IT-Standardisation in Healthcare - Coordination of international Activities

ITU workshop
Geneva, May 23-25th, 2003

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Status of IT Standardisation in Healthcare

postulates

- 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 ?

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Isolated islands

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, ...)
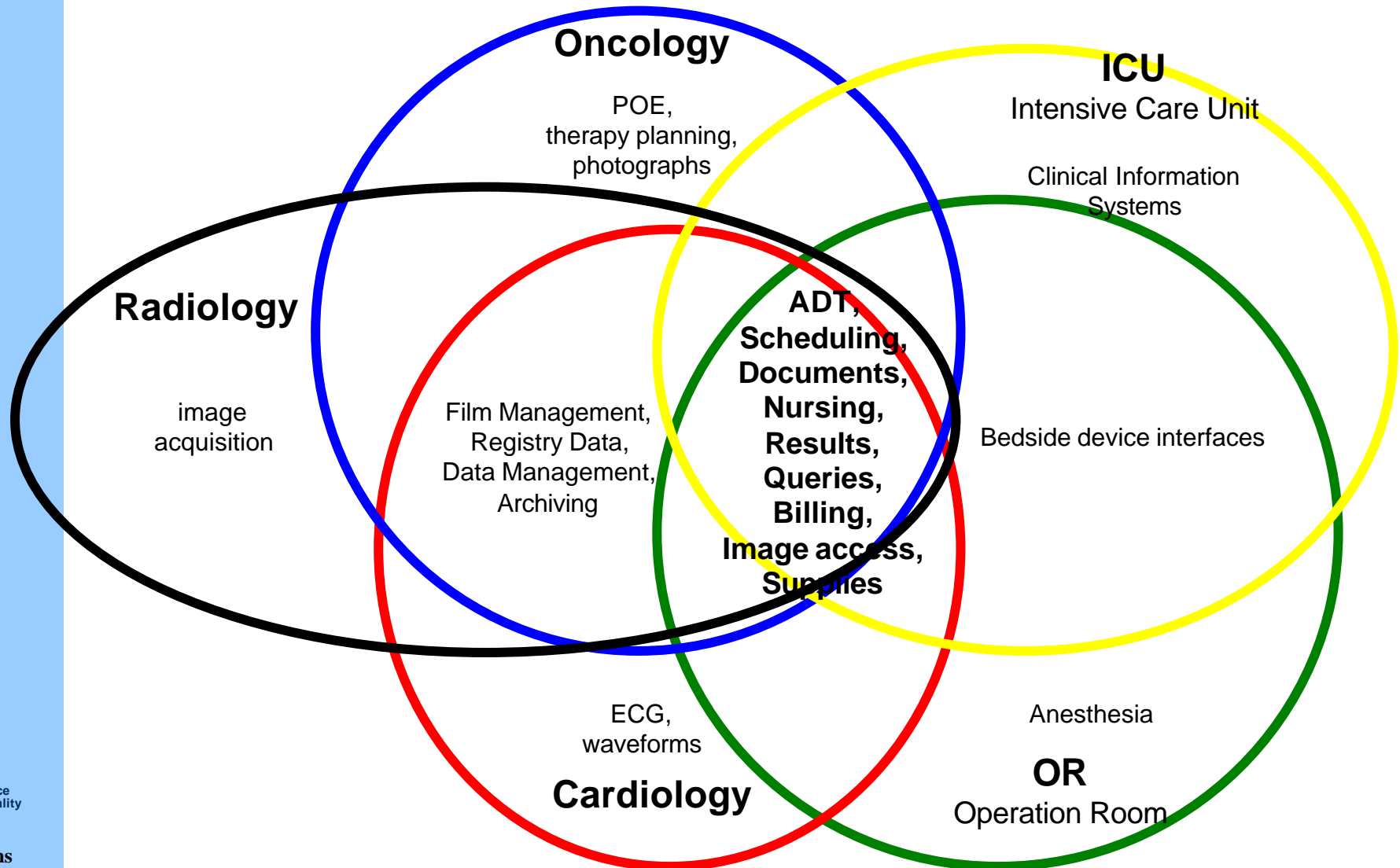
Intensive Care Unit:

IEEE 1073

Administration:

HL7; X.12; US, with international add-ons by affiliates

IT-Functionalities of departments overlap

Isolated islands

Oncology

POE,
therapy planning,
photographs

ICU
Intensive Care Unit

Clinical Information
Systems

Radiology

image
acquisition

Film Management,
Registry Data,
Data Management,
Archiving

**ADT,
Scheduling,
Documents,
Nursing,
Results,
Queries,
Billing,
Image access,
Supplies**

Bedside device interfaces

ECG,
waveforms

Anesthesia

OR
Operation Room

Cardiology

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From connectivity to interoperability

DICOM: evolution

Digital **I**maging and **Co**mmunciation in **M**edicine

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 ✓
3.   Security: de-identification of patient data, digital signatures ✓
4.   Structured Reporting: evidence reports with measurements;
     coded diagnosis of the radiologist   (✓)

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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

Domains connect together

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

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CDA= Clinical Document Architecture

Domains connect together

Goals of the IHE Initiative

Integrating the **H**ealthcare **E**nterprise (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

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IHE Roles and Transactions

Legend:
- Year1 Scope
- Year2 Scope Additions
- Year 2 Optional Transactions

Domains connect together

ADT Patient Registration

Patient Registration

HIS

Order Placer

New Order

Order Cancel

Department System Database

Department System Scheduler – Order Filler –

RIS

Patient Update

Procedure Update

Procedure Scheduled

Images Availability Query

PPS In-Progress / Completed

Performed Procedure Step Manager

Modality Worklist

IMAGING:
- *PACS*
- *Workstations*
- *Modalities*

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IHE = A Standards Harmonization Approach

Domains connect together

	HIS	RIS	PACS	Modality
HIS	HL7	HL7	––	––
RIS	HL7	HL7	HL7 / DICOM	DICOM
PACS	––	HL7 / DICOM	DICOM	DICOM
Modality	––	DICOM	DICOM	DICOM

IHE Goes Beyond Standards

IHE =

+ **Multi-Vendor**

+ Workflow-Driven
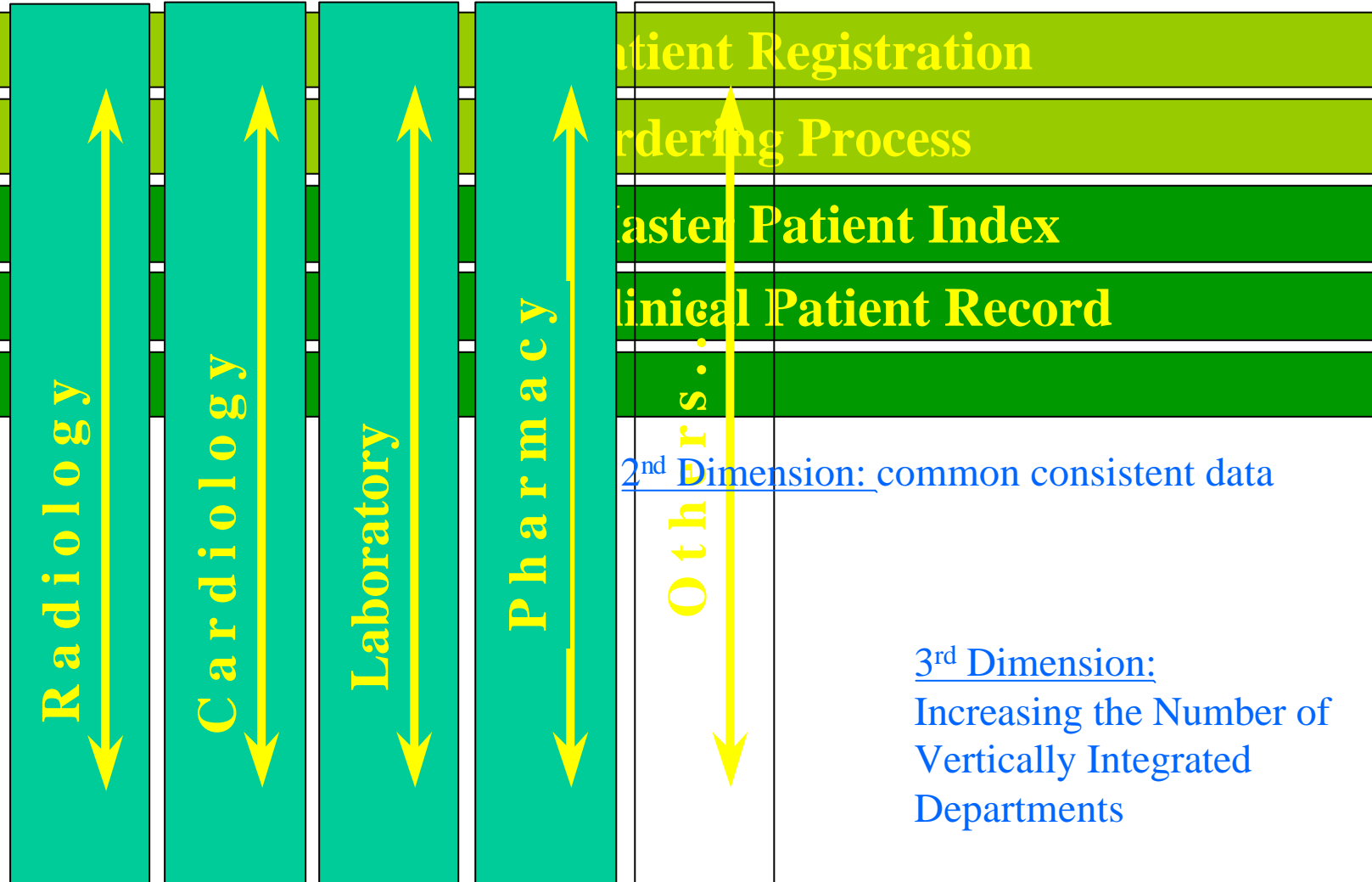
+ INTEGRATION

based on established medical IT Standards

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IHE Vision for Growth

A Multidimensional Expansion of Integration

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1st Dimension: Workflow inside department

Radiology **Cardiology** **Laboratory** **Pharmacy** **Others...**

Patient Registration

Ordering Process

Master Patient Index

Clinical Patient Record

2nd Dimension: common consistent data

3rd Dimension:
Increasing the Number of
Vertically Integrated
Departments

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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

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National standards will be transformed into international standards

NCPDP
National Council for Prescription Drug Programs

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)

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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)

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„IHE ist der Elchtest   für die Integration" (Prof. Klose, Marburg)

National standards will be transformed into international standards

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 Chabriais is medical Co-Chair of WG 10 "Strategy"
- Since 5. 12. 2002 Dr. Peter Mildenberger is biomedical Co-Chair of the DICOM Committee

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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

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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?

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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.

ISO/IEC 10746-2:1994 ITU-T Recommendations X.902, Information technology – Open Distributed 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;

National standards will be transformed into international standards

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 18307 TR:2000 Key Characteristics for Interoperability and Compatibility in Messaging and Communication Standards; 79 pages; 6.11.2000

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**" ; Part7: Electronic prescription

ISO 22857 CD (20.6.2002) "**Guidelines** on data protection to facilitate trans-border flows of personal health information" ;66 pages.

ISO/IEC 15408:1999 Information technology - Security Techniques – **Evaluation Criteria** for IT Security

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/IEC 17799:2000 Information Security Management

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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
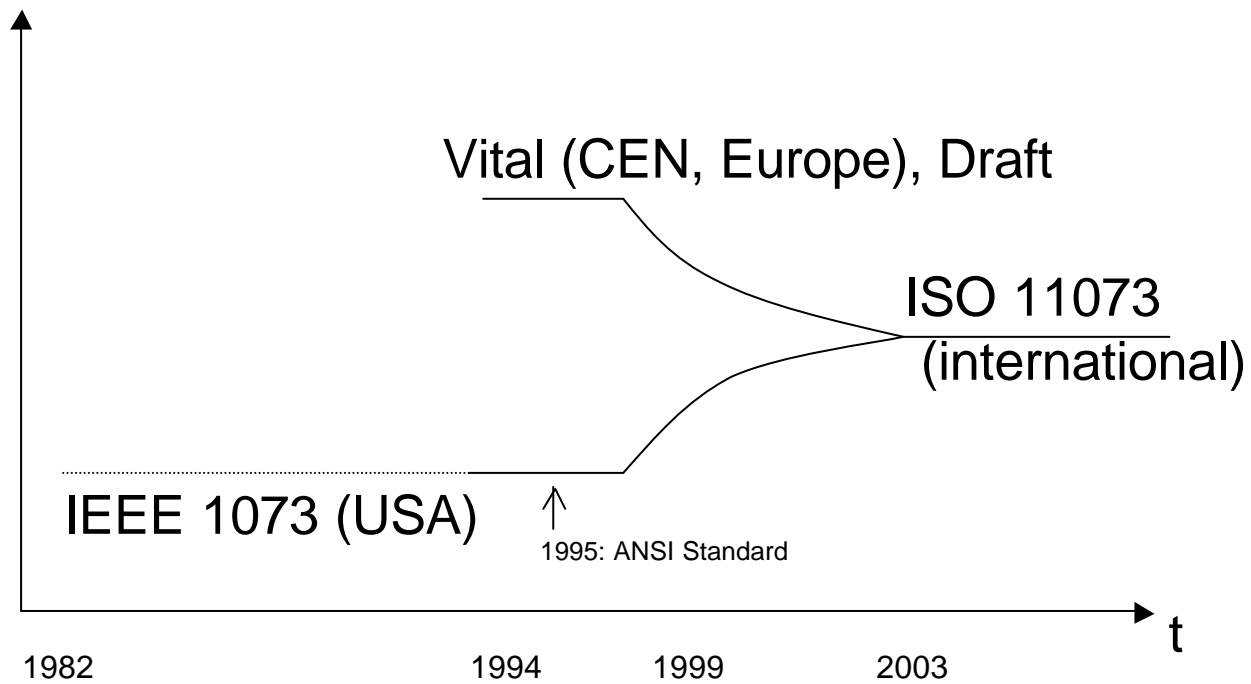
ISO Cooperations with HL7
Started for V2.x

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

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CEN, IEEE, ISO: Convergence

Vital (CEN, Europe), Draft

ISO 11073
(international)

IEEE 1073 (USA)   ↑
1995: ANSI Standard

t

1982   1994   1999   2003

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DIN NAMed
Fachbereich G "Medizinische Informatik"

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

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ANSI-HISB
American National Standards Institute
- Healthcare Informatics Standards Board

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

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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

ASTM 1902-97 Standard Guide for Management of Confidentiality and Security of Dictation, Transcription and Transcribed Health 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

**Healthcare IT standardisation
is not yet done**

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What are the success factors ?

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 **scop**e 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)

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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

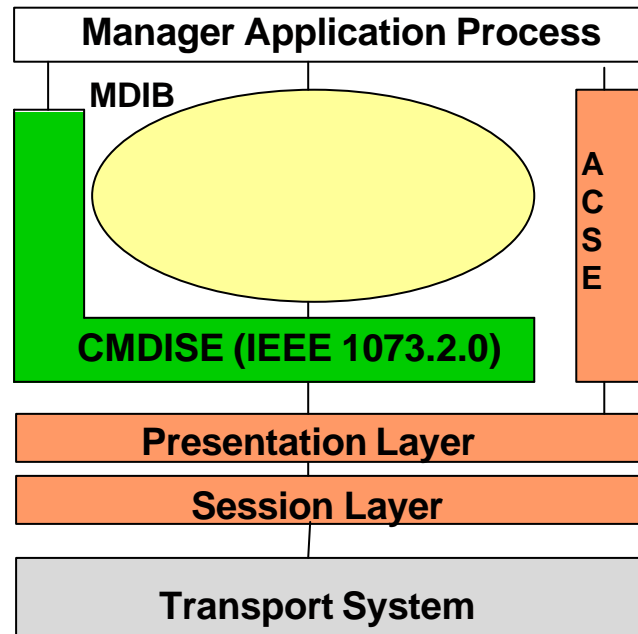# Siemens medical Solutions that help

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Communication between Manager and Agents:
Association

OSI/ISO Schichten

PC (Client)

Patientenmonitor (Server)

Manager Application Process

Agent Application Process

MDIB

MDIB

MDS

VMD

Channel

Channel

NU

RT-SA

AL

NU

AL

A C S E

A C S E

7

CMDISE (IEEE 1073.2.0)

CMDISE (IEEE 1073.2.0)

6

Presentation Layer

Presentation Layer

5

Session Layer

Session Layer

1 - 4

Transport System

Transport System
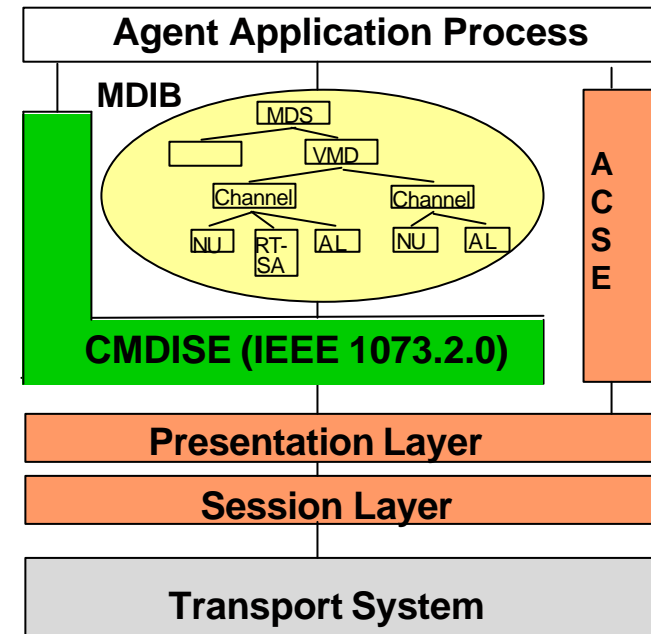
Physikalische Verbindung, z.B. IrDA - Cable Connected

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)

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