example, in the SeBW e-health expert survey, 64% of the respondents were of the opinion that openEHR should be important in the future (see section 3.2.2 for survey results and section 2.3.8 for details about openEHR). Moving towards open standards in e-health may gain more support in the foreseeable future due to the increasing demands of participation and support in the standards development process. It can be considered as one possible model for sustainable international standards development.

  However, for this to become a success model, several issues have to be addressed, for example to assure that all members are trustworthy and participate without hidden agendas or that committee leaders are appointed in an open process reflecting the interests of all stakeholders. Objectives that need to be fulfilled include verifiable results, i.e. solutions that do not discriminate any player. Furthermore, sustainable management models must be established to assure the survival of such activities.

[130] See http://ec.europa.eu/enterprise/enterprise_policy/cip/index_en.htm (October 2007); also http://ec.europa.eu/information_society/activities/ict_psp/calls/call_proposals_07/index_en.htm, call for proposals, for the currently planned large-scale pilots.

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W. Ed Hammond, Professor Emeritus, Department of Community and Family Medicine; Professor Emeritus, Department of Biomedical Engineering; Adjunct Professor, Fuqua School of Business Duke University; Chair, Health Level Seven; Chair, Joint Initiative Council, ISO/CEN/HL7, USA, 23 November 2007.

Dipak Kalra, Clinical Senior Lecturer in the Centre for Health Informatics and Multiprofessional Education, University College London, UK, 14 November 2007.

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Eric Maurincomme, Chairman of the Healthcare IT Committee COCIR, Vice-President Marketing & Business Development at Agfa HealthCare, Belgium, 23 November 2007.

Kees Molenaar, Chair CEN/TC-251 Health Informatics, Dutch Ministry of Health, Netherlands, 21 November 2007.

Other experts providing written opinions and input for this report

Charles Parisot, General Electric Healthcare Integrated IT Solutions, Manager Standards and Testing, US.

Angelo Rossi Mori, Consiglio Nazionale Delle Ricerche, Italy.

Yun Sik Kwak, Chair, ISO/TC251 Health Informatics; Kyungpook National University, Daegu, Korea.

Appendix I: Online survey questionnaire

Online Survey 2007:
ICT standards in the health sector

European expert survey on e-health standards

Interoperability of information and communication technology (ICT) applications is a serious challenge for the European health sector. empirica currently investigates the state of the art of standardisation in the field of ICT in the health sector. Special attention is given to standards for electronic health records. In the following, “ICT standards in the health sector” is abbreviated to “e-health standards”.

empirica asks a selected group of leading experts in the field of e-health standards to participate in this survey. We would be very pleased if you answered the following questions to support our analysis. Filling in the questionnaire will take you approximately ten minutes. If you wish to interrupt the survey and continue later, please click the related buttons at the bottom. If you encounter any difficulties or if you have any questions, please contact benjamin.jung@empirica.com.

This survey is conducted within the framework of e-Business Watch, a service for the European Commission, Enterprise and Industry Directorate General. Findings from the survey will feed into policy recommendations for the European Commission. For further information about this project, please visit http://www.ebusiness-watch.org. Results of the study will be made available to you on request; please see the last page of the survey.

In this survey, we consider “standards” in a more general sense, including standards defined by industry.

Question 1: Interviewee affiliation and origin

What type of organisation are you affiliated with? If several options apply, please choose the one that is most appropriate.

Code	Question	
1.1.1	☐ Health care provider (e.g. hospital)	
1.1.2	☐ ICT manufacturing or service company (hardware, software, networks)	
1.1.3	☐ Public authority (except SDO, e.g. Ministry of Health)	
1.1.4	☐ Standards development organisation (SDO)	
1.1.5	☐ Health association (professional or other)	
1.1.6	☐ University, research	
1.1.7	☐ Consulting	
1.1.8	☐ Other (please specify):	

Please state the continent of your origin:

Code	Question
1.2.1	☐ Europe
1.2.2	☐ America
1.2.3	☐ Asia
1.2.4	☐ Australia / New Zealand
1.2.5	☐ Africa

Question 2: Future importance of e-health standards development organisations

How important should the following e-health standards organisations in your opinion be in the future?

Code	*Question*					
		Should be very important	Should be rather important	Should be rather unimportant	Should be very unimportant	No answer
2.1	International Standardisation Organisation (ISO), TC 215 (health informatics)	☐	☐	☐	☐	☐
2.2	European Committee for Standardisation (CEN), TC 251 (health informatics)	☐	☐	☐	☐	☐
2.3	International Health Terminology SDO (IHTSDO), SNOMED-CT	☐	☐	☐	☐	☐
2.4	Health Level 7 (HL7)	☐	☐	☐	☐	☐
	Digital Imaging and Communications in Medicine (DICOM)	☐	☐	☐	☐	☐
2.5	Integrating the Healthcare Enterprise (IHE)	☐	☐	☐	☐	☐
2.6	openEHR	☐	☐	☐	☐	☐
2.7	If you like you can comment or note other standards you consider as important:					

Question 3: Current situation in e-health standards

Please indicate your level of agreement to the following statements:

Code	*Question*					
		I strongly agree	I slightly agree	I slightly disagree	I strongly disagree	No answer
3.1	There are generally too many e-health standards	☐	☐	☐	☐	☐
3.2	There are too many conflicting e-health standards	☐	☐	☐	☐	☐
3.3	There is a lack of widely used e-health standards	☐	☐	☐	☐	☐
3.4	There is a lack of sufficiently developed e-health standards	☐	☐	☐	☐	☐
3.5	There is a lack of e-health standards for electronic health records	☐	☐	☐	☐	☐
3.6	There is a lack of e-health standards harmonisation activities	☐	☐	☐	☐	☐
3.7	If you like, you can comment on the current situation in e-health standards:					

Question 4: Impacts of current e-health standards situation

Please assess whether the overall situation in e-health standards is supportive for the following items.

Code	*Question*					
	The overall situation in e-health standards is ...	very supportive	rather supportive	rather unsupportive	very unsupportive	No answer
4.1	...for systems interoperability within a single health service provider (for example separate systems within a hospital)	☐	☐	☐	☐	☐
4.2	...for systems interoperability between several health service providers (for example between two hospitals)	☐	☐	☐	☐	☐
4.3	...for systems interoperability in national health systems	☐	☐	☐	☐	☐
4.4	...for systems interoperability in cross-border care provision	☐	☐	☐	☐	☐
4.5	...for competitiveness of European ICT-for-health manufacturers and service companies	☐	☐	☐	☐	☐
4.6	If you like you can comment or note other impacts:					

Question 5: Current situation in e-health standardisation processes

Please tick the box indicating your level of agreement or disagreement to the following statements:

Code	*Question*					
	e-health standards development processes…	I strongly agree	I slightly agree	I slightly disagree	I strongly disagree	I do not know
5.1	…are currently too slow.	☐	☐	☐	☐	☐
5.2	…should be more focused on specific applications.	☐	☐	☐	☐	☐
5.3	…currently involve too many players.	☐	☐	☐	☐	☐
5.4	…should have stronger involvement of ICT user organisations, e.g. from hospitals.	☐	☐	☐	☐	☐
5.5	…should have stronger involvement of ICT industry	☐	☐	☐	☐	☐
5.6	…should be supported more strongly by the European Commission.	☐	☐	☐	☐	☐
5.7	…should be supported more strongly by national governments.	☐	☐	☐	☐	☐
5.8	…should have stronger involvement of national e-health competence centres	☐	☐	☐	☐	☐
5.9	If you like, you can comment on standardisation processes:					

Question 6: Barriers to adopt common eHealth standards in hospitals

An e-Business Watch survey in 2006 found that the use of proprietary standards for information systems is more prevalent in hospitals than in other, non-health sectors in Europe. Please state your level of agreement with the following possible reasons.

Code	*Question*					
	Hospitals IT managers may…	I strongly agree	I slightly agree	I slightly disagree	I strongly disagree	No answer
6.1	…not know about the existence of particular e-health standards	☐	☐	☐	☐	☐
6.2	…find many e-health standards too complex to understand	☐	☐	☐	☐	☐
6.3	…find internal process functionality more important than commonly used standards.	☐	☐	☐	☐	☐
6.4	…not see sufficient benefits of commonly used e-health standards	☐	☐	☐	☐	☐
6.5	…find that there is a lack of authorised certification for correct implementation of e-health standards	☐	☐	☐	☐	☐
6.6	…miss financial incentive to electronically exchange information with other health service providers	☐	☐	☐	☐	☐
6.7	If you like you can comment:					

Question 7: Final report contact information

The final report about ICT standards in the health sector will be available at the e-Business Watch web site.

Code	*Question*
7.1	If you like you can provide your email address so that we will send you the report as soon as it is ready for publication:

These were all our questions. We would like to thank you very much for taking the time for filling in the questionnaire.

The final report about ICT standards in the health sector will be available at the e-Business Watch website. You can provide your e-mail address so that we will send you the report as soon as it is ready for publication:

Appendix II: Online survey individual statements

In the following individual statements from the online survey, only typing errors were corrected. The statements are presented in full length except a few extraordinarily long statements with more than 1000 characters which were abbreviated.

Question 2: Future importance of e-health standards development organisations
IEEE should be involved.
ICPC / ICD / ICF
ETSI in relation to ubiquitous communication and RFID
It is just to say that any new IT solution for the hospital can and will only succeed if it satisfies 4 basic principals: 1. Supported by reliable and knowledgeable IT training and support 2. Improves patient safety 3. Saves time for health care workers 4. Improves efficiency and ultimately saves hospital money
National mirror groups to CEN
public authorities (e.g. EMEA), LOINC, ICD, ATC, WHO-FIC, ICH
HL7 Version 3 (not 2.x)!
AStM (CCR) Standards on eID, biometrics. Have a look to BioHealth.gsf.de
W3C, OASIS, IETF
We would like to see further collaboration between the SDOs national legislation over ehealth liability and responsibility, WHO standards
French PN13
W3C
Note that IHE is not a standards organisation in the formal sense! Also Continua should be mentioned here.
In my view, based on the available experiences to date, the industry led initiatives to standardisation are having the greatest impact.
Continuity of Care Record (CCR) and International Codification of Diseases (ICD)
CDISC should be somewhat important WHO should be somewhat important (drug dictionary) CCHIT and EurRec should be somewhat important (certification for EHR systems)
As a hospital, may we observe that: - The majority of products we use/develop do not seek to be ISO or CEN compliant. This should be a strong indication... - We would nevertheless like CEN standards to be important, as we can foresee the benefits (for example, the fact that they will be more easy to impose within the EC countries). - SNOMED CT, HL7, DICOM, IHE are and/or should be important standards. We have no opinion about if their respective standard organizations should be important. - openEHR should be very important. Unfortunately, the current situation is that the majority of hospital IT managers are either unaware of it, or do not believe that such products could obtain a sufficient level of abstraction to be applicable in varied real-life situations. - More generally, 2 types of standards should be important: - standards that describe medical data - standards that normalize exchanges of medical data.
Europe cannot effectively 'go it alone'. ISO is currently the leading standards organisation in the World, so we need to work with them.
“OASIS, OMG/CORBA, W3C
I am always intrigued by the adoption of 'standards' that were not the work of a "standards body".
Continua Health Alliance
“need to harmonize/synchronize all these different initiatives and organizations - too many right now”

Question 3: Current situation in e-health standards
If harmonizing means kind of work done by IHE, there are to be encouraged. If harmonizing means creating the nth "state of the art" and creating a new structure with no real practically usable results, it is totally unuseful.
There should be clear different approaches e.g. eHealth standards in hospital setting v.s. personal eHealth needs.
We've been researching on eHealth standard for decades, and advances seem terribly slow. Many groups redo what other did almost a decade ago. Some other approaches need to be included in current standardisation effort. Publicly available reference implementation may be one approach to speed up uptake of standards and innovative research in this field.
Standard's organizations are playing an influential role before the content of their standards has been thoroughly tested in real applications. When they are applied, as recently in the UK, they do not work, and cause considerable costs and setbacks for the very goal of standardization.
Keep it simple, common!
By mistake, eHealth is not user(patient) centric and is taken separately from eGov (citizen eID)...
The problem with eHealth standards are the people behind - they are only interested in the standardisation work - not the use. They should be re-organised (development of standards and implementation/use of standards) + focus on user driven standardisation.
There are conflicting i.e. alternative standards for several messaging problems but for several other problems there is a lack of standards. For EHR there is really only the EN/ISO 13606 standard that is international but not fully finalised in ISO and adopted to a very little extent yet.
Different kinds of problems: Some mature standards are not disseminated (messaging, communication with equipment) In other areas (EHR) mature standards are missing." With use case driven standards harmonisation such as IHE, this places a hierarchical structure around the use of standards. This needs simply to be better understood and deployed.
HL7 has two complexity issues 1. HL7 Int. org can't say NO to any new initiative 2. HL7 domain models do not reduce dependencies among players
CEN 13606 totally lacks any modelling process and any methodology for setting up criteria how to develop archetypes PLUS a lot more severe systematic defects"
Interoperability & open interfaces are very important. Also linkage to general electronic communications standards is important, no use to invent a wheel again just for healthcare.
As long as standards (e.g. CEN 251) are not publicly available (free of charge) they are not sufficiently known and not sufficiently used. There are also unnecessary efforts, e.g. translation into local languages. These translations are often of poor quality since the translators lack technical knowledge.
There are several hundreds and I know only some of them. The project BioHealth is an "enabler" for stakeholders to have access to information about standards and at the end to standards itself
I have no problem with lots of standards, provided that the market can choose. The problem is having lots of MANDATED standards. Good standards have conceptual integrity and are not horrible compromises
Standards for EHRs need to be about semantic interchange rather than internal structures of a particular implementation. It may not be necessary to exchange the full detail of the data-set, but at least episodic summaries and general health indicators - this may require standards about production of health record summaries.
The combination in between top-down and bottom-up is key - and this is the problem
Processes and practices are overlooked. COI and COP should be emphasized...

"There are a great many excellent efforts - and successes - worldwide with committed people working towards a (shared) vision of eHealth....but: 1. Development across the spheres of eHealth is fractured; it must come together 2. Pace is slow; we need the 'big picture' success stories: the real-world credentials that will add impetus and fire enthusiasm 3. There's a 'hearts and minds' battle still to win that demonstrates the role of standards.
I'm sure all support further collaboration and co-operation, in standards development and roll-out, that will ultimately underpin the successful delivery of the eHealth vision. " "degree of overlap and conflict with HL7 v3, snomed \sct and open ehr archetypes"
No more academic driven SDO work like CEN and HL7v3 - mch more practical implementation.
"My view is that the main problem is that there is not a single ""standard"" that has achieved strong industrial backing. "
Two issues: there are too many players in the standardisation arena and not always thinking on the benefit for the users. To be 'politically correct' instead of approach the problem in a pragmatic way and follow strict procedures are also key barriers.
Specifically in the field of EHR standard there is a regrettable lack of harmonization efforts. IHE XDS, HL7 CDA and EHRcom are all partial solutions, and specifically a harmonization between the first two (which are often combined in practical implementations) and the latter would be more than desirable. "The is no lack of eHealth standards for electronic health records. What lacks, in our opinion, is: - sufficiently developed standards (HL7 RIM, openEHR are still experimental) - harmonization between these standards (there are efforts, but what is needed is results)
About eHealth standards conflicts: we do not believe that there are too many conflicting standards. Currently, there are just a few standards which are sufficiently advanced in one particular field.
Conflicts often arise when successful specialized standards try to extend in order to cover fields that their consortia are not accustomed with.
Funnily enough, this reminds me of many modern software tools which, after having succeeded in one IT field, now release new versions that claim to provide solutions for virtually everything...
For the foreseeable future, we will continue to try and evolve effective universal standards. We have no way of knowing which of the current ones will 'win', so the process is evolutionary and involves many suboptimal interim solutions.
The Harmonization Initiative of ISO, CEN and HL7 - open to other SDOs, which have to be involved in, gives hopes
The business conditions for interoperability are not obvious or clear for many aspects of the EHR and PHR industries. Imaging (DICOM) and personal telehealth have much stronger business propositions for collaboration across different companies and geographies.
Question 4: Impacts of current e-health standards situation
Many (vendors) claims that they use standards - but nobody knows if this is correct?
The present and internationally working standards e.g. for imaging are doing a great job. A few European companies that worked with formal CEN and ISO standards have a tremendous potential but unfortunately most of the companies are either steered by US multinational or tries to become one
It's not easy to answer in this schema. today the focus of users is in-house communication and we are talking too much about cross-enterprise or cross-border communication. in most countries there are just small or no budgets for a cross-X communication (e.g. electronic patient records or personal records). but combined budgets and financing plans for a national or cross-enterprise communication are in preparation and it is the right way thinking of efficiency and building medical competence centres. thinking about standards we have a wrong focus today (-> were is the business case?).
"Within a single health service provider often proprietary solutions are used. Cross-border care provision based on messaging well developed in some countries. Closer integration is generally Very unsupportive"
We need genuinely open standards-making, based on what the market wants, not academic theories.

The problem is not the standard - seen from a technical perspective. It is the political will to make decisions - and to show a business case with high economic, cultural impact. It is not the fear of the ""transparent patient"", it is the fear of the transparent doctor, hospital or healthcare system!
real standards are very needed, but much more industry involvement and public funding is needed if standards are going to be used large scale.
Intra-hospital interoperability problems are mostly caused by lack of implementation of standards, not by lack of standards.
As a hospital, we have the impression that standards have been developed in with large scale interoperability needs in mind, rather than the internal needs within a healthcare agency.
At small enough scale, standards do not present a problem - universality is the real challenge.
ICT companies can charge for integration of disparate systems within a single healthcare provider and across multiple healthcare providers. There is no incentive for them to build their products to be standards compliant. The healthcare provider (purchaser) needs to change this dynamic by demanding "out of the box" interoperability from their vendors. Drive standards adoption through purchasing power...the ISVs aren't going to do this on their own. It affects a significant revenue stream for them.
Question 5: Current situation in e-health standardisation processes
The development process has to include also "deployment activities" where key players (users, govt) can play an important role. The public subsides (EC, member states) shall encourage Europeans to be more active in the "global SDOs" works.
Continua Health Alliance is doing good work in the US. We should have a strong and fast moving European Health Alliance?
KMEHR bis (Kind Messages for Electronic Health Record, belgian implementation standard) is in full development
I would prefer less but crucial standards
1. academic people claim they know the users' requirements, which results in inappropriate standards 2. there is no overall roadmap presenting a long-term view on eHealth standards
IHTSDO may play a crucial role in the future. SNOMED CT is a good vision but the ressources to put this vision into practice are insufficient. In the current situation where important future directions have to be set, IHTSDO cannot rely only on voluntary input by the members of its standing committees.
Governments should keep out. They know nothing.
I have concerns about the definition/identification of excellence centers. This is becoming more and more political every day and this issue becomes corrupted politically. e-health, to my experience, is not well understood. Mostly e- part is focused on and health part is overlooked.
ideally needs to be beyond EU too
Difficult to answer in general. What Standards Development process is meant? The EU Commission should not only support e.g. CEN but especially organisations like IHE, Continua.
healthcare professionals should also be involved
"The EC currently 'strongly supports' by initiating the e-health standards mandate; it is contained by its own rules and regulations on what it can do. The greater weakness appears to be the lengthy time-periods that the various standardisation organisations come to making firm decisions. On the other hand, this e.g., 3-year time-period can at least theoretically facilitate increased consensus-building. National governments could presumably do more by endorsing publicly and making part a need for particular (specified) standards of their tendering and procurement processes for ICT. There are at least five types of 'national e-health competence centres' throughout the Union. The extent to which 'national e-health competence centres' can act independently will depend structurally and institutionally on the extent that they are: a) part of a national government (ministry) e.g., NpFIT (UK), b) an entity delegated to act by a national ministry e.g., NL, c) an independent 'agency' e.g., DE, d) an academic or reseacrh institute e.g. STAKES, SF, e) a contractor/subcontract (e.g., the contractors successful as a result of tenders operated by NpFIT (UK). In order to ascertain their degree of autonomy/independence, and ability to influence standards, a study/survey of the attributes of national competence centres should be conducted."

(Too much) financial support for standardization by government bodies leads to a situation where standardization work becomes attractive for independent consultants as a mean of generating income. This causes standards to be produced not because of market needs but for sake of standardization, which is undesirable. This is the primary reason why industry stopped support of CEN TC/251 some 10 years ago. If stakeholders have an interest in standards, this interest should justify the investment needed for standard development. This certainly applies to industry, and at least to some degree to bodies representing users.
The support of EC & National governments should increase, for two reasons: - technical : to accelerate their development - political : to impose their use After all, the imposition of standards, in any field, is more a political decision rather than a technical one (the technical decision being the choice of the standard to be imposed)."
Industry must provide the lead in workable, deliverable standards. EC and Governments need to support the evolutionary process but not try to control it.
The current process is based on voluntary work. Without funding the corresponding experts properly (which is very different from country to country and, e.g., very weakly developed in Germany), the currently bad situation cannot be overcome.
The current non-commercial SDOs have too many consultants and academics who don't have a true marketplace stake in the result. In some cases, these parties profit from slowing down the process and taking longer to produce a result. Vendors don't have a vested stake in a good result as a tight interoperability spec would allow the purchasers of their systems to actually hold them accountable. To improve the dynamics, the government purchasers of healthcare systems need to take control of the standards bodies and drive tight interoperable specs that they can then use to hold the vendors accountable.
Question 6: Barriers to adopt common e-health standards in hospitals
They are totally focussed on the mandatory communications with payers and govt, missing totally the "health process" (only the billing and survey ones are priorities). Because such are National (vs. global for Medical standards), they are putting all energy and money on specific development.
The people involved cannot calibrate in clinical terms the REAL advantages of such a process, too technical, lack clinical knowledge base. the clinical professionals on the other hand lack the technical terminology to explain their needs
"they know about standards and the benefits. bit they have too much internal pressure and definitely no time to get into an standard. authorised certification is no guarantee for quality. it's other way around: the costs increase and the pressure for more than 20 certification processes in a IT company and short-termed changes in the certification process is a very big problem!! lets think about connect-a-thons and practicable, pragmatic evaluation processes and not certification!"
International standards needs national/local adjustments before implementation. This is a significant workload. Therefore proprietary solutions are interesting for hospital IT mangers
Public procurement processes are so difficult that standard-related demands are easily forgotten, as in many cases the evaluation of tenders would be even more difficult. Then hospitals get what they have asked, nothing more.
The biggest barrier is inertia and the desire by suppliers to preserve their legacy silos at all costs.
The standard-discussion is not really the most important one - but it it is a good one to have some "technical reasons" to camouflage other topics
Hospital organisational models are not mature. CMO is the chief; balanced scorecard applications are not in place. Hospital performance indicators, balanced score cards and clinical performance indicators, including outcome management are not well understood. Pharma industry does not want to be monitored or measured for ADEs.
are not involved in organisational business strategy
Existing information systems may not support e-health standards
"I find the question: find internal process functionality more important than commonly used standards"" very difficult to respond to. In principle, the two issues should not be in conflict with each other.

With regard to the question: "miss financial incentive to electronically exchange information with other health service providers"", much will depend on the degree of independence and autonomy of the particular hospital and its IT system/service. The incentives may not simply be financial: they could be mandated via regulation (e.g., with state-organised systems); dependent on policy directions of the particular country (e.g., the extent to which health providers are designated to cooperate, or the extent to which health provision needs to be provided cross-sector [hospital care, community care, home-based care, social care]; institutionally-driven (i.e., in principle, strategies followed by hospital IT managers should be congruent with the overall business strategy of the institution); depend on the extent to which hospitals operate within e.g., city or regional clusters; the extent to which the hospital IT manager is in independent control of his/her IT budget."
Standards are a means, not an end. They will be applied if there is a business case. To some degree, eHealth standards (and eHealth initiatives) are not sufficiently based on an analysis of business processes (workflows) and business cases (cashflows).
Hospital IT managers have to deliver local solutions that work locally. Financial incentives are needed for sharing of information across wider health communities.
Without common interest there is no reason for interoperability --> common business cases are essential.
Many IT managers don't understand how standards would allow them to commoditize the various vendors (hence the vendor resistance). Driving standards into the marketplace can help the IT managers reduce costs in the long run by creating a much more competitive marketplace.

Appendix III: Key e-health standards and their characteristics

Standard	Organisation	Current Version (release)	Previous Version (release)	Price (USD)	Licensing Fee	Open Process	Purchase From
HL7 v2.x	HL7	2.5 (Jun 2003)	2.4 (Oct 2000)	$25-$675	no	yes (voting restricted to members)	http://www.hl7.org/
HL7 v3.0	HL7	3.0 (2003)	n/a	$50-$600	no	yes (voting restricted to members)	http://www.hl7.org/
CDA	HL7	2 (Apr 2005)	1 (Nov 2000)	$0-$50	no	yes (voting restricted to members)	http://www.hl7.org/
RIM	HL7	1 (Dec 2003)	n/a	$15-$60	no	yes (voting restricted to members)	http://www.hl7.org/
CCOW	HL7	1.5 (May 2004)	1.4 (Jan 2002)	$0-$50	no	yes (voting restricted to members)	http://www.hl7.org/
EN 13606-1	CEN	n/a (Apr 2007)	ENV 13606-1 (Dec 2000)	$215	no	no	http://www.cen.eu/
EN 13606-2	CEN	n/a (Sep 2007)	n/a	$149	no	no	http://www.cen.eu/
EN 13606-3	CEN	n/a	ENV 13606-2 (Dec 2000)	$135	no	no	http://www.cen.eu/
EN 13606-4	CEN	n/a (Jun 2007)	ENV 13606-3 (Dec 2000)	$58	no	no	http://www.cen.eu/
EN 13606-5	CEN	n/a (Mar 2010)	ENV 13606-4 (Dec 2000)	n/a	no	no	n/a
IHE Profiles/Framework	IHE	n/a	n/a	Free	no	yes	http://www.ihe.net/
openEHR	openEHR	1.0.1 (Apr 2007)	1.0 (Feb 2006)	Free	no	n.a.	http://www.openehr.org/
SNOMED	IHTSDO	Released twice a year (Jul 2007)	(see current version) (Jan 2007)	n.a.	yes	Yes	National Member
DICOM	NEMA	PS 3 2007 (2007)	PS 3 2006 (2006)	Free	no	yes (voting restricted to members)	http://medical.nema.org/
ISO 18307:2001	ISO	2001	n/a	180	No	No	http://www.iso.org/
ISO 18308:2004	ISO	2004	n/a	110	No	No	http://www.iso.org/