GLOBAL STANDARDIZATION ACTIVITIES FOR INTEROPERABLE eHEALTH

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APAMI
AGENDA

- Background
- Structure
- Work Process
- Current status
- Issues and future
- Conclusion
- List of standards
GLOBAL SDOs

ISO (International Organization for Standardization) – Health informatics and others

IEC (International Electrical Commission) – Computer

ISO/IEC JTC1- ICT area

ITU (International Telecommunication Union) – Telecom.

UN/EDIFACT (UN/EDI Finance, Administration, Commerce and Transportation) – EDI

UN/CEFACT (UN/Center for Electronic FACT) and OASIS – XML and ebXML
GLOBAL SDOs (2)

HL7 (Health Level Seven) – EHR, Messaging & Commu.

DICOM (Digitized Image Communication in Medicine) – Medical image

IEEE (Institute of Electrical and Electronic Engineers) – Network and Device Communication

CEN (Committee for European Normalisation) – as ISO

OMG (Object Management Group) – UML, CORBA

GS1 – BarCode, RFID, Supply chain standards
WHO – Classification of diseases (ICD), ICF
IHTSDO – SNOMED-CT
LOINC – Observation names, codes
IHE (Integration of Healthcare Enterprise) –

“Connect-a-thon” demonstration of interoperability

“Interoperability Showcase” demonstration: XDS-Rad., Lab., Cardiol., Eyecare, Patientcare Device, Patientcare Coordination, IT Infrastructure

HIMSS (Health Information Management Systems Society) – CCHIT Certification

CCHIT=Commission on Certification of Health Information Technology
GLOBAL INTEROPERABLE eHEALTH DEVELOPMENT

“Examples”
“EU eHealth”
“Health-connect” in Australia
“Infoway” in Canada
“Connect for Health; NPfIT” in UK
“NHIN” in USA
“National EHR” in Japan
“e-Health and EHR” in Korea
“e-Health” in Malaysia
“NHII” in Taiwan
eHEALTH

An emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the internet and related technologies.

In a broader sense, the term characterizes not only a technical development, but also state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using ICT.

The use of ICT for health

ICT tools and services for health [CEN/TC251]
“Cost-effective and secure use of ICT in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research”

[CEN/TC251]
NEED FOR eHEALTH

- Use Case Scenario
- Interoperability among health information systems
- Standards:
  - Unique Identifiers (UID) and Object Identifiers (OID)
  - Data and document structure
  - Data and document interchange
  - Security
  - Terminology
  - Others
**Interoperability**: in the context of eHealth, interoperability is the way in which reliable data is provided and communicated in a secure, accurate and efficient way. It has to surmount barriers of national policies, culture, language, and systems of medical knowledge representation and use of ICTs.

Do we have appropriate standards?
INTEROPERABILITY LEVELS

- Technical interop. – plug and play, signal, protocol
- Structural interop. – simple, EDI, envelops
- Syntactic interop. – message, documents, vocabulary
- Semantic interop. – standard terminology, models
- Organization/service interop. – business process
ADOPTION OF STANDARDS

- Use case scenario based Modeling
- Profiling
- Standards gap analysis
- Selection of standards
CURRENT PROBLEMS OF STANDARDS

- Conflicting standards
- Conflicting versions
- Conflicting implementations of same standard
- Lack of specific standards
- Duplication of standards
- A premature market for HIT standards
- Political barriers: different health systems and often low support for standardization
CURRENT PROBLEMS OF STANDARDS(2)

- SDO barriers: seeking returns from an expensive standardization process
- Company barriers: seeking returns from own standardization
- ICT user barriers: seeking to prevent costs of using standards
- Lack of certification
GLOBAL HEALTH INFORMATICS SDOs AGREEMENT

CEN/TC 251
ISO/TC 215
HL7
Signed agreement on Oct. 11, 2006 in Geneva, Switzerland
“One context one standard and one test”
2nd GHITSS was held in Geneva on October 8 (Sun), 2006 – with HIT Industry Reps.

1st GHITSS was held in Hamamatsu, Japan on September 19 (Sun), 2005 – with HIT Nat’l Coordinators and Industry Reps.

“HIT standards are not sufficient to develop and deploy EHR, but there are duplications”

“Need of collaboration among HIT SDOs”
“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”
CEN/TC 251, ISO/TC 215, HL7 Agreement on Collaboration and Cooperation and Coordination

Signed by Chairs on October 11, 2006 in Geneva
CEN, ISO, HL7 CHARTER

Joint Initiative on SDO Global Health Informatics Standardization

CHARTER

Final Draft(v7)-March 30, 2007
Approved by all SDOs-August 27, 2007
Follow-up of the Agreement

Detailed working processes

Purpose: The Joint Initiative on SDO Global Health Informatics Standardization is formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counter-productive standardization efforts through...

Governance:

1. Joint Initiative Council
2. Joint Working Group
HL7 AND CEN/TC251 STANDARDS IN ISO/TC 215 TO BE INTERNATIONAL STANDARDS

‘Single set of standard for a single set of clinical business and single test’
JIC MEMBER SDO

[As of September 2008]
JIC (Joint Initiative Council)
Chair: Ed Hammond, PhD (HL7)
Secretary: Audrey Dickerson (ISO/TC215)

JWG (Joint Working Group)
Co-chairs: Melvin Raynolds (CEN/TC251)
           Don Newsham (ISO/TC215)
           Charles Jaffe, MD (HL7)
Secretary: Elizabeth Hanley (ISO/TC215)
FUNCTIONS

- JIC sets work processes, directions and policies
- JWG compiles existing standards and identify gaps with work items
- ISO/TC215 WG:s engage in standards development
## WORK PROCESS

<table>
<thead>
<tr>
<th>WTO* Stage / status</th>
<th>Body</th>
<th>Preliminary / preparation</th>
<th>Non-normative</th>
<th>Normative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Working draft (WD) then Committee draft (CD)</td>
<td>Workshop Agreement (CWA)</td>
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<td>HL7</td>
<td></td>
<td>Proposal</td>
<td>Draft for Membership Ballot</td>
<td>Implementation guidance</td>
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<td>Committee draft</td>
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*WTO*: World Trade Organization
WHAT HAPPENS WITH STANDARD?

- Each SDO follows own process for balloting
- IP is retained by SDOs
- The same standard published by SDOs
- IS gives advantage in international trade by meeting WTO “TBT.”
CURRENT STATUS OF JIC WORKS

- **ISO/FDIS 13606-1** Health informatics - Electronic health record communication - Part 1: Reference model (CEN published)

- **ISO/DIS 13606-2** Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (CEN published)

- **ISO/DIS 13606-3** Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (CEN final ballot)

- **ISO/DTS 13606-4** Health informatics - Electronic health record communication - Part 4: Security (CEN published)

- **ISO/CD 13606-5** Health informatics - Electronic health record communication - Part 5: Interface specification (CEN prEN)
CURRENT STATUS OF JIC WORKS(2)

- ISO/FDIS 27931 Health informatics - HL7 Version 2.5 messaging standard
- ISO/FDIS 27932 Health informatics - Clinical Document Architecture (Release 2)
- ISO/FDIS 19781 Health informatics - HL7 Electronic Health Record System Functional Model - Release 1
- ISO/DIS 11595 Health informatics - Pharmacovigilance - Test names and units for reporting laboratory results (CEN prEN)
- ISO/CD 27953 Health informatics - Pharmacovigilance - Structure and data elements for individual case safety reports (CEN prEN)
CURRENT STATUS OF JIC WORKS (3)

- ISO/DIS 21090 Health informatics - Harmonized Data Types for Information Interchange
- ISO/FDIS 27951 Health informatics – Common terminology services, release 1
ISSUES AND FUTURE

- Synchronizing SDO work processes
- Participation of industry
- Participation of domain experts and consumer
- Identify use cases and standards gaps
- Collaboration of TAGs within NMBs
- Participation of terminology/vocabulary SDOs
CONCLUSIONS

- Introduction to national eHealth projects and need of interoperability of Health Information Systems, hence need of standardization.

- The use-case scenarios should be identified and gap analysis of relevant standards should be performed on the basis of identified use-cases.

- Selection of appropriate standards and harmonization will then be performed.

- Selected standards will be implemented in developing interoperable eHealth systems.
ISO/TC215, CEN/TC251, CDISC and HL7 begin to work together in harmony to provide a single set of standard for a single set of clinical event to the global marketplace to achieve interoperability.

All SDOs share experts.
Q & A
For additional information or to become involved in any of the standards activities, contact:

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LIST OF RELEVANT INTERNATIONAL STANDARDS
REGISTRY

- IHE PIX Profile
- OASIS & UN/CEFACT ebXML
- ISO/TS 17120:2007 Health informatics - Country identifier standards
- ISO/DTR/CEN pr Health informatics - Guidance on Patient identification and Cross-referencing of identities
- ISO/TS 22220:2007 Health informatics - Identification of subjects of health care
- ISO/DTS 27527 Health informatics - Provider Identification
- ISO/CDTS 27790 Health informatics - Document Registry Framework
**EHR AND PHR**

- ISO/TS 18308: 2004 Health informatics - Requirements for an electronic health record architecture
- ISO/TR 20514: 2005 Health informatics - Electronic health record - Definition, scope and context
- ISO/TR 22221:2006 Health informatics - Good principles and practices for a clinical data warehouse
- ISO/FDIS 13606-1 Health informatics - Electronic health record communication - Part 1: Reference model (CEN published)
- ISO/DIS 13606-3 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (CEN final ballot)
ISO/CD 27953 Health informatics - Pharmacovigilance - Structure and data elements for individual case safety reports (CEN prEN)

prCEN/TS 15699 Health informatics - Clinical knowledge resources - Metadata (MetaKnow)

ISO/DIS 18308 rev Health informatics - Requirements for an electronic health record architecture

ISO/DTR Health informatics - Requirements and specifications of common essential information for health summary records

HL7 EHR Functionality

HL7 PHR Functionality
MESSAGING/INTEROPERABILITY

- HL7 V2.x, V3 RIM, CDA, CCD
- ISO/TR 18307: 2001 Health informatics - Interoperability and compatibility in messaging and communication standards - Key characteristics
- ISO/HL7 21731: 2006 Health informatics - HL7 version 3 - Reference information model - Release 1
- ISO/DIS 13606-2 Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (CEN published)
- ISO/CD 13606-5 Health informatics - Electronic health record communication - Part 5: Interface specification (CEN prEN)
MESSAGING/INTEROPERABILITY(2)

- ISO/CD 12967-1 Health informatics - Service architecture - Part 1: Enterprise viewpoint (CEN published)
- ISO/CD 12967-2 Health informatics - Service architecture - Part 2: Information viewpoint (CEN published)
- ISO/CD 12967-3 Health informatics - Service architecture - Part 3: Computational viewpoint (CEN published)
- ISO/CD 11615 Health informatics - Identification of medicinal products - Data elements and structure for the exchange of product information for drug dictionaries (CEN prEN)
- ISO/DIS 21090 Health informatics - Data types for use in health care interchange (CEN prEN)
- ISO/CD 10159 Health informatics - Messages and communication - Web access reference manifest
MESSAGING/INTEROPERABILITY(3)

- ISO/DTR 28380-1 Health informatics - IHE Global Standards Adoption Part 1 – Process
- ISO/DIS 27931 Health informatics - HL7 Version 2.5 messaging standard
  - ISO/DIS 27932 Health informatics - Clinical Document Architecture (Release 2)
  - ISO/DIS 25720 Health informatics - Genomic sequence variation Markup Language
  - ISO/FDIS 17113 Health informatics - Exchange of information between healthcare information systems - Development of messages
  - ISO/DTS 22224 Health informatics - Electronic reporting of adverse drug reaction
MESSAGING/INTEROPERABILITY(4)

- ISO/DTR 10895 Health informatics - Business requirements for the reporting of pharmacist services
- CEN prENV 12538 Medical informatics - Messages for patient referral and discharge
- CEN ENV 12539 Medical informatics - Request and report messages for diagnostic service departments
- CEN prEN 14822 Health informatics - General purpose information components
- CEN prEN 13940 Health informatics - System of concepts to support continuity of care
- CEN prEN 1613:2004 Medical informatics - Messages for exchange of laboratory information
CEN prEN 13607 Health informatics - Messages for the exchange of information on medicine prescriptions

IHE XDS Profiles
SECURITY AND CONFIDENTIALITY

- **IS 17090-1: 2008** Health informatics - Public key infrastructure - Part 1: Framework and overview
- **IS 17090-2: 2008** Health informatics - Public key infrastructure - Part 2: Certificate profile
- **IS 17090-3: 2008** Health informatics - Public key infrastructure - Part 3: Policy management of certification authority
- **ISO/TS 21091: 2005** Health informatics - Directory services for security, communications and identification of professionals and patients
- **ISO/TS 22600-1: 2006** Health informatics - Privilege management and access control - Part 1: Overview and policy management
ISO/TS 22600-2: 2006 Health informatics - Privilege management and access control - Part 2: Formal models

IS 22857: 2004 Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health information

ISO/DTS 13606-4 Health informatics - Electronic health record communication - Part 4: Security (CEN published)

ISO/IEC 27799 Health informatics - Security management in health using ISO/IEC 17799 (CEN final ballot)

ISO/FDIS 27789 Health informatics - Audit trails for electronic health records (CEN prEN)
SECURITY AND CONFIDENTIALITY (3)

- ISO/CDTR 11636 Health informatics - Dynamic on-demand virtual private network for health information infrastructure
- ISO/DTR 11633 Health informatics - The information security management guidelines for remote maintenance services for medical devices and health information systems
- ISO/DTS 21547-1 Health informatics - Secure archiving of electronic health records Part 1: Principles and requirements
- ISO/DTS 21547-2 Health informatics - Secure archiving of electronic health records Part 2: Guideline
- ISO/DTS 22600-3 Health informatics - Privilege management and access control - Part 3: Access control management
• ISO/TS 25237:2007 Health informatics - Pseudonymisation

• CEN prEN 13608 Health informatics - Security for healthcare communication

• CEN ENV 12251:2000 Health informatics - Secure user identification for healthcare - Management and security of authentication by passwords

• CEN prEN 13729 Health informatics - Secure user identification for healthcare - Strong authentication using microprocessor cards

• ISO/TS 21298:2008 Health informatics - Functional and structural roles
DEVICE

- ISO/IEEE 11073-10201:2004 Health informatics - Point-of-care medical device communication - Part 10201: Domain information model


- ISO/IEEE 11073-30200:2004 Health informatics - Point-of-care medical device communication - Part 30200: Transport profile - Cable connected


- IS 18812:2003 Health informatics - Clinical analyser interfaces to laboratory information systems - Use profiles
ISO/TR 21730:2007 Health informatics - Use of mobile wireless communication and computing technology in healthcare facilities - Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices

ISO/IEEE/CD 11073-20301 Health informatics - Point of care medical device communication - Part 20301: Application profile - Optional package, remote control (CEN prEN)

ISO/IEEE/CD 11073-00000 Health informatics - Point of care medical device communication - Part 00000: Framework and overview (CEN prEN)

ISO/IEEE/CD 11073-20202 Health informatics - Point of care medical device communication - Part 20202: Application profile - Baseline (CEN prEN)
ISO/IEEE/CD 11073-20201 Health informatics - Point of care medical device communication - Part 20201: Application profile-Polling mode (CEN prEN)

ISO/IEEE 11073-30300:2004 Health informatics - Point-of-care medical device communication - Part 30300: Transport profile - Infrared wireless

ISO/IEEE/DIS 11073-60101 Health informatics - Point-of-care Medical device communication - Application gateway, HL7 (v2) observation reporting interface

ISO/IEEE/DIS 11073-20102 Health infodevice communication - Application profiles MIB Elements

ISO/IEEE/DIS 11073-20200 Health informatics - Point-of-care Medical Device Communication - Application profile, Association Control Function
ISO/IEEE/DIS 11073-91064 Health informatics - Standard communications protocol (CEN EN1064:2007)

HEALTH CARD

- **IS 20301:2006** Health informatics - Health cards - General characteristics

- **IS 20302:2006** Health informatics - Health cards - Numbering system and registration procedure for issuer identifiers

- **IS 21549-1:2004** Health informatics - Health cards - Patient healthcard data - Part 1: General structure
  - **IS 21549-2:2004** Health informatics - Health cards - Patient healthcard data - Part 2: Common objects
  - **IS 21549-3:2004** Health informatics - Health cards - Patient healthcard data - Part 3: Limited clinical data
  - **IS 21549-4:2006** Health informatics - Health cards - Patient healthcard data - Part 4: Extended clinical data
HEALTH CARD(2)

- IS 21549-7:2007 Health informatics - Health cards - Patient healthcard data - Part 7: Medication data (CEN final ballot)
- IS/FDIS 21549-5 Health informatics - Health cards - Patient healthcard data - Part 5: Identification data (CEN final ballot)
- IS/FDIS 21549-6 Health informatics - Health cards - Patient healthcard data - Part 6: Administrative data (CEN final ballot)
- IS/DIS 21549-8 Health informatics - Health cards - Patient healthcard data - Part 8: Linkage and reference data (CEN prEN)
TERMINOLOGY AND CODE

- **IS 17115:2007** Health informatics - Vocabulary for terminological systems
- **IS 18104:2003** Health informatics - Integration of a reference terminology model for nursing
- **ISO/CD 11595** Health informatics - Pharmacovigilance - Test names and units for reporting laboratory results (CEN prEN)
- **ISO/CD 11616** Health informatics - Identification of medicinal products - Pharmaceutical product identifiers (CEN prEN)
- **ISO/CD 11238** Health informatics - Identification of medicinal products - Structures and controlled vocabularies for ingredients (CEN prEN)
- **ISO/DIS 27951** Health informatics - Common terminology services (Release 1)
ISO/CD 11239 Health informatics - Identification of medicinal products - Structures and controlled vocabularies for pharmaceutical dose form, units of presentation and routes of administration (CEN prEN)

ISO/CD 11240 Health informatics - Identification of medicinal products - Structures and controlled vocabularies for units of measurement (CEN prEN)

CEN prEN 12611 rev Health informatics - Categorial structure of systems of concepts - Medical devices

CEN prEN 1828 rev Health informatics - Categorial structure for classifications and coding systems of surgical procedures

ISO/IEEE/DIS 11073-10103 Health informatics - Point-of-care Medical Device Communication - Nomenclature, Implantable Device, Cardiac
ISO/DTS 22789 Health informatics - Conceptual framework for patient findings and problems in terminologies
IHTSDO SNOMED-CT
WHO ICD10, ICD9CM, ICF, RxNorm
LOINC Observation names and codes
CEN prEN 14463 Health informatics - A syntax to represent the content of medical classification systems
CEN prEN 1068:2004 Health informatics - Registration of coding schemes
CEN prEN 21610 Health informatics - Identification of medicinal products
IS 12052:2006 Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management

IS 17432:2004 Health informatics - Messages and communication - Web access to DICOM persistent objects

IS 18232:2006 Health informatics - Messages and communication - Format of length limited globally unique string identifiers

IS 11073-90201:2007 Health informatics - Point-of-care medical device communication - Part 90201: Medical waveform format - Encoding rules (CEN prEN)

ISO/DIS 11073-10102:2007 Health informatics - Point-of-Care Medical device communication – Nomenclature annotated ECG
TELEHEALTH

- ISO/TS 16058:2004 Health informatics - Interoperability of telehealth systems
PATIENT SAFETY

- ISO/TS 25238:2007 Health informatics - Classification of safety risks from health software
- ISO/TR 27809:2007 Health informatics - Measures for ensuring patient safety of health software
- ISO/DTS 29321 Health informatics - Application of clinical risk management to manufacture of health software (CEN prEN)
- ISO/DTS 29322 Health informatics - Guidance on risk evaluation and management in the deployment and use of health software (GREMIDUHS) (CEN prEN)
- ISO/DTS 29321 Health informatics - Application of clinical risk management to manufacture of health software (CEN prEN)
• ISO/TR 21730:2007 Health informatics - Use of mobile wireless communication and computing technology in healthcare facilities - Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices