HEALTH INFORMATION TECHNOLOGY STANDARDS FOR INTEROPERABLE eHEALTH

Yun Sik Kwak, MD, PhD
Dept Med Info., Kyungpook Nat’l Univ
Daegu, Korea
ISO/TC 215
APAMI
HL7 Korea

AGENDA

- New Paradigm
- International Standards
- Medical terminology coding
- List of Relevant Standards
- Conclusion
NEW PARADIGM OF HEALTH INFORMATION TECHNOLOGY

“Connect and Integrate Patient Safety and Risk Management”

LHR
PHR
EMR

GLOBAL INTEROPERABLE EHRS DEVELOPMENT

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

GLOBAL HEALTH INFORMATICS STANDARDS DEVELOPMENT

“Interoperable EHRS”
e-HEALTH

Digitized health including care, health promotion, knowledge management, decision support, administrative activities, learning, and all aspects of health and healthcare domain.

It is synonymous to EHRS.

WHY STANDARDS?

Need of interoperability among different health information systems and medical devices and host computer(s) for:

- EHRS
- Easy development and deployment of interfaces
- Reduction of costs
INTEROPERABILITY

- **Interoperability**: ability of two or more system or components to *exchange information* and to *use the information* that has been exchanged.


  - **Functional interoperability**: Message format and content
  - **Semantic interoperability**: Terms (SNOMED-CT, LOINC), units
  - **Service (Business) Interoperability**: SOA, HISA

**Vision**: Plug and play (PnP)

EU DEFINITION OF INTEROPERABILITY

- **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.
STANDARD

“Something set up as a rule for measuring or as a model to be followed (Webster Dictionary)”

WHAT IS STANDARD?

ISO definition

“document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context”
## GLOBAL SDOs

<table>
<thead>
<tr>
<th>Organization</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO</td>
<td>Health informatics and others</td>
</tr>
<tr>
<td>IEC</td>
<td>Computer</td>
</tr>
<tr>
<td>ISO/IEC JTC1</td>
<td>ICT area</td>
</tr>
<tr>
<td>ITU</td>
<td>Telecom</td>
</tr>
<tr>
<td>HL7</td>
<td>EHR, Messaging &amp; Commu.</td>
</tr>
<tr>
<td>UN/EDIFACT</td>
<td>EDI</td>
</tr>
<tr>
<td>UN/CEFACT</td>
<td>XML and ebXML</td>
</tr>
</tbody>
</table>

## GLOBAL SDOs (2)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>DICOM</td>
<td>Medical image</td>
</tr>
<tr>
<td>IEEE</td>
<td>Network and Device Communication</td>
</tr>
<tr>
<td>CEN</td>
<td>as ISO</td>
</tr>
<tr>
<td>OMG</td>
<td>UML, CORBA</td>
</tr>
<tr>
<td>WHO</td>
<td>Classification of diseases (ICD), ICF</td>
</tr>
<tr>
<td>IHTSDO</td>
<td>SNOMED-CT</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical Object Identifiers Nomenclatures Codes</td>
</tr>
</tbody>
</table>
**STANDARDS CONFORMANCE TESTING ORGANIZATIONS**

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

---

**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
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 STANDARDS REQUIREMENT

BUSINESS SUSTAINABILITY

• Business cost reduction
• Healthcare effectiveness
• Energy effectiveness
• Balancing green environment
HL7, CEN/TC251, CDISC, IHTSDO
STANDARDS IN ISO/TC 215 TO
BE INTERNATIONAL
STANDARDS

‘Single set of standard for
a single set of clinical business and
single test’
(No duplications and confusions)

WHY MEDICAL TERMINOLOGY
CODING?
ELECTRONIC HEALTH RECORD (EHR)

2003 IOM’s EHR

“(1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery.”

EHRS (EHR SYSTEMS)

ISO TR 20514:2005, Health Informatics – EHR Definition, scope and context

- Institutional EHRS: the same as current hospital medical chart
- Shared EHRS: lifelong EHR
- Population EHRS: for public health statistics without personal names but only necessary data
- Personal EHRS: for personal use
HEALTH CARE: INFORMATION INTENSIVE INDUSTRY

- Control of Health Care Costs ...
- Improved Quality of Care ...
- Improved Health Outcomes ...
- Appropriate Use of Health Technology...
- Compassionate Resource Management...
  - ... depend upon information
  - ... ultimately Patient Data
  - ... increasingly augmented by genomic data

[Chris Chute]

CLINICAL PROCESS

Central Role of Terminology

Clinical Database → Observational Data

Terminology

Patient Encounters → Expert Systems → Clinical Guidelines

Medical Knowledge
HOW DO WE REPRESENT PATIENT DATA?

- Controlled Terminologies
  - SNOMED
- Standard Vocabularies
  - LOINC
- High Level Classifications
  - ICD-10, DRGs
- Within the context of information models
  - ISO, HL7, openEHR, ...

STRATEGIC ROLE OF VOCABULARY

- Interface to Knowledge Resources
  - Guidelines, Critical Paths, Reminders
  - Decision Support, Reference
- Support Practice Analysis
  - Quality Improvement
  - Clinical Epidemiology
  - Outcomes Analyses

[Chris Chute]
SO WE ARE ALL USING HL7, WHAT IS THE PROBLEM?

\[
\text{OBX|1|CE|ABO^ABO GROUP| O^Type O|}
\]

\[
\text{OBX|1|CE|BLDTYP^ABO GROUP| TYPEO^Type O|}
\]

\[
\text{OBX|1|CE|ABOTYPE^ABO GROUP| OPOS^Type O|}
\]

\[
\text{OBX|1|CE|883-9^ABO GROUP| F-D1250^Group O|}
\]

Equivalence not obvious to computer

TERMINOLOGY AS CRUCIAL REQUIREMENT

*Without* Terminology Standards...

- Health Data is *non*-comparable
- Health Systems *cannot* Interchange Data
- Secondary Uses (Research, Efficiency) are *not* possible
- Linkage to Decision Support Resources *not* Possible

[Chris Chute]
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)

EHR AND PHR(2)

- 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
MESSAGING/INTEROPERABILITY(5)

- 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
SECURITY AND CONFIDENTIALITY (2)

- 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
SECURITY AND CONFIDENTIALITY (4)

- 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
### DEVICE(2)

- **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)

### DEVICE(3)

- **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
DEVICE(4)


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 21549-4:2006 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)
## TERMINOLOGY AND CODE(2)

- **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

## TERMINOLOGY AND CODE(3)

- **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
IMAGE AND BIOSIGNALS/WAVE FORM

- 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)

PATIENT SAFETY(2)

- 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
CONCLUSIONS

- Introduction to national EHR 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 EHR systems.

Q & A
CONTACT INFORMATION

For additional information or to become involved in any of the standards activities, contact:

Yun Sik Kwak

(V) +82 (0)53-420-6050
(E) yskwak@knu.ac.kr