



International Symposium on Biomedical Informatics
Barcelona June 26-27, 2007

Standards and ontologies in biomedical informatics

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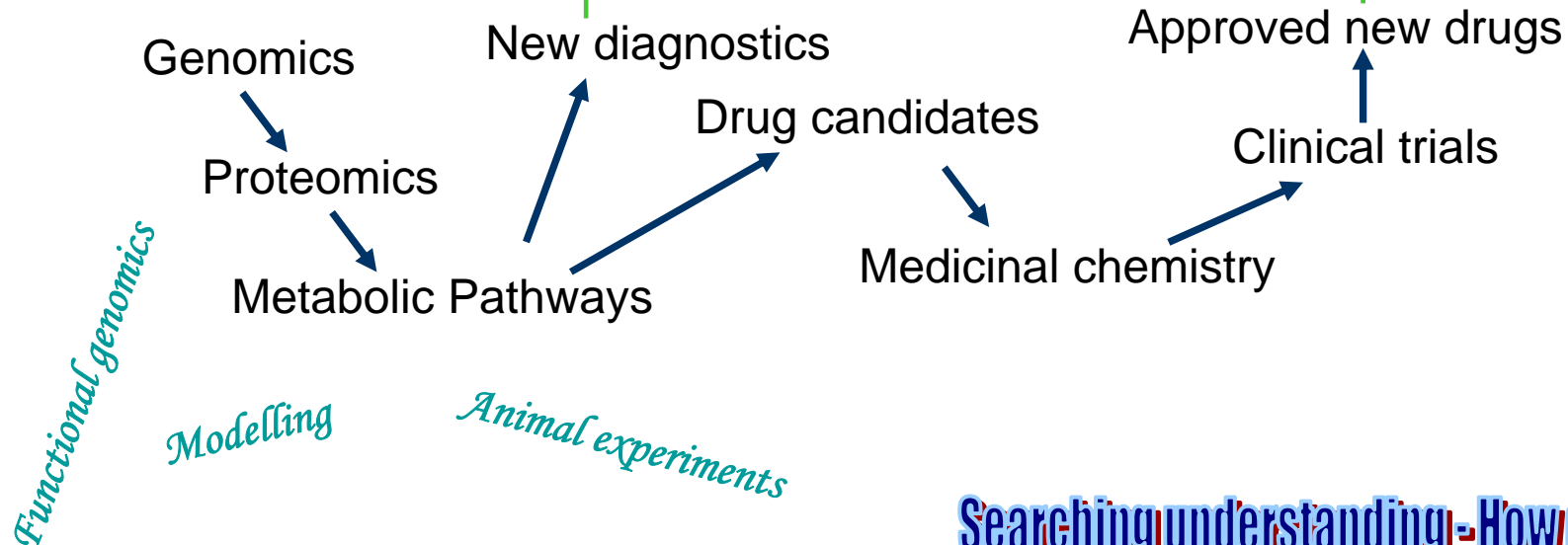
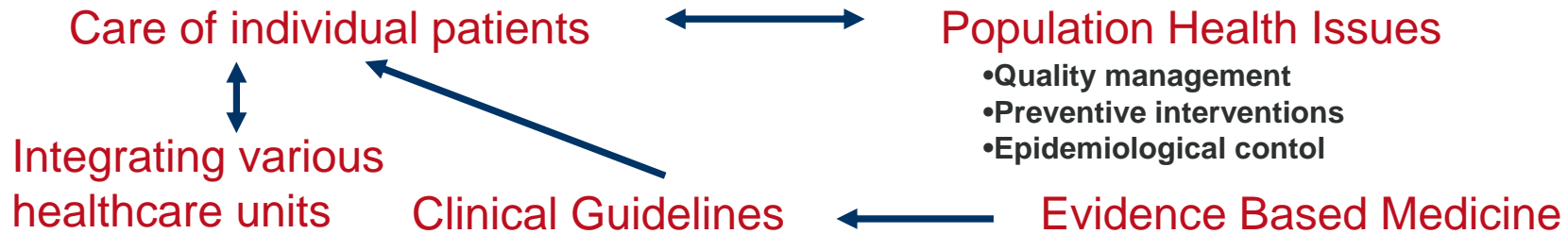
Chairman of European Health Informatics in CEN/TC 251 1997-2006



- What is Biomedical Informatics?
 - Common requirements for standards
- Standards as a basic tool for reaching societal goals of eHealth – nationally and in the EU
- Some facts about the standardisation system
- Examples of recent results of interest to both healthcare and some aspects of research
- Informatics research, Semantic Mining and dissemination/exploitation through standards



Managing health - individuals and populations



Searching understanding - How does it work



YES - But

A major challenge for biomedical informatics is to make more efficient the processes

within **health management** and **within research**

In health management we are not only suffering hard from the huge gap between the molecular (or nano) knowledge and the useful knowledge to manage health in clinical practice.

A major issue is that we are not able to efficiently using the knowledge that is existing because information management is largely not working well in practice

In Europe we are probably killing >100 000 persons a year because of this



Health care

- Ontological principles
- Terminological systems
- Information security
- Information modelling techniques
- Imaging representation
- Representing observations including units of measure
- Identifiers for medicinal products

Biomedical research

- Ontological principles
- Terminological systems
- Information security
- Information modelling techniques
- Imaging representation
- Representing observations including units of measure
- Identifiers for pharmaceutical products



eEurope –

An Information Society For All

The Action Plan of the
European Commission includes
Health on-line as one of the key areas:

“ To develop an infrastructure of **interoperable** systems for medical care, disease prevention and health education through national and regional networks which connect citizens, practitioners and authorities on-line.”

A new mandate from the European Commission March 2007



Mandate to the European Standardisation Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth.

- ICT in the service of health provides tools for health authorities and professionals, as well as personal health systems for patients and citizens.
- Example components include health information networks, electronic health records, telemedicine and telecare services, personal wearable and portable communication systems, health portals, and many other ICT –based tools that assist disease prevention, diagnosis, health monitoring and lifestyle management.
- Additionally, appropriate eHealth has the potential to provide the European citizen with improved access to better health systems and to empower citizens in managing their own health.



- In order to make *eHealth* services available and beneficial for EU health professionals and citizens, it must be guaranteed that these services are compatible and interoperable.
- There is general agreement that global standardisation, based on consensus between all the relevant stakeholders, is the prerequisite to achieve such interoperability.



- 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
- All patient cases can be used to generate new knowledge



- **All patient cases can be used to generate new knowledge**

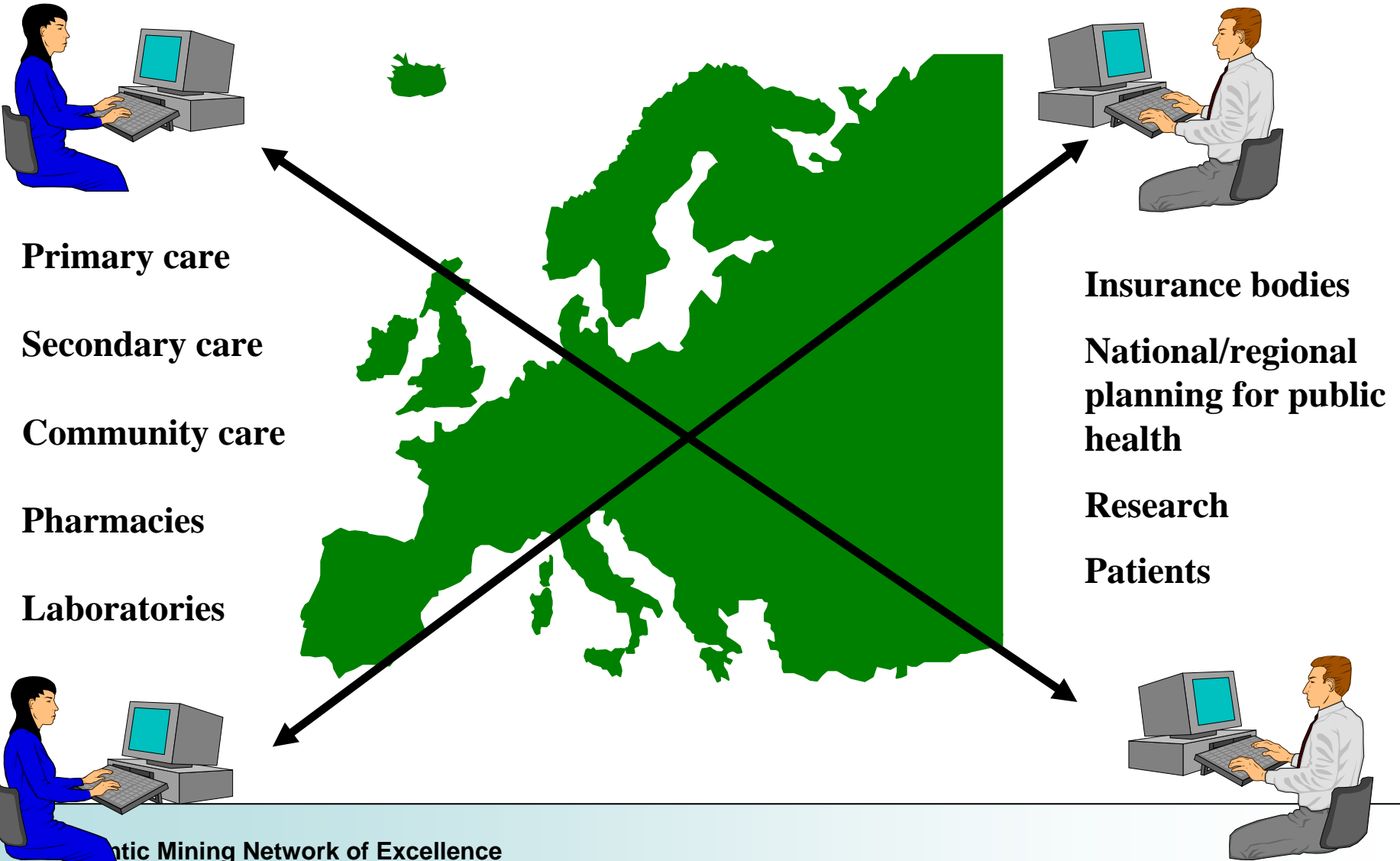
If all health records used in routine care are kept following a standard structure with agreed terminologies ...

it might be possible to perform studies on large numbers of persons in a very efficient manner combining clinical observations with laboratory investigations.

Hypothesis generation also for functional genomics
Addressing therapeutic evaluations also in routine practice including multiple diseases and therapies

and also to construct prospective clinical studies much easier

Standards - a Key to Interoperability





- 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



- 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



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



- Many of the health informatics standards are used as **toolboxes**
- Various groups, in Europe often in a national co-operation, produce real interoperability specifications with these tools
- This is not a failure of standards !



- Many industrial suppliers of ICT solutions have had good use of standards for their internal developments
 - In the overall design of architectures
 - In producing internal interfaces between different modules
- Of course this also prepares for external systems interfaces for interoperability where required



- Standards in general also have an important role in **defining a product or its characteristics**
- Standards are used quite a lot in procurements and discussions between suppliers and healthcare organizations
- European CEN and now also ISO International Standards and Technical Reports have an important role to give a common framework and terminology for health information systems
- One recent example is the ISO/TR 22790: Health informatics - Functional characteristics of prescriber support systems



- Some of the Health Informatics standards are Guidelines for management of health information intended to be used by the healthcare organizations
 - Especially in the security area
 - The ENVs 12924, 13608 and 13729 standards have had this role and since a year we have the EN 14884 and 14885 standards that give important guidance on transborder situations.
 - We are looking forward to use the ISO 27799 Health informatics – Security management using ISO/IEC 17799 developed jointly between CEN and ISO



- Nationwide implementations of a few message standards in some countries linking hospitals with primary care and pharmacies.
 - Much of what is in large scale use today are the standards from 10-12 years ago in Edifact syntax
 - In the process of updating to the new generation standards. RIM-GPIC-XML



If everybody body wants standards it should be easy to have one common organisation or ...

- **In each country a National standards body**
– **BSI, DIN, AENOR, AFNOR, SIS etc**
- **On a European scale we have CEN**



European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

- **And Internationally we have ISO**

ORGANISATION
INTERNATIONALE DE
NORMALISATION



INTERNATIONAL
ORGANIZATION FOR
STANDARDIZATION

Several standards bodies contribute to e-Health



- International bodies with significant work specific for e-Health and part of the **eHealth Standardization co-ordinaztion 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
 - GS1
 - *IHTSDO (SNOMED) pending formalisation*



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eHealth Standardization and Coordination Group

[WHO](#) > [WHO sites](#)

eHealth Standardization Coordination Group

The eHSCG is a platform to promote stronger coordination amongst the key players in all technical areas of e-health standardization. The group is a place for exchange of information and will work towards the creation of cooperation mechanisms to:

- Identify areas where further standardization is required and try to identify responsibilities for such activities;
- Provide guidance for implementations and case studies;
- Consider the requirements for appropriate development paths for health profiles of existing standards from different sources in order to provide functional sets for key health applications;
- Support activities to increase user awareness of the existing standards, and case studies.

USEFUL INFORMATION

[eHSCG standards list \[pdf 401kb\]](#)
which compiles the most important standards in eHealth

[Frequently Asked Questions](#)
Submitted to the eHSCG regarding the use of ICT standards for health applications

[WHO resolution on eHealth](#)
which was passed during the 58th World Health Assembly in Geneva, on May 23, 2005.



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

What are the roles of these?



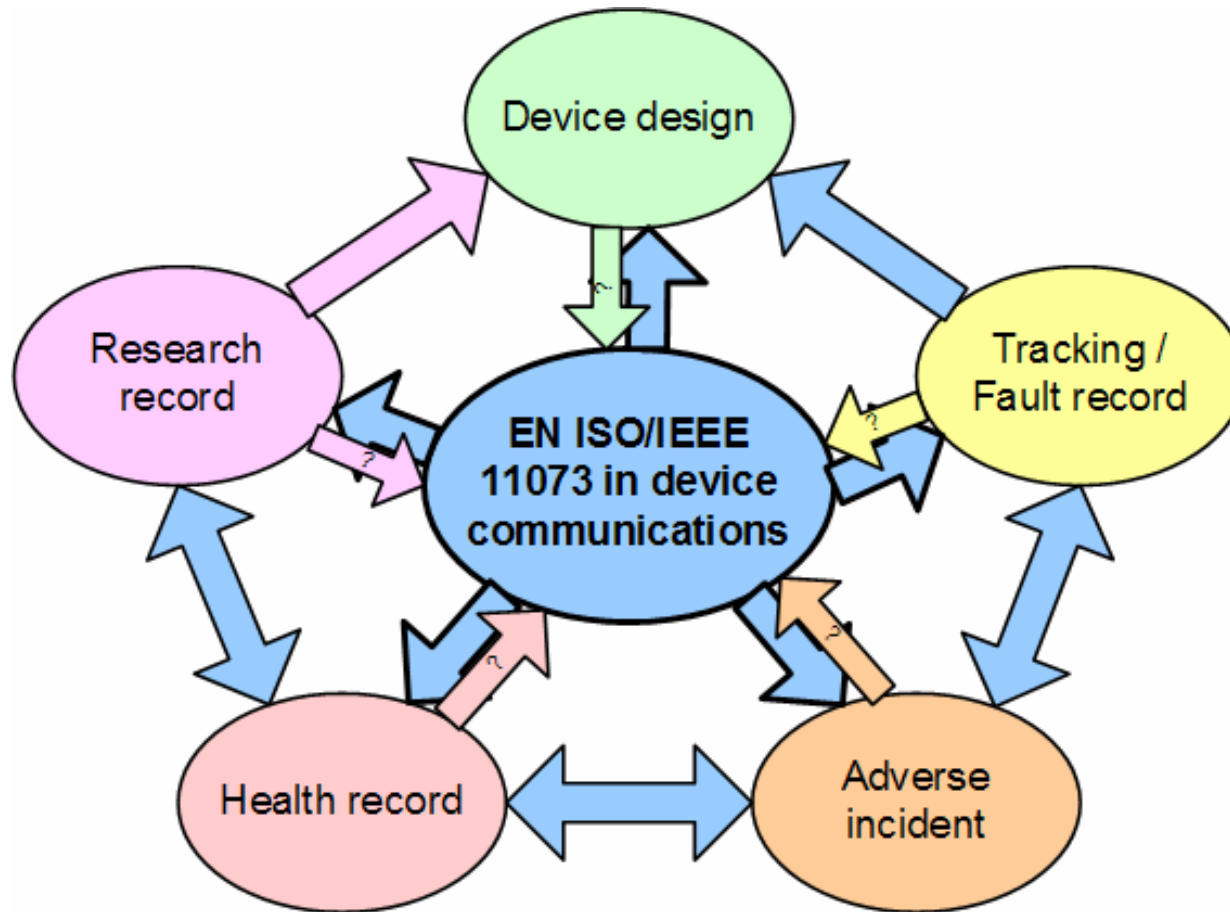
- ISO the International organization for standardization
 - Is made up of its 152 national member bodies
 - Started health informatics in 1998
- CEN is the European standardization organization
 - 30 member countries also members of ISO.
Linked to the European Union
 - The EU sometimes uses CEN to make detailed technical regulation as part of the European Policies
 - Started Health informatics in 1990
Close co-operation with ISO



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



- Important work on Point of Care Medical Device Communication
- **Joint 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





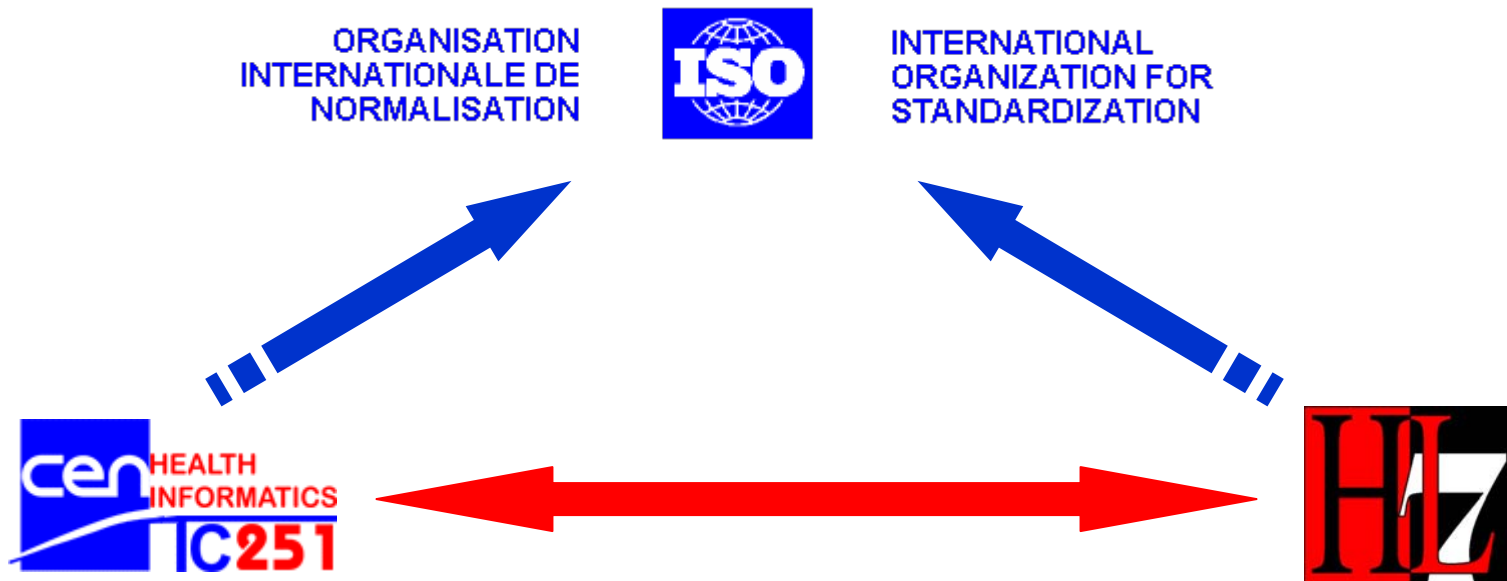
- De facto world wide standards for Radiology, Ultrasound etc.
- Now endorsed as formal standards in CEN and soon in ISO.



- 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)
- Very few V3 messages from HL7 are actually agreed and published. Early adopters develop their 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



“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”





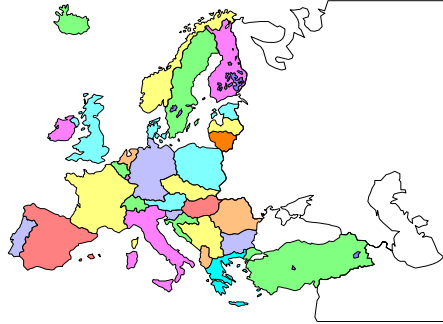
- OASIS is a not-for-profit, international consortium that drives the development, convergence, and adoption of e-business standards.
- Its IHC Technical Committee aims at providing a forum for the global healthcare community to articulate and coordinate requirements for XML- and Web services-based standards.



- GS1 is an organisation dedicated to improving the efficiency and visibility of supply and demand chains, globally and across sectors. Includes the GS1 System of standards as well as GS1 BarCodes, GS1 eCom, GS1 GDSN, EPCglobal and Traceability.
- In Healthcare GS1 standards are used in 56 countries to identify pharmaceutical products



- 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



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

30 EU and EFTA countries are members + candidate observers

CEN/TC 251
Technical Committee on Health Informatics

www.centc251.org



- 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



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



- I: Information models
 - Steve Kay, UK
- II: Terminology and knowledge representation
 - Magnus Fogelberg, Sweden
- III: Security, Safety and Quality
 - Colin Nolder, UK
- IV: Technology for interoperability
 - Melvin Reynolds, UK



- ENV 13606 was approved in 1999
- EN 13606 is a major further development now with its core part one approved as full European standard
- 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
- Very strongly linked to European R&D projects
- Collaboration with the Open Electronic Health Record Foundation





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 as a basis for the description.
- In February 2007 all parts were accepted after revision to go for the final formal vote.



Workpackage 8: Participation in Standardization

- Promoting the building of information exchange standards that build on research in ontologies and knowledge representation to enable
 - safe integration for the care of the individual
 - efficient analysis of accumulated health information to generate new knowledge

Research



Standardization



- The Semantic Mining project has a unique number of key individuals working in standardization
 - Chair of the global eHealth Standardization Co-ordination Group, joining ISO, CEN, HL7, ITU, IEEE, DICOM, OASIS and WHO
 - Convenor of the WG on Terminology and Knowledge representation in Europe
 - Project leader of the Electronic Health record standardization in CEN and ISO – Dipak Kalra
 - Project leader of the ISO/CEN work on Health informatics – Vocabulary for Terminological systems. Anders Thurin
- A number of results are now coming to maturity and have become or are about to be published as full standards



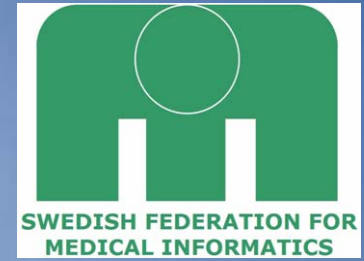
- **CEN/TC 251 – some recent results**
 - **Electronic Health Record Communication EN 13606**
Part 1: Reference model now approved as a European Standard February 2007 and on the way to become an international ISO standard. **Strong link with WP 26 of Semantic Mining.**
 - **Health Informatics – Service Architecture EN 12967 parts 1 - 3**
has passed the formal Enquiry and is likely to be published summer 2007
 - **Health informatics – Concepts to support continuity of care EN 13940-1**
 - **Categorial structure for Anatomy.** Ready for publication
 - **Metadata för knowledge resources** Final vote
 - **Classification mark-up language CLAML** a new distribution format for terminologies used by WHO. Final vote
 - **Representation of dedicated kinds of property in laboratory** . EN 1614. Ready. Research topic is mapping to SNOMED



- **ISO/TC 251 – some recent results**
 - **Health informatics – Vocabulary for terminological systems ISO 17115**
 - **Electronic Health Record Communication EN ISO 13606**
This is also processed as an international standard and is coming very close to final approval also as an international standard
 - **ISO/TR 20514: EHR, definition, scope and context**
 - **Health Informatics – Service Architecture EN 12967 parts 1 - 3**
This European work will also be the basis for an ISO standard
 - **ISO 17090: Health informatics – Public Key Infrastructure**
 - **ISO 27799: Health informatics – Security management in health using ISO/IEC 17799**
 - **ISO/TS 22600-1 Health informatics - Privilege management and access control - Part 1: Overview and policy management, Part 2: Formal models**
 - **ISO/TS 21091: Health informatics — Directory services for security, communications, and identification of professionals and patients**



- There are many difficult issues and several important contributing standards bodies to global eHealth
- Important standards have been developed in joint european and international co-operation and are now ready to be put into use for both clinical care applications and to the benefit of biomedical research.
- The formal standardisation system with CEN and ISO is very important to achieve political agreements in a number of countries on what standards to actually use
- A number of standards problems remains. Please try the existing bodies for your requirements rather than inventing new bodies with your friends



**See you at MIE 2008 in Göteborg,
Sweden.
26-28 May, 2008**

**eHealth beyond the horizon,
get IT there**

www.mie2008.org