

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

**Global Standards Co-operation to  
Support Developing eHealth Services  
and some European news: The Focus  
Group Recommendations on  
Interoperability and new CEN work**

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# Information and Communication Technologies can make the world healthier

- But how do we move from demonstrators to national and even international implementations?
- One giant system for all ??
- Standards are necessary to obtain many of the potential benefits of ICT
  - Not only for interoperability but also to maintain a healthy competitive market of better and better products based on innovation

# Many standards exists but not THE standard

- Healthcare and Biomedical Science is highly complex and develops rapidly
- **eHealth** is a short word but includes a variety of difficult issues
  - The use of Technology to improve health care delivery processes

but also the use of ICT for health systems development at large:

- Education of citizens and professionals for care and prevention
- Public health surveillance and planning
- Knowledge management with biomedical research and guidelines

# **Standards exists as building blocks for many aspects**

- **Real applications even in one clinical domain require a number of standards**
  - **Often local or national profiling is also necessary.**
  - **Cross-border communication includes additional complications**
    - **Languages or multilingual reference terminologies**
    - **Character sets**

# Several standards bodies contribute to e-Health

- **International bodies with significant work specific for e-Health and part of the eHealth Standardization co-ordination Group (eHSCG)**
  - **ISO/TC 215 Health informatics**
  - **CEN/TC 251 Health informatics**
  - **ITU-T/SG 16 Multimedia communication**
  - **IEEE/P1073 Point of Care medical devices**
  - **HL7 Health care messaging**
  - **DICOM Medical imaging communication**
  - **OASIS**

# What are the roles of these?

- **ISO the International organization for standardization**
  - Is made up of its 142 national member bodies
  - Started health informatics in 1998
- **CEN is the European standardization organization**
  - 28 member countries also members of ISO. Linked to the European Union
  - Started Health informatics in 1990  
Close co-operation with ISO

# **ITU**

## **International Telecommunications Union- a United Nations body**

- **Important standardization activities for multimedia communication (videoconferencing) for realtime telemedicine consultations**

# IEEE – Institute of Electrical and Electronics Engineers

- Important work on Point of Care Medical Device Communication
- Jointly work with ISO and CEN
- A number of significant standards published recently
  - Health informatics -- Point-of-care medical device communications -- Part 10101: Nomenclature
  - Part 10201: Domain information model
  - Part 20101: Application profiles -- Base standard
  - Part 30200: Transport profile -- IrDA based -- Cable connected
  - Part 30300: Transport profile -- IrDA based -- Infrared wireless
- More than 30 parts are in the pipeline

# **DICOM - Digital Image Communication**

- **De facto world wide standards for Radiology, Ultrasound etc.**
- **Now endorsed as formal standards in CEN and soon in ISO.**

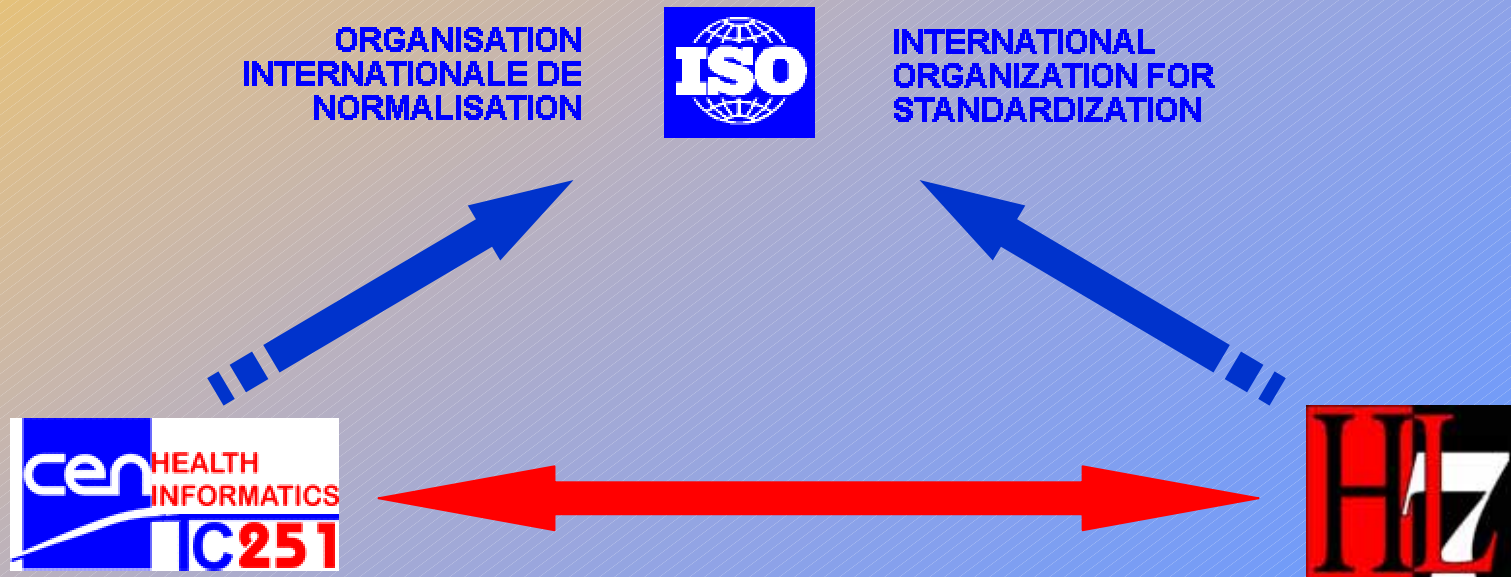
# HL7

A US based organization with international affiliates  
in 25 countries

- Started with the development of messages to connect various parts of Hospital Information Systems.
- Began an important new generation of message development some 8 years ago the V3 methodology based on a common Reference Information Model (the RIM)
- This is now balloted to become an international standard in ISO and is used by CEN since a three years for the new development of messages
- Very few V3 messages from HL7 are actually agreed and published. Early adopters develop there own messages based on V3 methodology
- HL7 co-operate with CEN and ISO and a lot of interactions take place.
- But there are also differences in methodologies and in particular in relation to Electronic Health Record representation

## 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”



# **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**

# World Health Organization is an important member of the eHSCG

- **WHO eHealth department**
  - with Mr Yunkap Kwankam head of the eHealth unit is the co-chair the eHealth Standardization Co-ordination Group
  - Hosts the web site of the group [www.eHSCG.org](http://www.eHSCG.org)

# 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

- **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
  - **Answering questions on standards**
- **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

# 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)
- Take special consideration to the requirements of developing countries
  - Assistance offered for the development of national eHealth strategies related to standards

# The global co-operation for standards is necessary

- A major issue is promotion and education on standards that exists
- eHealth standardization will need to continue to be developed for many years as different services are required and as technology and basic informatics principles evolve
- Pragmatic solutions must be found in the contexts where interoperation is required

# CEN/ISSS e-Health Standardization Focus Group

Final report

## Current and future standardization issues in the eHealth domain:

### **Achieving interoperability**

- A study initiated by DG Enterprise with nearly 100 participants from healthcare and industry working Dec 2003-Feb 2005 with the task:
  - To consider, with all the relevant stakeholders, priorities and objectives for eHealth standardization and how the CEN system and others can contribute

Available at [www.CENeHealth.org](http://www.CENeHealth.org)

# Conclusions of the Focus Group

- Health informatics standards are essential to achieve the goals of eHealth in Europe for
  - **Interoperability** between systems and patient information exchange
  - **Market efficiency** by providing Increased understanding between all market actors with a common technical framework
  - Facilitating **meeting of non-functional requirements** to ensure safety, security and legal requirements

# Conclusions of the Focus Group

- **European or whenever possible global standards (as opposed to no standards or conflicting national standards) are essential for an open market to:**
  - **The benefit of both buyers and suppliers**
  - **Facilitate cross-border communication**
  - **Meet the obligations of the EU Directive 98/34 and WTO principles**

## Standards activities need positive and active support from:

- **Member States** in pursuing their national or regional strategies and policies and particularly in regard to their obligations to EU Directives and WTO agreements;
- the **Commission** in promotion and in financial support;
- healthcare **professionals** and other users in participation in standards creation and requirements specification;
- **suppliers** in participation in standards development and implementation of standards in products.

# Focus Group Main Recommendation

- The Member States, with the Commission, should establish a permanent platform with a mandate, and the necessary resources to promote e-Health interoperability based on standards and to facilitate co-operation between Member States.
- This eHealth interoperability platform should report to the High Level Group on Health Services and Medical Care set up by the EU Health Council.

# Recommendation 2: Improving access to records

- The Member States, with the Commission, should give significant momentum to national and Europe-wide **secure access to clinical records** and to achieving full **semantic interoperability** of personal health data and information through **strong support to existing and emerging European standards** for electronic health record communication.

(This is based on the near final standard EN 13606 that is now also balloted in ISO that can give semantic interoperability and not just free text exchange)

## **The Focus Group gives further recommendations on:**

- **Reducing medication-related errors and e-prescribing**
- **Safety of health informatics products**
- **Quality of information - Metadata for knowledge resources**
- **Efficiency of healthcare processes - Workflow models and clinical pathways**
- **Electronic transfer of prescriptions**
- **Information exchange to support inter-working and the mobile citizen**
- **Case-mix groupers based on diagnoses and procedures**
- **Quality indicators**
- **Improving availability of standards**
- **Commission's support to European standardization**
- **Towards an international multilingual reference terminology**
- **Security services**
- **Health cards**





# A political mandate

and financial support from EU and EFTA

- EU and EFTA policies have given CEN a mandate to produce standards for Healthcare Informatics in Europe
- A small funding from CEC mainly for co-financing of project teams and central co-ordination
- European funding has been extremely important in speeding up the process
- But for the last years there has been no new funding

# 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**

# **EN 14822: 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. EN 14720 Health informatics – Service request and report messages use the GPICs
- This is a result of the harmonisation with HL7
- Approved for publication August 2005

# **Health informatics – Service request and report messages – Part 1: Basic services including referral and discharge**

**This EN 14720-1 was approved as a European standard January 2005 and is now being implemented in many national contexts including Sweden**

**This standard is a major milestone in the next generation model based standards based on a common global RIM**

# Electronic Health Record Standards Development

- ENV 13606 was approved in 1999
- prEN 13606 is a major further development still under final adoption in CEN and now also ISO
- The new development is 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



# 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**

# System of Concepts to Support Continuity of Care

- The prestandard from 2000 has been improved and balloted as prEN 13940 first half of 2005.
- An important basis for defining standards and system solutions for health informatics
  - Actors
  - Health issues, Situations (episodes, periods..)
  - Knowledge management (Guidelines, plans..)
  - Responsibilities (Mandates ..)
  - Record Management

# **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**

# Final Conclusion

- **Let's work together to make e-Health a routine aspect of health services for all citizens of the world using standards as an enabler and not an obstacle to innovation**