IT-Standardisation in Healthcare - Coordination of international Activities

ITU workshop

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Status of IT Standardisation in Healthcare

- IT-standardisation began in **isolated islands**, and has achieved different maturity
  - the nearer to hardware, the more success

- Evolution from connectivity to **interoperability** (bottom-up)
  - from *data exchange* to *workflow, information exchange, data models*

- domains just begin to grow together
  - high-level standards for EHR have not yet made their way

- national and regional standards will not survive, and migrate into **international standards**
  - Consolidation among SDOs needed?

- Healthcare IT- standardisation is not yet done
  - what are the success factors?
Standardisation-Islands: hospital departments

Radiology:
DICOM; Secretariat NEMA; international contributions

Pharmacy:
NCPDP National Council for Prescription Drug Programs; US

Laboratory:
POCT 1-A (IEEE, HL7, NCCLS); US
National Committee for Clinical Laboratory Standards
plus many national standards (LOINC, ...)

Intensive Care Unit:
IEEE 1073

Administration:
HL7; X.12; US, with international add-ons by affiliates
IT-Functionalities of departments overlap

- **Oncology**: POE, therapy planning, photographs
- **ICU (Intensive Care Unit)**: Clinical Information Systems
- **Bedside device interfaces**
- **ADT (Admissions, Discharge, Transfer)**: Scheduling, Documents, Nursing, Results, Queries, Billing, Image access, Supplies
- **Anesthesia**
- **OR (Operation Room)**
- **Cardiology**: ECG, waveforms
- **Radiology**: Image acquisition
- **Film Management, Registry Data, Data Management, Archiving**

Isolated islands
From connectivity to interoperability

**DICOM: evolution**

**Digital Imaging and Communication in Medicine**

1982: founded by ACR and hosted by NEMA
1985: Standard V 1.0: file formats only
1988: Standard V 2.0: 50 pin Point-to-Point connector; not implemented
1988: SPI (Standard Product Interconnect) from Si, Ph; not accepted
1992: DICOM 3.0: networking, object oriented, accepted and supported by whole industry
2001: about 2000 pages; growing exponentially

**Topics:**

1. Data formats; image objects  ✓
2. Workflow messages: worklist, performed procedure step ✓
4. Structured Reporting: evidence reports with measurements; coded diagnosis of the radiologist  ✓
HL7: evolution

Past: messages in ASCII-format, with redundancy

Version 2.5:
- modern XML-message format as option

Version 3.0 +:
- CDA (Clinical Document Architecture) since 1996, now balloted
- Level 1 much more primitive than DICOM Structured Reports
- mostly syntax for headers in documents (patient, provider, encounter, time stamp, signature), but not a structure of medical content in data items;
- base für SCIPHOX (D) (hospitals with physicians)
- Implementations also in UK, GR, SF, CN

V 3.0 RIM (Reference Information Model)
- consistent message generation model for healthcare
- not yet complete, may need until end 2003 for positive ballot
DICOM WG 20 / HL7 Image Integration SIG

Common Workinggroup of DICOM and HL7
Scope: to align the standardization in clinical documents especially in CDA when progressing towards Level 3

• DICOM SR (Structured Reporting) provides already the semantics to describe medical / clinical relationships between data which shall also be the content of CDA Level 2
  goal: CDA Level 3 will map to DICOM SR

• Access to the Internet for DICOM Persistent Objects, include DICOM MIME Type in HL7 V3.0

CDA= Clinical Document Architecture
Goals of the IHE Initiative

Integrating the Healthcare Enterprise (typ. hospital)

Founded 1998 by RSNA (Radiological Society of North America) and HIMSS (Healthcare Information & Management Systems Society)

Clinical Workflow Optimization

- Continuity & Integrity of Patient Information
- Foster Communication among diverse Healthcare Information Systems from different vendors
- Avoid Repeating Tasks (like typing patient name)
- Eliminate Data Redundancy
- Eliminate Rigid & Costly Proprietary Solutions

- Use *existing standards* wherever possible, thus saving the invested development of the companies,
- And improving quality of products
IHE Roles and Transactions

Domains connect together

**SIEMENS**

**IMAGING:**
- PACS
- Workstations
- Modalities
IHE = A Standards Harmonization Approach

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IHE Goes Beyond Standards
IHE =

+ Multi-Vendor
+ Workflow-Driven
+ INTEGRATION

based on established medical IT Standards
IHE Vision for Growth

A Multidimensional Expansion of Integration

1st Dimension: Workflow inside department
- Radiology
- Cardiology
- Pharmacy
- Others...

2nd Dimension: Common consistent data
- Master Patient Index
- Clinical Patient Record
- Other...

3rd Dimension: Increasing the Number of Vertically Integrated Departments
CIC
Connectivity Industry Consortium (Laboratory)

MEDICA, 21.11.2002:
„The CIC has achieved its goal to develop a standard for point-of-care connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC. The NCCLS has approved the standard earlier this year and it is co-published by HL7 and IEEE as POCT1-A. International approval through ISO, CEN is initiated.“

NCCLS (National Committee for Clinical Laboratory Standards)
• is ANSI accredited
• hosts ISO TC 212 „Clinical Laboratory Testing and In Vitro Diagnostic Test Systems“
• 50 standards are recognized by FDA
A bunch of NCPDP standards was proposed for adoption by ISO.

NCPDP Standard Claims Billing Tape Format (V2.0)
NCPDP Billing Unit Standard (V1.4)
NCPDP Standard Diskette Billing Format (V2.0)
NCPDP Telecommunication Standard Format (V3.2)
NCPDP On-Line Real-Time Drug Utilization Review (ORDUR)
  • Member Information
  • Prescription Information
  • Prescriber Information
  • Pharmacy Identification
NCPDP Manufacturer Rebate Standard/X12 Implementation Guide (V1.0)
NCPDP Magnetic Stripe Standard Format (V2.0)
NCPDP Batch Transaction Standard (V1.0)
NCPDP Compound Transaction Implementation Guide (V1.0)
NCPDP Professional Pharmacy Service Implementation Manual (PPS) (V3.2-4.1)
NCPDP Prior Authorization Standard (V1.0)
NCPDP Prescriber/Pharmacist Interface Script (V1.0)
IHE: a global approach

IHE started in US, but spreads geographically

- IHE Europe
  - sponsored by ECR, COCIR, EU
- IHE France (SFR, GMSIH, AFNOR)
- IHE Deutschland (DRG, VDK, DKG, DFG, ZVEI)
- IHE Italia
- IHE UK
- IHE Japan (JIRA)

„IHE ist der Elchtest für die Integration“ (Prof. Klose, Marburg)
DICOM: a global standard

Secretariat at NEMA, U.S..

In the DICOM Committee the following biomedical societies are members:

• RSNA, ACR, ACC (Cardiology), Am. Dental Assoc;
  Am. Academy of Ophthalmology; National Cancer Institute
• Canadian Institute of Health
• European Society of Cardiology
• Deutsche Radiologische Gesellschaft
• Societe Francaise de Radiologie
• Societa Italiana di Radiologia Medica
• Japan IRA
• Korean PACS Standards Committee
• Biomedical Society of Taiwan

• Since 2001 Joel Chabrias is medical Co-Chair of WG 10 “Strategy”
• Since 5. 12. 2002 Dr. Peter Mildenberger is biomedical Co-Chair of the DICOM Committee
CEN

CEN TC251 started early in the 1990s (G. Klein)

WG1: Information models (F. Freriks)
WG2: Terminology and Knowledge Bases (G. Holmberg)
WG3: Security, safety and quality (G. Trouessin)
WG4: Technology for Interoperability (M. Reynolds)

...it is important that while focussing on the European needs of health actors and suppliers of systems, we should **promote international solutions through ISO** whenever feasible.

**agrees to collaborate with HL7**... to obtain unification of their set of standards for healthcare communication and to make the results **globally available to ISO**.

But only 1 prENV did it to an accredited EN

CEN EN 1828:2001 Categorial Structure for classifications and coding systems of surgical procedures; 14 pages
CEN Output

**Terminology and Architecture (14)**

u.a. CEN ENV 13606 : Electronic health record communication

*Was occasionally implemented, but interoperability did not work*

**Data Security and Privacy (8)**

*more requirements than implementable specifications*

**Interoperability (15)**

e.g CEN ENV 12922: 1997 Medical Image Management – Part 1: Storage Commitment Service Class; **Obsolete by DICOM**

e.g. CEN ENV 13939:2001 Medical Data Interchange: HIS/RIS-PACS and HIS/RIS-Modality Interface; 51 pages; by WG IV, and NAMed G2; Annex C (p 13-51) is normative and consists of DICOM suppl 10 ”Basic Worklist Management”

*What is the added value for industry?*
ISO / TC 215 Health Informatics

Secretariat now finally hosted by HIMSS

WG1: Health records and modelling coordination
WG2: Messaging and communication
WG3: Health concept representation
WG4: Security
WG5: Health cards

Three of the five ISO/TC 215 working groups have convenors working also in CEN/TC 251.

On 7.8.1998 ISO/TC 215 called out for existing standards to look for candidates for adoption. About 50 were proposed, e.g.

- all the CEN ENVs,
- the ASTM PS 100 to 109; and ASTM 1762, ASTM 1902.
- HL7 2.3
- IEEE 1073 for ICUs
- NCPDP xx for pharmacies

HIMSS= Healthcare Information & Management Systems Society
ISO / TC 215 Scope (1)

Terminology; for use by SDOs or committees (5)
ISO 17113 DIS Exchange of information between healthcare information systems –
Development of messages; 76 pages; Definition of Actor, RIM, HMD, CMC, …
ISO 17115 CD Vocabulary for terminological systems; 13 pages; medical entity dictionary and
reference terminology
ISO 17117 TS:2002 - Controlled health terminology; Structure and high-level indicators
ISO 21667 TS Health indicators conceptual framework
ISO/IEC 19501 Information Technology – Unified Modeling Language (UML)

Interoperability (6)
ISO 18812 prEN Clinical analyser interfaces to laboratory information systems - Use profiles together
with CEN
ISO/IEC 7826-2:1994 Information technology – General structure for the interchange of code values; Part
2: Registration of coding schemes.
Processing – Reference Model –
ISO nnnnn TS Draft (25.4.2002) Interoperability of telelearning systems
ISO/IEC nnnnn TR: (Draft 25.4.2002) – Interoperability of telehealth systems and networks; Part 1:
Introduction and definitions (19 pages); Part 2: Real-time systems (50 pages)
ISO 11073 PoC Medical Device Communication; 230 pages;
ISO / TC 215 Scope (2)

Data Security and Privacy (8)

ISO 7498:1989 Information processing systems – Open systems Interconnection – Basic Reference Model; Part 2: Security Architecture; *Definition of terms* like audit trail, confidentiality, consent, credentials, ..

ISO 17090 TS *digital signature* requirements; based on the underlying X.509(2000) standard which is implemented in the US


ISO 21089 TR (Draft 20.3.2002) Trusted end-to-end information flows; 50 pages; *Definitions and terms* (-page 20) include HIPAA.

ISO 21549 CEN CD "Patient healthcard data"; Part 7: Electronic prescription


ISO/IEC 15408-1: Introduction and General Model (62 pages)

ISO/IEC 15408-2: Security functional requirements (354 pages)

ISO/IEC 15408-3: Security Assurance requirements (222 pages)

ISO / TC 215 cooperations

ISO Cooperations with IEC
Joint standards

ISO Cooperations with CEN
25 of 40 work items are based on CEN work

ISO Cooperations with IEEE
Merges IEEE1073 and CEN Vital

ISO Cooperations with HL7
Started for V2.x

ISO Cooperations with DICOM
• strategy of DICOM: not too early, because DICOM works faster
• many references to ISO standards within DICOM standard
• start with specific topic “Web-access to DICOM persistent objects”

• Joint meetings since Jan 2001 of TC 215 WG2 with DICOM WG10,20, HL7, ASTM, IHE “IT Infrastructure Comm” for security topics
CEN, IEEE, ISO: Convergence

IEEE 1073 (USA)

Vital (CEN, Europe), Draft

ISO 11073 (international)


1995: ANSI Standard

National standards will be transformed into international standards
Sector G mirrors exactly the structure of ISO / TC 215 by its working groups

G 1 "Modellierung"
G 2 "Kommunikation"
G 3 "Terminologie"
G 4 "Sicherheit"
G 5 "Karten"

founded in Feb/March 2000
Objectives *:
1. To develop the guiding principles to be used by standards development organizations relating to healthcare informatics standards to support the development of:
   A common **reference information model** for healthcare information;
   A common reference **terminology** model for healthcare information;
   A common **method for implementation** of healthcare information exchange;
   A common trust framework (**privacy and security**) for healthcare information and records;
   A common approach for **coordination and conflict resolution between SDOs**.

* However, their results are less impressive than their objectives
ASTM E 31
Standards Committee on Health Informatics

Scope, Mission:

ASTM Committee E31 develops standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare and healthcare decision making, including patient-specific information and knowledge.

… Standard also address policies for integrity and confidentiality and computer procedures that support the uses of data and healthcare decision making.

ASTM was host of ISO / TC 215 secretariat
ASTM E 31
Standards Committee on Health Informatics

A bunch of ASTM standards was proposed for adoption by ISO...

ASTM PS 100-97 Authentication of Healthcare Information Using Digital Signatures
ASTM PS 101-97 Security Framework for Healthcare Information
ASTM PS 102-97 Internet and Intranet Healthcare Security
ASTM PS 103-97 User Authentication and Authorization
ASTM PS 107-97 Information Access Privileges to Health Information
ASTM PS 108-97 Individual Rights Regarding Health Information
ASTM PS 109-97 Training of Persons Who Have Access to Health Information
ASTM E 1762-95 Electronic Authentication of Health Care Information
ASTM E 1869-97 Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Computer-Based Patient Records

... but implementations have been rare!
Data Models

...still work in progress

DICOM:
Radiology-centered, but proven in practical daily life

HL7 V3.0 RIM:
For the whole hospital enterprise, and multiple site settings;
not yet completed

GEHR Good Electronic Health Record:
Consists of Object Model und Exchange Format;
Open Source; implemented in Australia;
good contacts to CEN TC 251
Success factors for Healthcare IT-Standardisation

• cooperative work of the major Stakeholders:
  • **User** (requirements, real life use cases)
  • Industry (technology, product quality, product maintenance)
  • Academics (concepts, knowledge management)
  • legislative (legal framework)
    (e.g. 1 User-Co-Chair, 1 Vendor-Co-Chair)

• clearly defined **scope** of SDO; written down in strategy papers

• **cooperation** between SDOs of diverse domains

• **transparent** WG-structure („national mirror bodies“)

• **business** propositions

• **speed** (new version each 12 months)

• **intensity** of work
  (DICOM WG6: 6 Sessions p.a. à 1 week, + Tecons)
Success factors for Healthcare IT-Standardisation

To avoid:

- Double work, waste of expert resources
- Inflation of bodies and conferences
- National presumptions
- Burning of tax money
Siemens medical Solutions that help
Communication between Manager and Agents:

**Association**

**OSI/ISO Schichten**

1 - 4

5

6

7

**Manager Application Process**

MDIB

CMDISE (IEEE 1073.2.0)

Presentation Layer

Session Layer

Transport System

**Agent Application Process**

MDIB

CMDISE (IEEE 1073.2.0)

Presentation Layer

Session Layer

Transport System

Physikalische Verbindung, z.B. IrDA - Cable Connected

- Medical Device Information Base (Vital): Objektbaum
- ENV 13735 (Intermed): Application Profiles
- Common Medical Device Information Service Element: Verwaltet die Objekte
- Transport and Lower Layers (IrDA)