

ISO, ITU, IEC, CEN, IEEE, DICOM, HL7, WHO, OASIS

**Co-operation for better health-**

**The eHealth Standardization  
Co-ordination Group**

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# **Information and Communications Technology can make the world healthier**

- **Standards are necessary to obtain many of the potential benefits of ICT**
  - **Extending demonstrators to national and international implementations**
  - **For all patients**
    - **at a reasonable cost**
- **The objectives of the health care sector should be the basis for standardization priorities**

# **A Communicating Health System**

- **All health information is made available for continuous care**
- **Knowledge based systems are interacting with patient data**
- **Effective co-operation between professionals**
- **Active patients are a part**
- **eLearning: professionals and patients**
- **All patient cases can be used to generate new knowledge**

# **E-health services required**

- **Communicating health records**
  - Different health care organizations need to be able to communicate structured health records electronically.
  - Different levels of care such as primary care to a hospital or over different geographical borders.
  - This is also the basis for effective public health surveillance
  - The lack of implemented standard structures for electronic health record is a major difficulty. The CEN ENV 13606 was a major step and is developed further in international co-operation

## **E-health services required**

- **Service request and report messages**
  - This has been one of the first uses of ICT for health with several generations of standards
  - These are firstly services where lab tests are sent electronically from a lab often attached to a hospital to different clinical departments and to the primary care health centers serviced by that institution
  - Other examples are service requests and booking electronically of e.g. diagnostic imaging services and discharge letters

## **E-health services required**

- **Requests for interpretation of images**
  - This is a special form of service request messages that due to the often very high amounts of data involved
- **Administrative messages**
  - There are many examples of the world where administrative messages related to payment of health services sometimes with prior authorization before services are performed, constitute good examples of making the health care systems more effective using ICT.

## **E-health services required**

- **Electronic prescription and medication information**
  - Medicine costs are in developed countries around 20 % of total health care spending and there is a large demand from governments and other bodies to make this more effective using electronic communication to the pharmacy and often to a payment body.
  - Separate but related are the strong requirements for electronic availability of at least the medication part of the health record can be communicated to different healthcare professionals as authorized.

## E-health services required

- **Real-time consultation services**
  - There has been a lot of projects where real-time consultation, telemedicine in a restricted meaning has been deployed
  - They can include only Videoconferencing between professionals, often with the patient present in one end for discussing a specific case. Sometimes other special information from images or special signals from physiological monitoring, EKG etc has been accompanying.
  - Despite unresolved issues of financial steering, videoconferencing will continue to grow but do not replace the need for structured information.

## **E-health services required**

- **Knowledge bases as encyclopedias and interacting with individual data**
  - **Scientifically based knowledge on diagnostic procedures and interpretations as well as recommended treatment protocols should be made globally available through the networks. The users are both health professionals at different skills and the citizens/patients.**
  - **If individual patient data from a local electronic health record should be able to interact with such knowledge systems, standards for information representation are a major issue.**

# **E-health services required**

- **Education for health professionals at different levels**
  - **The challenges are not technical. The generation of the educational knowledge and training resources requires a lot of work and international co-operation. Adaptation to basic state of the art to different presentations formats and languages and a possibility to distribute free of charge to the users in developing countries requires new type of financing and co-operation between academic centers and other types of educational ICT tools and international organizations.**

# Different reasons to want standards for different actors

- **Healthcare providers (Hospitals, doctors and other professionals)**
  - Enable interoperability between different units and systems to increase efficiency of care
  - Lower costs for buying systems by having a large competitive (international) market
- **Systems suppliers (software companies)**
  - Enable the provision of modular systems where one product can tie into the total needs of the customers
  - Large market for their "standard" product – less maintenance problems than with customer specific special solutions

# Standards and authorities

- **Public health authorities in many countries sees standards as an important way of increasing the efficiency of the sector**
  - **Leading to better quality with minimum resources. In many western countries healthcare expenditures are not increasing anymore**
- **Standards enable the collection of statistical information for surveillance and planning purposes**
- **Standards for Informatics may help the authorities to exert quality control of health care information systems and medical devices. We are moving towards certification of software.**



# Standardization

Activity of establishing, with regard to actual or potential problems, **provisions for common and repeated use**, aimed at the achievement of the optimum degree of order **in a given context**

Definition from ISO/IEC Guide 2

# The context

- **Karolinska Hospital**
- **Stockholm region**
- **Sweden**
- **Europe**
- **The World**

# Several standards bodies contribute to e-Health

- **E-Health depend on intersector standards**
  - ITU
  - ISO/IEC JTC1
  - IETF
  - W3C
  - ..... (many more also informal consortia do important developments)
- **International bodies with significant work specific for e-Health part of the eHSCG**
  - ISO/TC 215 Health informatics
  - ITU-T/SG 16 Multimedia communication
  - IEC/TC 62 Medical devices (electric aspects)
  - CEN/TC 251 Health informatics
  - IEEE/P1073 Point of Care medical devices
  - HL7 Health care messaging
  - DICOM Medical imaging communication
  - OASIS

# World Health Organization

- **WHO eHealth department**
  - with Mr Yunkap Kwankam head of the unit co-chair the eHealth Standardization Co-ordination Group
- **The group welcome other representatives of the users of standards for eHealth**

# **e-Health Standardization Coordination Group (eHSCG)**

## **Overall objectives**

- **To promote stronger co-operation amongst the key players in the e-Health Standardization area**
- **To promote the use of standards for e-Health**

# e-Health Standardization Coordination Group (eHSCG)

## Terms of Reference

- **Coordination group on all aspects of e-health standardization**
  - Sharing experiences and information on all relevant fields including terminologies
  - Not steering participating parties
- **Strengthen the cooperation amongst the SDOs**
  - Avoiding duplication of efforts
  - Promoting exchange of specifications and experts where relevant
- **Focus on technical aspects taking into consideration regulatory, economic, medical and social issues**

# e-Health Standardization Coordination Group (eHSCG)

## Terms of Reference

- **Consider development paths of new standards required by the user community**
  - Using where appropriate existing standards from different sources
  - Influencing inter-sector standards development with health requirements
- **Guidance for implementations of e-Health applications**
  - Providing information on relevant standards and standards activities
  - Information on products and companies using standards
  - Best practice examples and case studies

# e-Health Standardization Coordination Group (eHSCG)

## Terms of Reference

- Increase awareness of availability of existing standards and the importance of standardization among relevant decision makers (health authorities, health professionals and industries)
  - Conference presentations and reports
  - Website (hosted by ITU)
- Meet regularly co-located with related technical standardization meetings
- Consider the requirements of developing countries

# **Many standards exist but are not used enough**

- **A lot remains to be done**
  - **There will be a continued need for standards development meeting new application requirements and technical frameworks**
- **We need global co-operation**
  - **Respecting pragmatic decisions to use specifications from different bodies (national, european and international)**

In Europe we decided in 1990 that many of the issues that needed standards for health informatics would best be solved on a European scale rather than national



There was no international work and it was felt that there was a need to support **one internal market** for IT products in all of the European Union.

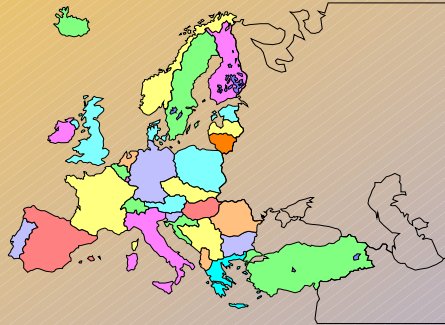
There is also a large number of citizens moving between these countries for work, studies and vacation. **Interoperability** of health information systems was desired



# European policies important for eHealth standardization

- The Community action plan for public health 2003-2008
- The eHealth declaration May 2003
- The eEurope 2005 action plan
- Health Telematics Working Group of the High Level Committee on Health Final report April 2003 (DG SANCO)
- Cross-border health care: Report on Patient mobility approved by the health ministers December 8, 2003
- The Commission Follow-up on patient mobility (COM(2004) 301, 2004-04-20)

# Standardization of Health Informatics in Europe



***CEN = Comité Européen de Normalisation  
European Committee for Standardization***

**22 EU and EFTA countries are members + candidate observers**

## **CEN/TC 251**

Technical Committee on Health Informatics

**Secretariat is managed by SIS - Swedish standards institute**

**[www.centc251.org](http://www.centc251.org)**

# Scope of CEN/TC 251

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

**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 and convenors

- **I: Information models**
  - Gerard Freriks, Netherlands
- **II: Terminology and knowledge representation**
  - Magnus Fogelberg, Sweden
- **III: Security, Safety and Quality**
  - Gilles Trouessin, France
- **IV: Technology for interoperability**
  - Melvin Reynolds, UK

# Working Group I: Information Models

- **Electronic Health Records**
- **General Purpose Information Components**
- **Messages for various purposes including e-prescriptions**
- **Service architecture for health information interchange**
- **Patient Data Cards**

# Electronic Health Record Standards Development

- EN 13606 Task force is working under the leadership of Dipak Kalra
- The prestandard is developed based on existing experiences and the new ideas on a dual model approach
  - A reference information model
  - A template/archetype for specific uses
- Collaboration with the Open Electronic Health Record Foundation



# Health informatics - General Purpose Information Components

**Part 1: Overview**

**Part 2: Non-clinical information**

**Part 3: Clinical information**

These use: **Health informatics – Data types**

- This is an essential core for all future information models in CEN for Messaging, Records and HISA. prEN 14720 Health informatics – Service request and report messages use the GPICs
- This is a result of the harmonisation with HL7
- GPICs has been submitted to ISO

# EN 12967-1

- **Health informatics – Service architecture**
  - Part 1: Enterprise viewpoint**
  - Part 2: Information viewpoint**
  - Part 3: Computational viewpoint**
- **The revision is based on the existing ENV (HISA) and the Short strategic study Health Information Infrastructure. The model is using ISO/IEC 10746 Open distributed processing – reference model as a basis for the description.**

## **Working Group II: Terminology and Knowledge bases**

- **Semantic organisation of information and knowledge**
- **Terms, concepts and interrelationships of concepts**
- **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**

# Working Group III: Security, Safety and Quality

- **Guidelines for management of security for health**
- **Detailed protocols for various core security services based on inter-sector standards.**
- **Data protection in the context of the EU data protection directive, particularly for communication outside of Europe.**
- **Access control policy bridging and systems for Anonymisation.**

# Working Group IV: Technology for interoperability

- **Intercommunication of data between devices and information systems**
  - including clinical analysers, medical imaging and Intensive Care Unit equipment
- **Integration of data for multimedia representation**
- **WG IV has an important collaboration with IEEE and ISO/TC 215 for Point-of-Care Medical Devices and with DICOM for imaging**



## **ISO - collaboration with CEN**

**ISO/TC 215 Health informatics was established in 1998 proposed by the US but with strong support from Europe**

# Vienna agreement between CEN and ISO



- There are many examples with thousands of standards processed in collaboration between CEN and ISO.
- The Vienna agreement intends to
  - Avoid duplication of effort and divergence
  - Allow parallel voting process where feasible
- In health informatics a number of European prestandards ENVs have been the starting point for ISO/TC 215 work items
  - Vienna agreement allows the improved ISO documents to be processed in parallel as full European standards.



- CEN/TC 251  
Health Informatics

- ISO/TC 215  
Health Informatics

- - WG I Information Models

- - WG 1 Health Records and Modelling Co-ordination

- - WG IV Technology for Interoperability

- - WG 2 Messaging and Communication

- - WGII Terminology and Knowledge representation

- - WG 3 Health Concept Representation

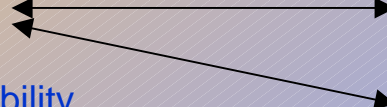
- - WG III Security, Safety and Quality

- - WG 4 Security

- - Task Force Cards

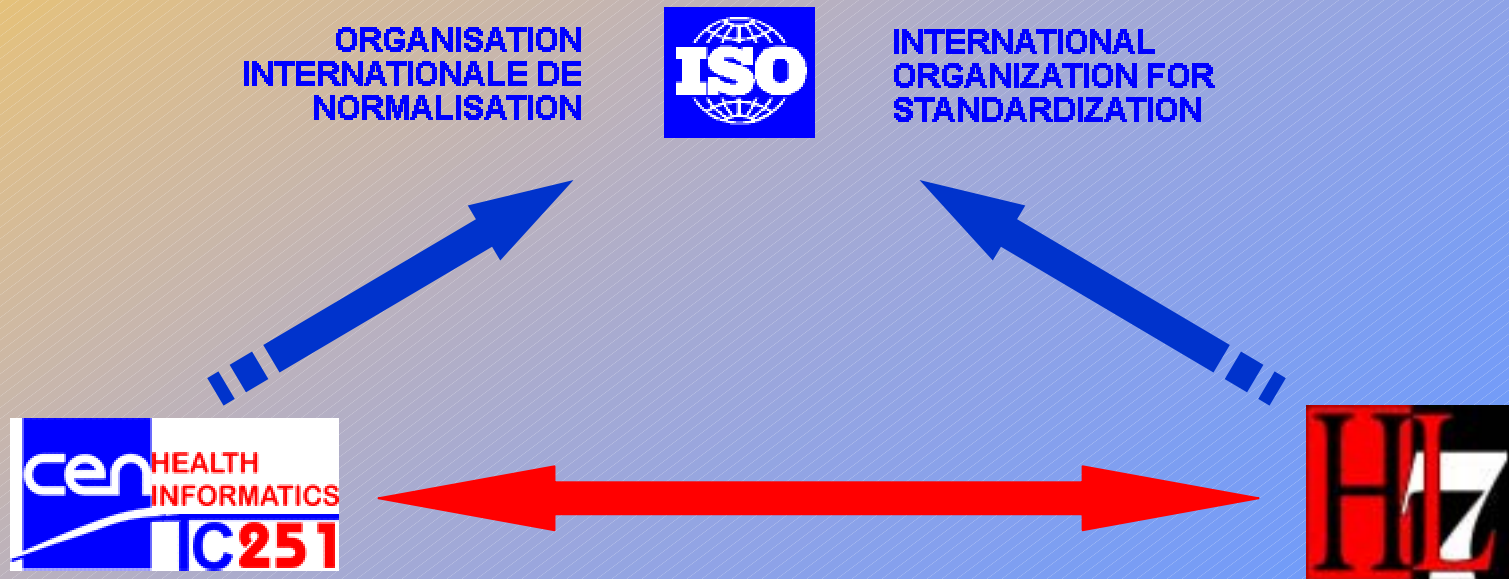
- - WG 5 Health Cards

- - WG 6 Pharmacy and medicines business



The Memorandum of Understanding from 2000

“CEN/TC 251 and HL7 agree to collaborate in the spirit of mutual appreciation, respect and openness to seek pragmatic solutions to obtain unification of their set of standards for healthcare communication and to make the results globally available to ISO”





## HL7 pressrelease May 2000

**"HL7, operating in the United States, develops the most widely used healthcare-related electronic data exchange standards in North America, while CEN/TC 251, operating in 19 European member states, is the preeminent healthcare information technology standards developing organization in Europe. The intent of the memorandum is to intensify collaboration between the two groups and move toward the development of technically identical and interchangeable U.S and European standards."**



## Results

**“The collaboration has been useful and certainly should continue “**  
(HL7 board conclusion)

- CEN has started to fully use the HL7 RIM as the basis for its information models
- Despite minor differences in current methodology being tried in the first new generation standards – the common ground continue to increase
- HL7 has started to recognize many of the CEN principles for EHR standards
- First set of derived results are near final acceptance and publication

# Final Conclusion

- **Let's work together to make e-Health a routine aspect of health services for all citizens of the world**