The *e*Europe Action Plan

The world economy is moving from a predominantly industrial society to a new Information Society, offering tremendous potential for growth, employment and inclusion. These changes, perhaps the most significant since the Industrial Revolution, are far-reaching and global and they are not just about technology. They will affect everyone, everywhere. Bringing communities, both rural and urban, closer together, creating wealth, sharing knowledge, they could enrich everyone's lives. Managing this transformation represents a central economic and social challenge for the European Union (EU).

Space for figure from e-Accessibility brochure

The success of the new economy will depend on consumers' ability to take full advantage of the opportunities on offer. For this, they need to be able to access the information they seek and interact successfully on the Internet. If markets are to develop and business is to flourish, consumer confidence must be built.

To ensure that the whole of Europe reaps the benefits of the Information Society, in 1999, the European Commission launched a new initiative ? *eEurope 2002* ? *An Information Society For All.* eEurope is intended to accelerate positive change in the Union and is a key element in the strategy for modernizing the European economy. It aims to secure equal access by all of Europe's citizens, to promote computer literacy and, crucially, to create a partnership environment between the users and providers of systems, based on trust and enterprise. Its ultimate objective is to bring everyone in Europe ? every citizen, every school and every company ? on-line as quickly as possible.

An action plan has been drawn up which outlines eleven key areas where effort should be concentrated; one of these is Health on-line.

Health on-line objectives and standardization

The eEurope Action Plan 2000 stated the challenge as:

" The prime objective of this action is to develop an infrastructure of user friendly, validated and **interoperable systems for health education, disease prevention and medical care**. Many of the tools for the building of such an infrastructure exist, however efforts are needed at Member State level to move towards the implementation of the infrastructure in a coherent way which enables them to use technology to achieve their health objectives."

The member states have a major role for achieving the goal stated above. However, in order to achieve interoperability and meeting the challenges of the borderless Internet, Community action is also required, particularly for standards supporting the actual building of the health systems by member states and by the private sector.

The use of information technology and the building of a Health Information Infrastructure are rapidly changing the health sector but we are still only in the beginning of full utilisation of today's technology for this field. The use of information technology can increase the efficiency of the sector and help to contain costs. "Health on-line" can also improve the quality of care, maximise the effectiveness of health spending, empower the citizens and has the potential to reduce some of the safety hazards associated with modern powerful medical technology.

The lack of products complying with standards is one of the main reasons for the sub optimal use of ICT for health. In key areas, 11 years of standardization efforts have resulted in a number of important technical specifications developed by CEN under mandates from the European Commission and EFTA. These European standards are however used unevenly among the member states and most ICT of the sector is still using proprietary, or in a few cases national solutions, preventing a European market for products as well as creating barriers to cross-border communication of health related information.

Why Standards for Health Informatics ?

The overall purpose of health services is to provide an increasingly good quality care for the patient/citizens not only in their home environment but also throughout Europe. Standards are a prerequisite for:

Preventing health hazards, e.g. drug hypersensitivity
The present lack of standardised ICT communication that prevents appropriate access to health records may result in important clinical risks for the patients. This is an important safety issue that has not been recognised sufficiently. E.g. a number of adverse drug reactions could have been prevented if information had been made available on-line that existed elsewhere in another health institution. It is also well recognised that appropriate decision support systems with standard interfaces to the clinical routine situation e.g. for drug therapy can decrease sub optimal drug use and reduce costs.

Patients are starting do demand that "their" data should be available on-line
Citizens are increasingly demanding that professional health information related to their case should be possible to obtain from whatever source at the point of care, wherever this may be.

Improve efficiency by enabling professional co-operation in new ways

Health Information and Communication Systems are essential in order to improve efficiency by enabling effective integration and co-operation of health professional resources over time and space.

Quality management requires aggregated data
ICT systems are required to manage the important process of quality management and control that involves activities of public authorities as well as of actions within the provider organizations and research institutions. The aggregated information on health monitoring should be made available also to the citizens/patients as described in the proposed Community strategy for health.

Integration of modular systems from different suppliers
Implemented standards are often crucial for any communication, and are important for the open very complex health care systems with many different organizations and units with information systems from different suppliers providing different parts of the total ICT support. The suppliers are generally welcoming standards that enable modular systems solutions and a well defined market.

Many standards issues require professionals and authorities not just industry
In many areas of health information standardization, the suppliers alone can not be the driving force; this is a task of the health professionals, healthcare service providers and authorities.

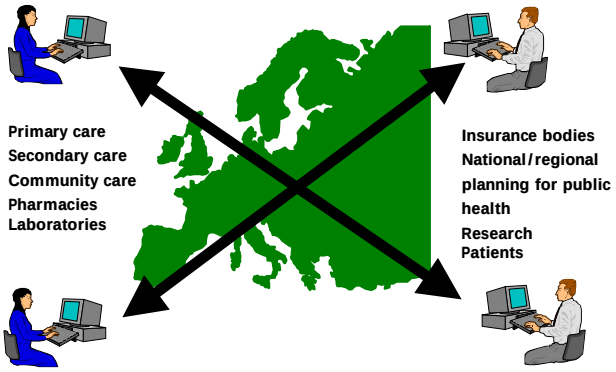
Standards can lower costs and facilitate procurement
The buyers of ICT solutions will often want to refer to existing relevant standards when requesting proposals from suppliers according to the public procurement directive. Technical standards enables a better working market with competing offers from suppliers active also in several countries, although health care information systems in many cases need national adaptation. Standards on the market will decrease costs for the ICT support, particularly when the requirements to integrate different systems are considered. Integration through communication is a key factor to improve the health systems.

National, European and Global action

Healthcare is still largely a national concern and most of the communication requirements are within the regions that make up the countries. However, there is in Europe a growing need for cross-border communication and the market for health information solutions is starting to become pan-European and in some areas it is global. While European standards activities are essential, we must also co-operate globally through ISO and with other bodies. In addition there is an important task in each country to develop national implementation guidelines for European and international standards.

Use of ICT in the European health sector

The healthcare sector is large and complex with many different application requirements. There are a number of different types of actors that need to communicate for various healthcare purposes. The requirements are diverse and very complex. The goal is to allow all of these to communicate as required without technical obstacles.



The following health ICT application areas may be identified and need special attention:

- Patient administration and financial systems
- Electronic healthcare record systems
- Pharmacy and electronic prescription systems
- Knowledge based systems
- Intensive care unit systems
- Laboratory Information Systems
- Homecare and Telecare applications
- Radiology Information Systems
- Bioinformatics

While these systems suppliers and users are diverse there are also important overlaps and need for co-ordination, largely because the patient/citizen is the center of it all.

It is important to distinguish both the links and the borderline between healthcare informatics and general problems of using information and communications technology (ICT). A suitable infrastructure of generic inter-sector standards and products are important to ensure efficient use of ICT in healthcare.

Standardization for Health – CEN/TC 251

The Comité Européen de Normalisation (CEN) is the recognised European standardization organisation covering all areas other than electrotechnical (CENELEC) and telecommunications (ETSI). There are twenty national standards bodies of the EU, EFTA and candidate countries that are members of CEN. They send representatives, vote on standards and implement European standards as national standards.

Technical Committee 251 is dedicated to Health Informatics and was established in 1990. The European Commission, considering the importance of health for all citizens, has supported the work in this area under special mandates, which has allowed an intensive activity in many fields, partly in collaboration with the European R&D activities for health telematics.

The Mission of CEN/TC 251 is to

- Develop standards and related reports of high quality serving the needs of its stakeholders to enable efficient use of information and communications technology to improve European health services
- Support a European market for health information systems products and actively promoting the development of a global market through collaboration with ISO/TC 215 and some other standards organisations in the field

The Scope

Standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems.

This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality.

CEN/TC 251 Working Groups

WG I: Information Models

WG I develop domain model based reference architectures in UML (unified modelling language) for evolvable information systems meeting a variety of different purposes of health systems.

An important area of WG I work is standards for the Electronic Health Record. The published prestandard ENV 13606 that was an important milestone is now further developed together with the OpenEHR Foundation and the Eurorec Institute.

Another important area is standards for messages to meet specific healthcare business needs for the communication of healthcare information. A major revision of previous separate messages has been made based on a common reference information model. General purpose information components (GPICs) have been defined to meet Service Request and Report messages in a coherent way for implementation in XML.

WG I is also working on the definition of a general service architecture for health information interchange that can connect legacy systems as well as new developments.

In addition, WG I address standards applicable to the storage and transfer of healthcare information using patient data cards.

WG II: Terminology and Knowledge bases

Working group II is working on the Semantic organisation of information and knowledge. The focus of the work is:

- Terms, concepts and interrelationships of concepts
- Structures for concepts systems including those for multi-axial coding schemes.
- Guidelines for the production of coding systems and knowledge bases
- Systematisation of the semantic structure behind the names of compositions and headed sections of the health care record

Production of coding schemes is usually outside the scope.

WG III: Security, Safety and Quality

The current European and national legislation emphasises the importance of quality, safety and security. Security of information systems is usually defined as the prevention of breaches of confidentiality, integrity and availability. In addition WG III is concerned with accountability.

WG III has developed guidelines for management of security for health with protection profiles for various application areas and detailed protocols for various core security services based on inter-sector standards.

WG III is working on guidelines for handling data protection in the context of the EU data protection directive, particularly for communication outside of Europe. It is also working with Access control policy bridging and systems for Anonymisation.

Another area is guidelines for Safety procedures and Quality of health information systems.

WG IV: Technology for interoperability

This WG develop standards that enable interoperability of devices and information systems in health informatics.

?? Intercommunication of data between devices and information systems

?? Integration of data for multimedia representation

Devices include, for example: clinical analysers, medical imaging and Intensive Care Unit equipment, clinical workstations and cards.

WG IV has an important collaboration with IEEE and ISO/TC 215 for standards for Point-of-Care Medical Devices with a large series of new standards coming as joint publication.

WG IV also collaborates with DICOM for imaging standards without attempting to replace the work of this globally recognised body.

Examples of standards from CEN/TC 251

WG I	**Information models**
ENV 1613	Medical informatics – Messages for exchange of laboratory information
ENV 12018	Medical informatics - Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)
ENV 12538	Medical informatics – Messages for patient referral and discharge
ENV 12539	Medical Informatics - Request and report messages for diagnostic service departments
ENV 12612	Medical Informatics – Messages for the exchange of healthcare administrative information
ENV 13606	Health Informatics - Electronic healthcare record communication - Part 1: Extended architecture Part 2: Domain termlist Part 3: Distribution Rules Part 4: Messages for the exchange of information
ENV 13607	Health Informatics - Messages for the exchange of information on medicine prescriptions
ENV 13730	Health informatics - Blood transfusion related messages – Part 1: Subject of care related messages Part 2: Production related messages
WG II	**Terminology and Knowledge bases**
ENV 1614	Healthcare informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences
EN 1828	Health informatics - Structure for classification and coding of surgical procedures
ENV 12381	Medical informatics - Time standards for health care specific problems
ENV 12435	Medical informatics - Expression of the results of measurements in health sciences

ENV 12610	Medical informatics - Medicinal product identification
ENV 13940	Health informatics – System of concepts to support continuity of care
ENV 14032	Health informatics - System of Concepts to Support Nursing
CEN/TS 14463	Health informatics – A syntax to represent the content of medical classification systems
WG III	**Security, Safety and Quality**
ENV 12388	Medical Informatics – Algorithm for digital signature services in health care
ENV 12924	Medical Informatics – Security categorisation and protection for healthcare information systems
ENV 13608	Health Informatics - Security for Healthcare communication - Part 1: Concepts and terminology Part 2: Secure data objects Part 3: Secure data channels
ENV 12251	Health Informatics - Secure user identification - Management and security of authentication by passwords
ENV 13729	Health Informatics - Secure user identification - Strong authentication using microprocessor cards
WG IV	**Technology for Interoperability**
ENV 1064	Medical informatics – Standard communication protocol - Computer-assisted electrocardiography
ENV 12052	Medical Informatics - Medical imaging communication
ENV 13728	Health informatics – Instrument interfaces to laboratory information systems
ENV 13734	Health informatics -Vital signs information representation
ENV 13735	Health informatics - Interoperability of patient connected medical devices
ENV 14271	Health informatics - File exchange format for vital signs

Frontpage

The usual CEN/ISSS format but with the title

Health on-line

eEurope
and the CEN CENELEC and ETSI logos in the bottom.

Backpage

The usual CEN/ISSS format but under the descriptions of CEN, CENELEC and ETSI the following text should appear:

CEN/TC 251 Health informatics

The co-ordination of the work in Health Informatics is carried out by the Swedish Standards Institute – SIS, that operates the secretariat of the technical committee and the web-site: **www.centc251.org**

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